Accreditation, Quality Assurance

P0001

ACCURACY OF DETERMINATION OF FREE LIGHT CHAINS (KAPPA AND LAMBDA) IN PLASMA AND SERUM BY SWEDISH LABORATORIES AS MONITORED BY EXTERNAL QUALITY ASSESSMENT

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BACKGROUND-AIM

Free light chain (FLC) measurements are important for the diagnostic workup of monoclonal gammopathies. As FLC are heterogenous, it is possible that different reagents and instruments for measuring concentrations of FLC give diverging results that affect the assessment of patients with monoclonal gammopathies. The aim of the present study was to investigate the agreement between different clinically used FLC methods using data from the Swedish external quality assurance (QA) programme.

METHODS

Method comparisons of the two FLC assays N-Latex FLC (Siemens) and Serum Freelite (The Binding Site) were performed using four instrument platforms and the resulting concentrations and ratios derived. Results from 27 external quality assessment rounds distributed by Equalis (Uppsala, Sweden) to 11-16 Swedish hospital laboratories during 2015–2020 were investigated.

RESULTS

The κFLC measurements deviated significantly over time, but when only nephelometry was used, the deviation from the mean was lower (median ranges: -5% to 13%). The CV was significantly higher for the Freelite assay (mean CV=8.7) than for the N latex assay (mean CV=5.7) (p=3e-5). The correlation between all combinations of reagents and instrument platforms used was generally good (R=0.87-0.93), and the correlation slope was acceptable (0.81-1.2). For λFLC measurements, no clear concordance between the combinations of instruments and reagents is apparent, deviating between -40% to +48% from the mean.

CONCLUSIONS

The imprecision in λFLC directly affects the κFLC/λFLC ratio, which may be of importance for the clinical assessment of individual patients and especially the differentiation between monoclonal and polyclonal gammopathies.

Accreditation, Quality Assurance

P0002

TWO-SITES SIGMA METRICS AND MEASUREMENT UNCERTAINTY OF 18 SHORT TURNAROUND TIME ASSAYS ON THE ROCHE COBAS SYSTEMS IN ASL ROMA 1 LABORATORIES.

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BACKGROUND-AIM

ISO 15189 requires that laboratories determine measurement uncertainty (MU) for each measurement procedure and evaluate the comparability of results between different equipment, sites, or both. ASL Roma 1's Clinical Pathology unit (CP) is organised in two sites: a hub in St. Filippo Neri Hospital (SFN) and a short turnaround time spoke in St. Spirito in Saxia Hospital (SSP), both operative 24 hours.

METHODS

BIO-RAD internal third-party quality control (QC) data of two Roche Cobas c8000 (SFN) and two Roche Cobas PRO analyzers (SSP) from May to October 2022 have been used to calculate bias (compared to peer group mean) and imprecision (CV) to compare with total allowable error (TEa). Sigma metrics (SM) were calculated for both sites by the equation: Sigma=(TEa–|bias|)/CV from pooled data at 2 levels for 18 assays: pancreatic amylase (PA), total bilirubin (TB), calcium (Ca), creatine kinase (CK), creatinine (CR), phosphate (P), glucose (G), aspartate and alanine aminotransferase (AST/ALT), lactate dehydrogenase (LD), lipase (LP), magnesium (Mg), C reactive protein (CP), potassium (K), total protein (TP), sodium (Na), urea (UR) and troponin T (TT, 1 level only) using TEa goals calculated with EFLM Biological Variation (BV) data (accessed november 2022), CLIA 2022 amendments for chemistry assays and RiliBÄK 2019. MU has been calculated by Unity Real-Time software (BIO-RAD) by equation $U=2\sqrt{(SD^2+(bias/\sqrt{3})^2+SDbias^2)}$ and compared to maximum allowable uncertainty (MAU) calculated from within-subject variation (CVi) of EFLM BV database as MAU=2*0.75*CVi.

RESULTS

Pooled Sigma metrics were >4 Sigma or better for 12 (SFN) and 15 (SSP) out of 18 assays at level 1 and for 15 (SFN) and 16 (SSP) out of 17 at level 2; MU was below MAU for all assays except Na, Ca, Mg, TP and ranged from 1.4% (Na, SSP, level 2) to 13.7% (TB, SSP, level 1).

CONCLUSIONS

SM for data from two sites of CP and four different analysers showed >4 Sigma performance or better for most of assays tested and very close results between instruments and sites. Some analytes yielded MU higher than MAU, despite small CV and high S value; this discrepancy is due to analytical goal selection: low values of CVi for electrolytes and total protein lead to stringent analytical performance specifications.

Accreditation, Quality Assurance

P0003

HOW MANAGE A PRECISION INTRA-ASSAY STUDY IN THE ABSENCE OR INSUFFICIENT QUANTITY OF INTERNAL QUALITY CONTROL? EXAMPLE OF IMMUNORADIOMETRIC ASSAY OF ALPHA SUBUNIT IN HUMAN SERUM.

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BACKGROUND-AIM

Intra-assay precision is the first step to complete during bio analytical method validation. In compliance with the requirements of the international standard NF EN ISO 15189:2012, this study must be carried out analyte by analyte and at various concentration levels, with the optimal number of determinations being at least 20. Under certain circumstances, the absence or insufficient quantity of control material or the difficulty of obtaining sera from patients with pathological levels of the analyte to assess in sufficient volume may make such study difficult to achieve.

METHODS

This is particularly the case for the determination of alpha subunit (SUA) in human serum by immunoradiometric assay (IRMA alpha subunit Beckman Coulter, Immunotech, Czech Republic), as the packaging of the 2 quality controls provided in the kit only allows to perform 5 determinations per control (two vials of 1000 µL for a test sample of 100 µL). In order to address this issue, the purpose of our work was to prepare our own control samples by overloading a pool of serum samples with calibration solutions provided in the assay kit (calibrator number 6 at 10.9 IU/L in SUA).

RESULTS

Thus, two in-house control samples could be carried out at 1.24 IU/L (initial pool of sera) and 3.17 IU/L (initial pool of sera overloaded) in SUA to achieve the precision intra-assay study (22 and 21 determinations at the low level and high level of SUA respectively). The coefficients of variation (CV) obtained with these samples were for the low level of 2.76% and 1.92% for the high level. These CVs are similar to those referred in the manufacturer's data sheet, namely 4.23% for a value of 0.81 IU/L and 2.22% for a value of 3.56 IU/L of SUA.

CONCLUSIONS

This methodology is easy to carry out, and can be applied to analyses other than SUA. Furthermore, it allows the execution of control samples which have similar concentrations of analytes to those described in the intra-assay precision studies of datasheets provided by the manufacturers.

Accreditation, Quality Assurance

P0004

PERFORMANCE EVALUATION OF CLINITEK STATUS ANALYZER

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BACKGROUND-AIM

A review of CLINITEK Status Analyzer was performed in order to determine its suitability for our laboratory needs.

METHODS

Our first step was to analyze 29 urine samples to measure urobilinogen, proteins, pH, nitrites, leukocytes, ketones, glucose and blood levels. A comparison was conducted between CLINITEK Status analyzer and the Siemens Healthineers CLINITEK Novus analyzer (currently in use in our laboratory). Kappa index and Spearman correlation were then calculated.

RESULTS

Results for Kappa index were 1 for urobilinogen; 0,61 for proteins; 0,385 for pH; 0,83 for nitrites; 0,407 for leukocytes; 0,463 for ketones; 0,580 for glucose and 0,869 for blood. Results for Rho of Spearman are 1 for urobilinogen; 0,808 for proteins; 0,768 for pH; 0,849 for nitrites; 0,931 for leukocytes; 0,463 for ketones; 0,829 for glucose and 0,980 for blood.

CONCLUSIONS

There is moderate agreement between the raw results of both types of urine strips with the exception of urobilinogen, nitrites and red blood cells, which demonstrate good to very good agreement. Ketones and pH, which have the lowest Kappa indexes, are the most problematic parameters. In contrast, every parameter except ketones has a high correlation index, greater than 0.75, meaning that the measured parameters are very closely correlated or perfectly correlated. Based on the data, we can conclude that although the parameters do not fall into the same categories exactly, they are all in agreement that the positive ones are due to the two methods, and the negative ones are due to the devices. Thus, when a positive ++ is obtained by one method, it is possible to obtain either a positive + or ++ or ++ + by the other, but they will always be positive; there is rarely a positive result (of whatever degree) from one device against another negative result from the other device. Only ketones do not agree, which could be due to the small sample size. Of the 29 samples, 27 are concordant and only two are discordant. With a larger sample, disagreements can be diluted, improving both agreement and correlation. It is acceptable in general for CLINITEK Status equipment to be used in our laboratory, while monitoring ketones or increasing the number of samples.

Accreditation, Quality Assurance

P0005

PERFORMANCE EVALUATION OF CLINITEK ADVANTUS ANALYZER

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BACKGROUND-AIM

A review of CLINITEK Advantus analyzer was carried out to determine its suitability for our service.

METHODS

The following parameters of the strip are first evaluated in 76 urines: urobilinogen, proteins, pH, nitrites, leukocytes, ketones, glucose and blood. A comparison was conducted between this equipment and the Aution Eleven AE-4020 analyzer. Two situations were considered in order to calculate the Kappa index: 1) direct comparison of the categories of results obtained from both urine strips, and 2) category classification into pathological and non-pathological results. For blood, the results were compared with the Siemens Healthineers' Atellica 1500 automated urinalysis system. For glucose, they were compared with the Atellica Solutions automated platform's glucose (hexokinase) assay (cut-off <15 mg/dL).

RESULTS

In the direct comparison between the result cathegories of both urine strips, we obtained a Kappa index of 0,448 for urobilinogen; 0,448 for proteins; 0,730 for pH; 0,730 for nitrites; 0,319 for leukocytes; 0,319 for ketones. In the categorization into pathological/non-pathological the Kappa index was 0,580 for urobilinogen; 0,763 for proteins; 0,699 for leukocytes; 0,699 for ketones; 0,462 for glucose and 0,891 for blood.

CONCLUSIONS

Concordance indexes in the direct comparasion indicate a low degree of agreement between raw results of the two types of urine strips, except for nitrites. This occurs because the parameter's cut-off points are different for positive values and indications. Concordance indexes are moderate/good once the results are dichotomized as pathological/non-pathological, which means presence or absence of analytes, thus proving their usefulness in our laboratory. The blood from the Advantus strips showed high agreement (Kappa: 0,891) with the strips from the Atellica 1500 automated urinalysis system. Glucose, however, does not show agreement with the Atellica CH hexokinase method (Kappa: 0,462). It is acceptable in general for CLINITEK Advantus equipment to be used in our laboratory, while monitoring glucose.

Accreditation, Quality Assurance

P0006

DETERMINANTS OF HODGKIN LYMPHOMA AMONG PALESTINIANS

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BACKGROUND-AIM

This study aims to examine Epstein-Barr virus (EBV) positivity among HL cases in Palestinian.

METHODS

Part I: A case-control study was conducted including 63 pathologically confirmed HL cases and 85 cancer-free controls. Study participants were administered a questionnaire-based interview covering different risk factors of HL including lifestyle factors, medical history, family history and proxies of infection.
Part II: A retrospective-cohort study including 30 HL paraffin-embedded blocks were retrieved, then slides were immunohistochemically stained to confirm HL diagnosis and to determine EBV positivity in HL cases. A total of 162 HL pathology reports were used to define the HL disease characteristics.

RESULTS

Mean age at diagnosis for Hodgkin lymphoma cases was 23 years with a male to female ratio of 1:1. Nodular sclerosis was the most common subtype with 51.1%, followed by mixed cellularity with 39.1%. EBV was found to be positive in about 33% of the cases. Family history of cancer in first-degree relatives was associated with 4.6 folds increase in the risk of HL. While tonsillectomy was associated with 4.2 folds increased risk of HL, physical activity played a protective role. Moreover, early exposure to infections as indicated by proxies of infections like exposure to pets and delayed birth order both found to decrease the risk of HL.

CONCLUSIONS

In conclusion, this is the first study to investigate HL among Palestinians, thus further studies with larger sample size are required.

Accreditation, Quality Assurance

P0007

DEFINITION AND APPLICATION OF PERFORMANCE SPECIFICATION FOR MEASUREMENT UNCERTAINTY OF 34 ROUTINE CLINICAL CHEMISTRY TESTS

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BACKGROUND-AIM

Laboratories should regularly estimate and evaluate (using pre-defined analytical performance specifications, APS) the measurement uncertainty (MU) of their performed tests. It is consequently essential to appropriately determine APS for MU and maintain it for its intended use. Therefore, the definition of an allowable MU is crucial to ascertain if the estimated MU for a given test result may significantly affect its interpretation. This study aimed to categorize and determine APS for MU and evaluate whether current measurement systems can meet them.

METHODS

Thirty-four performed clinical chemistry tests via two Beckman Coulter AU5800 analyzers with accepted comparability examination results were allocated to the models defined during the 2014 EFLM Strategic Conference to derive APS for MU. For most measurands assigned to the BV-based model 2, we retrieved their biological variation for APS from the EFLM BV database. Our laboratory estimates and evaluates the MU of quantitative test results every year according to ISO 15189 Standard, using the so-called top-down approach, and estimated MU were derived from long-term internal QC data with the same QC mean of two analyzers, assuming that all significant systematic error (bias) is calculated and corrected by the IVD manufacturer.

RESULTS

We yielded 98 MU data from 34 measurands on their different concentration level of QC in 2022, in which 30 assays were three levels and the others were two. A mix APS for MU among varying levels QC of tests was employed with 12 clinical outcome Model 1 from NCEP, 73 BV-based Model 2, and 13 state-of-the-art Model 3, respectively. In daily practice, 19 items fulfilled optimum, 39 desirable, and 15 minimum APS. The other 25 items met Model 1 and Model 3 APS. While creatinine level 1 QC mean 0.91 mg/dL with relative standard uncertainty 5.0% exceeded the CV goal of 3.4% (0.75CVi minimum BV-based APS).

CONCLUSIONS

Except for a low-concentration creatinine with the standard measurement uncertainty (SD) of 0.046mg/dL, APS was adjusted to model 3 with the new absolute SD goal of 0.066mg/dL (1/3 USA CLIA 2019 TEa). In our clinical setting, the remaining 24 assays fulfilled at least the minimum BV-based Model 2 APS for MU. TG, Cholesterol, HDL-c, and LDL-c met Model 1, and ALP, NH3, Alcohol, Mg, Na, and UIBC met Model 3 APS.

Accreditation, Quality Assurance

P0008

PERFORMANCE EVALUATION OF THREE BLOOD GLUCOSE MONITORING SYSTEM USING ISO 15197:2013

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BACKGROUND-AIM

Blood glucose monitoring is an essential component of diabetic management and should provide sufficient analytic quality to allow adequate therapy for diabetic patients.
The standard ISO 15197:2013 is widely accepted for accuracy evaluation of blood glucose monitoring system (BGMS). This study evaluated the performance of 3 BGMS (ACCU-CHECK®, Barozen® and Gmate®) under routine hospital condition.

METHODS

Based on the guidelines of ISO 15197 system accuracy, measurement repeatability and intermediate measurement precision were assessed. For system accuracy, a total of 98 venous blood samples of different concentrations were pooled in this study and glucose levels were determined by three BMGS. The results were compared with those of central laboratory system. Measurement repeatability and intermediate measurement precision were assessed using control sample materials. Standard deviation(SD) and coefficient of variation(CV) were calculated for glucose concentrations <100mg/dl and >100mg respectively. Coefficient of determination(R2) for linearity of the 3 systems were also calculated.

RESULTS

The SD and CV ranges for measurement repeatability of 3 BGMS on the same day were 0.65-1.57 mg/dl and 1.3-2.7% (<100mg/dl) respectively, and 2.81-4.32 mg/dl and 1.2-1.6 %(≥100mg/dl). Assessment of intermediate measurement precision of 3 BGMS showed SD 1.21-1.58 mg/dl and 2.2-3.3% (<100mg/dl), respectively, and 2.51-3.23 mg/dl and 1.1-3.3 %(≥100mg/dl). Coefficients of determination(R2) for linearity of the each three systems were >0.99.When glucose levels were <100mg/dl and ≥100mg/dl, >95% of indivisual BGMS test strip lot results were within ±15 mg/dL and within ±15 % of the average measured value of reference measurement, respectively. In Concensus Error grid analysis, all results were distributed in zone A and B.

CONCLUSIONS

All three BGMS fulfilled ISO 15197:2013 accuracy limit criteria and Concensus Error grid criterion. And this study showed that all three BGMS can provide reliable results for patients and clinicians to manage the diabetes mellitus. Applying criteria of ISO 15197:2013, differences in the accuracy of the test systems were observed. These differences are due to lot-to lot variability and applied comparison method, probably.

Accreditation, Quality Assurance

P0009

ENSURE HBV AND HCV VIRAL LOAD TEST RESULTS ARE TRACEABLE TO THE HIGHEST POSSIBLE ORDER OF TRACEABILITY

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BACKGROUND-AIM

Laboratories shall establish and maintain metrological traceability of their measurement results and ensure they are traceable to the highest possible order of traceability. Where it is impossible to provide traceability to the International System of Units (SI), it is consequently essential to compare with consensus standards or results of reference measurement procedures and link them to an appropriate reference. This study aimed to ensure the metrological traceability of our HBV and HCV viral load test results via consensus standards purchased from the Taiwan Food and Drug Administration (TFDA).

METHODS

We obtained working reagents for HBV DNA (Lot 92-08-W) and HCV RNA (Lot 93-09-W) NAT Assays from TFDA national standard with assigned consensus standards of 1000 IU/mL and 890 IU/mL and the measurement uncertainty SD for the logarithmic value of the titre were 0.44 and 0.49, respectively. Both consensus standards were processed simultaneously with their internal QC and patient samples by personnel who routinely perform HBV and HCV viral load assays via Roche Cobas 4800 analyzer in August 2022. The pre-defined acceptability criteria were the expanded measurement uncertainty using a coverage factor of K=2 of the consensus standards. Therefore the bias of HBV DNA and HCV RNA viral load logarithmic results should be within 0.88 and 0.98 around the assigned value, respectively.

RESULTS

Under the prerequisite of internal QC in control, the test results of both consensus national standards for HBV and HCV viral load assays were 1810 IU/mL and 847 IU/mL, respectively. The estimated bias of HBV DNA and HCV RNA viral load logarithmic results were 0.26 and -0.02, both of which were accepted by pre-defined criteria. This study ensured the metrological traceability of our HBV and HCV viral load test results in daily clinical practice via the Roche Cobas 4800 system.

CONCLUSIONS

Where it is not possible to provide traceability to the SI Units, this study showed a feasible pragmatic approach to fulfill the traceability requirement of the ISO15189 standard. Our laboratory evaluates and maintains the metrological traceability of HBV and HCV viral load assays every two years according to ISO 15189 Standard, using the consensus national standards purchased from FDA in Taiwan.

Accreditation, Quality Assurance

P0010

FIRST EXPERIENCE OF EXTERNAL QUALITY ASSESSMENT OF IMMUNOHEMATOLOGICAL TESTING IN MEDICAL LABORATORIES OF THE REPUBLIC OF BELARUS

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BACKGROUND-AIM

External quality assessment (EQA) of laboratory tests is an integral part of the quality system of medical laboratories and a criterion for compliance with the requirements of the ISO 15189 standard. In 2022, for the first time in the Republic of Belarus, an EQA for immunohematological testing was conducted, in which 516 laboratories took part.

METHODS

The following samples were used as control samples (CS) for EQA: 5-10 ml of whole blood (sample No. 1, 2 variants); 5-10 ml of preserved erythrocytes (sample No. 2, 3 variants); 5-10 ml of blood serum (sample No. 3, 3 variants). CS were prepared by Republican Scientific and Practical Center of Transfusiology and Medical Biotechnologies (RSPC TMB). The values obtained in CS in the laboratory of the RSPC TMB were accepted as assigned. The evaluated parameters were the following: determination of the blood group according to the ABO and Rh systems in samples No. 1 and No. 2; determination (screening) of alloimmune anti-erythrocyte antibodies in sample No. 3; determination of antibody titer in sample No. 3. CS were blinded, marked and labeled by National Antidoping Laboratory (Republican Centre of Laboratory Diagnostics).The tests were carried out by the participants by any means and methods available in the laboratory.

RESULTS

The results of EQA for determining the blood group according to the AB0 system (173 participants) are satisfactory in 97.7%, unsatisfactory in 2.3% of cases; the results of EQA for determining the blood group according to the Rh system (173 participants) are satisfactory in 74.6%, unsatisfactory in 25.4% of cases; the results of EQA for the determination of alloimmune anti-erythrocyte antibodies and their titer (170 participants) are satisfactory in 84.1%, unsatisfactory in 15.9% of cases.

CONCLUSIONS

All participants with unsatisfactory results are recommended to analyze their activities in terms of conducting testing for which an unsatisfactory result was obtained (assessment of the correctness of the method, the reagents used, the sufficiency of staff training) to identify possible reasons for obtaining unsatisfactory results, take corrective measures and eliminate the risk of obtaining unsatisfactory results in routine diagnostic activities. It is planned to conduct additional training of laboratories and a repeated EQA in 2023.

Accreditation, Quality Assurance

P0011

RISK MANAGEMENT IN CLINICAL LABORATORIES BY MEANS OF DAFO ANALYSIS: ¿WHAT HAS SARS COV-2 POSTED?

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BACKGROUND-AIM

The DAFO analysis is the most widely used strategic tool to carry out this situation diagnosis and the final objective is for all parties involved in the activity to identify weaknesses, threats, strengths and opportunities.
SARS CoV-2 has meant a substantial change in the way of working of the entire healthcare organization, including the clinical laboratory.
Therefore, the objective of the present work is to make a DAFO matrix of the clinical laboratory including in it the implications of the SARS CoV-2 incursion.

METHODS

1. Identification and evaluation of the internal factors of our organization that affect negatively (Weaknesses, D) and positively (Strengths, F).
2. Identification and evaluation of the external factors of our environment that affect negatively (Threats, A) and positively (Opportunities, O).
3. SWOT graph of situation diagnosis.
4. Analysis of the diagnosis and identification of key factors for success.
5. Re-focusing the organization so that its services are provided in a more effective way.

RESULTS

STRENGTHS: Qualified and trained staff, good staff adaptation and collaboration, motivation and teamwork.
WEAKNESSES: Lack of clinical guidelines, difficulty in implementing new techniques, overload of emergency laboratory work, numerous analytical data on which to perform analyses.
OPPORTUNITIES Inclusion of new tests, Development of joint protocols with clinics, Alliances with other laboratories. Change in the way of teaching (telematic) Promotion of research, Disease very analytically conditioned which gives visibility to the clinical laboratory.
THREATS: Pressure on care Other nearby hospitals with more infrastructure and techniques.
The factors are weighted according to their relevance and a total of 100 points are distributed. The Cartesian graphic representation of the pairs D and A versus F and O is made and the points are joined to obtain the DAFO vector. In our case, we are in the area called "playing field", indicating that our organization is adequate to the demand but that it must be continuously improved.

CONCLUSIONS

The refocusing of our organization was aimed at exploiting opportunities by increasing the visibility of the laboratory and mitigating weaknesses such as increased pressure of care and work overload in some areas.

Accreditation, Quality Assurance

P0012

EDUCATION AND TRAINING OF YOUNG SCIENTISTS IN EQA SCHEMES OPERATION AND MANAGEMENT

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BACKGROUND-AIM

The benefits of participating in external quality assessment schemes for both the patient and the clinical laboratories are known. However, the retirement of older and experienced scientists, makes imperative the need for new members of the scientific staff, who will undertake to maintain and also expand the operation of the EQA provider. In this direction, ESEAP recruits young laboratory scientists to train them on all the aspects of the EQA schemes.

METHODS

In the beginning, new colleagues need to familiarize themselves with the statistical analysis (consensus mean, CV %, SD, SDI, Δ%) used to evaluate the results and the graphs for displaying the statistics (histograms, Levey-Jennings diagrams, and Youden Plot). A lot of important information can be extracted from these.
The statistical processing of the results is one of the most critical parts, as the possible causes of erroneous results should be detected at that moment. These causes may be related to the pre-analytical, analytical, or meta-analytical phase. Although, sample shipments are always accompanied by instructions for their handling, preparation, and reconstitution, sometimes in the laboratory these instructions may be lost or ignored resulting in improper dilution of the lyophilized control samples and consequently wrong results (pre-analytical errors). Moreover, some of the most common errors are the wrong entry of results due to typing errors, wrong reporting units of measurement, or entering results of the first control sample in the second and vice versa (post-analytical errors).

RESULTS

Another point of interest for someone new to EQA is the commutability of samples and the need for grouping specific methods or analytical systems. Some analyzers consistently measure higher or lower analyte concentration than others in the EQA samples, so a separate statistical analysis needs to be done and used within the group of these analyzers. Thus, a bad result in the statistical analysis of all laboratories may not be bad in the group of laboratories with the same analytical system.

CONCLUSIONS

Finally, the younger staff has to understand that EQA schemes are dynamic in nature and there is a continuous improvement of services by developing the existing schemes or designing new ones that cover new needs.

Accreditation, Quality Assurance

P0013

CRITICAL VALUES OF LABORATORY RESULTS AS A QUALITY INDICATOR OF THE TESTING PROCESS IN THE DEPARTMENT OF LABORATORY DIAGNOSTICS IN PUBLIC HEALTH INSTITUTION „HEALTH CENTER DOBOJ"

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BACKGROUND-AIM

Critical values of laboratory results are defined as extremely abnormally high or low results that threaten the patient's life if appropriate therapeutic measures are not taken urgently. Timely notification of critical values is included in the consensus list of post-analytical quality indicators and has a high priority for evaluating and monitoring the occurrence of errors in the post-analytical phase. This research aimed to estimate the frequency of individual critical values that have been found, recorded, and immediately reported to the family doctor during two years of follow-up, as well as to evaluate the collaboration of the laboratory with other services of the health center.

METHODS

This retrospective study was conducted in the laboratory from the 1st of January 2020. until 31st of December 2021. Critical values of blood count parameters (leukocytes, erythrocytes, hemoglobin, and platelets), biochemistry parameters (glucose, creatinine, lactate dehydrogenase-LDH, C-reactive protein-CRP, electrolytes-sodium, potassium), and hemostasis parameter (prothrombin time-PT) were monitored.

RESULTS

During the data collection period, a total of 66 944 patients were admitted to the laboratory and 351 559 analyses were performed. The total number of critical values was 175 i.e. 0.05%. The following frequencies were obtained from the total number of recorded critical values: 50.9% PT, 11.4% hemoglobin and erythrocytes, 8.6% CRP, 7.4% potassium, 6.9% platelets, 5.7% leukocytes, 5.1% glucose, 2.9% creatinine and 1.1% LDH.

CONCLUSIONS

PT was the parameter with the most frequent critical values. There was adequate communication about critical values of laboratory parameters between the laboratory and other medical services within "Health Center Doboj", which is extremely important for emergency intervention to save patients' lives.

Accreditation, Quality Assurance

P0014

DIAGNOSING GESTATIONAL DIABETES USING POINT-OF-CARE GLUCOSE INSTRUMENTS

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BACKGROUND-AIM

In Norway, primary healthcare can use their point-of-care (POC) glucose instruments to diagnose patients with gestational diabetes, and diabetes if HbA1c cannot be used. The POC instruments must fulfil the National analytical performance specification (APS) for glucose which should be within +/- 7.5% from the true value. How can the POC users know if they fulfil these requirements?

METHODS

Noklus provides an external quality assessment (EQA) scheme for POC glucose with commutable control materials for most of the glucose instruments used in primary healthcare. For the POC instruments using commutable control samples, the results from each instrument group are compared with the target value which is obtained by using the certified reference material NIST (SRM965b) in four levels. Based on the mean bias from the three last surveys, the instrument groups are classified in three categories as a) recommended, b) not recommended and c) not applicable (neither recommended nor not recommended). To be able to use the POC instrument to diagnose gestational diabetes each participant must 1) use a recommended instrument and 2) get “good” performance in a diagnostic relevant level in the EQA scheme. “Good” participant performance is defined as each participant EQA result within +/- 5% of the peer group target interval (target interval = target value +/- 0.1 mmol/L).

RESULTS

In May 2023 the list of recommended POC glucose instruments contains Ascensia Contour, Contour XT/next/next ONE and HemoCue Glucose 201RT. 70% (n=1639) of the participants use these instruments and 83% (n=1357) of these have “good” performance in the EQA scheme and can thus use their POC instruments to diagnose gestational diabetes.

CONCLUSIONS

Noklus has developed a system to decide if users of POC glucose instruments in primary healthcare fulfil the National APS for diagnosing patients with gestational diabetes.

Accreditation, Quality Assurance

P0015

BRAZILIAN EXTERNAL QUALITY ASSESSMENT PROGRAM ON MOLECULAR DETECTION OF SARS-COV-2 – A REPORT FROM 2020 – 2022

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BACKGROUND-AIM

Health strategies for the management of COVID-19 pandemic rely on diagnostic tests. External Quality Assessment Programs (EQAP) provide an independent assessment of the effectiveness of analytical systems, improving the health strategy's quality. Here, we aimed to assess the diagnostic accuracy of molecular methods for SARS-CoV-2 by analyzing the results of an EQAP conducted by a Brazilian EQAP provider accredited by ABNT NBR ISO/IEC 17043:201.

METHODS

The quality control materials were inactivated lyophilized suspension of Vero cells (BCRJ 0245/ATCC CCL-81) infected with viable SARS-CoV2 particles and cultured under BSL-3 conditions. The EQAP surveys were conducted from May 29, 2020, to November 1, 2022, and the accuracy of several molecular tests was assessed. The percentage of correct results (%CR), sensitivity (SE), specificity (SP), false positive (FP), and false negative (FN) were calculated and analyzed according to the applied method (RT-PCR, RT-LAMP, and Nicking Enzyme Amplification Reaction - NEAR) and its classification [laboratory-developed (LDT) and in vitro diagnosis (IVD)].

RESULTS

A total of 351 laboratories from 10 countries participated, and 5121 datasets were analyzed. The percentage of %CR, SE, SP, FP, and FN were for each method: for RT-PCR (N=4555) 95.02%, 98.3%, 91.72%, 8.28%, and 1.7%; for RT-LAMP (N=42), 78.57%, 88.89%, 70.83.%, 29.17%, and 11.11%; and for NEAR (N=524) 99.24%, 98.95%, 99.58%, 0.42%, and 1.05%, respectively. RT-LAMP presented lower %CR, SE, SP, and higher FP and FN than the other methods ($P<0.05$, for all comparisons). LDT had lower %CR (90.76% vs. 96.44%) and SP (87.25% vs. 94.44%) and higher FP (12.75% vs. 5.56%) compared to IVD test ($P<0.05$, for all comparisons). The EQAP also revealed that 90% of laboratories using RT-PCR, 100% using NEAR, and 50% using RT-LAMP presented $\geq$ 80% of correct results.

CONCLUSIONS

NEAR and RT-PCR showed similar diagnostic accuracy and both higher compared to RT-LAMP. IVD tests had higher diagnostic performance compared to LDT. The EQAP revealed overall good performance for laboratories. We cannot exclude the impact of a small sample size on RT-LAMP results. Attention points and improvement opportunities go for those using RT-LAMP and LDT.

Accreditation, Quality Assurance

P0016

THE ROLE OF THE BRAZILIAN EXTERNAL QUALITY ASSESSMENT PROGRAM IN THE IMPROVEMENT OF GLYCATED HEMOGLOBIN MEASUREMENT

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BACKGROUND-AIM

The glycated hemoglobin (HbA1c) is an essential parameter for managing diabetes mellitus. The National Glycohemoglobin Standardization Program (NGSP) and the International Federation of Clinical Chemistry (IFCC) were essential for the harmonization process to reduce the variability of measurements. In Brazil, a proficiency testing provider accredited by ABNT NBR ISO/IEC 17043:2011, provides an External Quality Assessment program (EQAP) for HbA1c. The objective of this study was to evaluate the performance evolution of laboratories (labs) participating in this EQAP from 2009 to 2022.

METHODS

The performance of methods harmonized (MH) and not-harmonized (MNH) by NGSP, IFCC, and IFCC/NGSP were evaluated. The methods were: boronate affinity chromatography (BAC), ion exchange chromatography (IEC), electrophoresis (EP), direct (DR), enzymatic (EZ), photometry (PT), ion exchange HPLC (HPLC), immunofluorescence (IF), immunoturbidimetry (IT), turbidimetry (TB) and chemiluminescence (CL).

RESULTS

A total of 771 labs (706 from Brazil and 65 from other countries) submitted 43960 datasets. In 2009, the coefficient of variation (CV) among labs was 8.6%, and in 2022 the CV was 4% ($P<0.0001$). The methods that presented the lower median CV were CL (1.5%), EZ (3.8%) and HPLC (4.2%), and the higher median CV was observed in IEC (9.1%), TB (8.8%) and IF (7.35%) ($p<0.0001$). In 2010, the percentage (%) of labs using MH by NGSP, IFCC and IFCC/NGSP were 21%, 22.22%, and 30.45% respectively; for the labs using MNH was 26.34%. In 2022, these % were 18.32%, 21.20%, and 42.41% respectively, and for labs using MNH was 18.06%. The reduction in the % of MNH and the increase in the % of labs using MH by both IFCC/NGSP was statistically significant ($P<0.05$). The median of CV of MNH was 8.15% and for MH was 4.8% (IFCC), 5.2% (NGSP), and 4.7% (IFCC/NGSP) ($P<0.0001$).

CONCLUSIONS

There was a reduction in the median CV from 2009 to 2022 and in the proportion of labs using MNH during the same period. Also, the median CV of MNH was higher than MH. These findings could raise the hypothesis that harmonization of HbA1c improves lab performance and could impact the quality of routine clinical results.

Accreditation, Quality Assurance

P0017

COMPARISON OF TROPONIN T ON COBAS E801 AND E411

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BACKGROUND-AIM

Determination of troponin is one of the more common requirements in daily clinical practice to rule out or confirm myocardial infarction. The goal of the research is verification of methods for determining troponin T and comparability of results obtained on Cobas e801 and e411 (Roche Diagnostics, Indianapolis, USA).

METHODS

Method verification (according to CLSI guidelines) was performed for the determination of troponin T on commercial control samples (three levels of control) BioRad Cardiac Marker Plus Control (Biorad Laboratories, Marnes-la-Coquette, France) on both analysers. Accuracy, imprecision in series and day-to-day imprecision were tested over 5 days in triplicate. Results are shown as coefficient of variation (CV) and compared with Westgard rules and with CV provided by the manufacturer.
Methods comparison was conducted using 25 patient samples. Statistical analysis was performed using the MedCalc 12.4.0.0 programme (MedCalc, Mariakerke, Belgium). The correlation between the obtained values was shown by Spearman's correlation coefficient, which was 0.977. A Passing-Bablok regression analysis was also performed, including the Cusum test for linearity. Statistically significant value is $P < 0.05$.

RESULTS

The measured values of the commercial controls were within the manufacturer's recommended values for both analysers. Imprecision in series and day-to-day imprecision results were within the manufacturer's criteria. Troponin T imprecision values in all controls were below 2 % on the e801 analyser, and below 6 % on the e411 analyser, which is within the acceptance criteria according to Westgard (I = 15.3 %).
Passing-Bablok regression showed that there is no constant or proportional measurement error between analysers ($y = 1.4297+0.9428x$). Cusum test for linearity showed no significant deviation from linearity ($P > 0.10$).

CONCLUSIONS

The verification of the method provided results that meet the specifications of the manufacturer and Westgard. The statistical processing of the data proved the comparability of the results obtained on the two analysers, which is good for monitoring patients and the success of treatment, since patients do not have to be monitored on a specific analyser, which facilitates routine work. The manufacturer's reference values are the same on both analyzers.

Accreditation, Quality Assurance

P0018

QUALITY INDICATORS IN THE INSTITUTE OF CLINICAL LABORATORY DIAGNOSTIC

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BACKGROUND-AIM

Defining and constantly monitoring quality factors is an obligation, stated by BAS EN ISO:15189-2018, that must be enforced by laboratories. Measurement of indicators should include different phases of laboratory work. Those factors should be monitored during laboratory phases, and using the gathered data laboratories should run self-diagnostics that would indicate any errors.
The study aimed to design and review quality indicators during the last year and compare them using sigma values to improve laboratory performance.

METHODS

In the Institute every non-compliance during the preanalytical, analytical, and post-analytical phases was evident. To assess the quality of the preanalytical phase the number of hemolyzed samples and clotted samples was counted, to assess the quality of the analytical phase the analytical variation coefficient and the number of controlled samples that fit in the allowed range were monitored and to asses, the post-analytical phase Turnaround time was monitored.

RESULTS

The total number of samples was 358838, and of those 358838 samples 4797 were unacceptable hemolyzed samples, or 1.3%, which meets the desired acceptance criteria. The total number of samples of hematological tests was 220471, and of those 220471 samples, 1431 were clotted samples, or 0.65%, which is below the minimum acceptance criteria for the sigma values. Analytical coefficients of variation in the stated period were satisfactory. For all analyzes, control samples that were inside ±2SD were used, and the optimal acceptance criterion was met. The criterion for the post-analytical phase was the time required to issue 90% of the emergency samples of hsTnI and K. The completion time of 90% of the samples was within the desired acceptance criteria for sigma values.

CONCLUSIONS

Preanalytical phase turned out to be the most important. The number of clotted samples collected for hematological analysis that were under the minimal acceptance criteria for sigma value was not satisfactory. To obtain better quality during the preanalytical phase correctional measures were introduced. Most of these measures can be summed providing better education and insight into how to correctly gather blood samples outside of the Institute.

Accreditation, Quality Assurance

P0019

IMPLEMENTATION OF NEW QUALITY INDICATOR FOLLOWING THE DEMING CYCLE

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BACKGROUND-AIM

Never-ending improvement is the heart of Quality approach in medical laboratories. The Deming Cycle, or Plan-Do-Check-Adjust (PDCA), is a four-step iterative approach to improve processes. With the PDCA method, we defined new quality indicators involved in the sample registration process in our medical laboratory, notably concerning patient misidentification (ea. false, incomplete or discordant identification). Firstly, the study aims to quantify non-conformities (NCs) in sample registration process and secondly to develop and to implement specific action plans in order to improve all identified issues.

METHODS

The first step of the Deming cycle was the investigation of the past situation. Analysis code previously used to indicate NC in sample registration process in our laboratory information system (LIS) was a global and undefined code. The second step aims to clearly identify the problem. New analysis codes were implemented in order to categorize the NCs most observed in the sample registration process. Data retrievals from our LIS were done at different timepoints.

RESULTS

Among all the registered NCs, the NC1 corresponding at patient misidentification is the most dominant NC as compared to the others NC with 72% of occurrence. Data filtering revealed that 75% of NC1 were found on analysis prescriptions and/or samples from general practitioners. A Pareto chart was constructed in order to highlight the importance of different NC1 causes. We observed that 80.7% of NC1 were caused by only 26.4% of general practitioners. Additional filter showed that the general practitioner with the highest number of analysis prescriptions, present 58% of his analysis prescriptions that are not compliant with respect to the patient identity.

CONCLUSIONS

Patient misidentification is an important cause of pre-analytical errors in medical laboratories. Corrective action has been decided by biologists and the Quality Management in order to limit the NC1 with the creation of a pre-labelled analysis request form. The 3rd and 4th steps of Deming cycle are dedicated to monitor the effect of the corrective action. Indeed, the objective of this new request form for the general practitioners is a decrease of at least 50% of NC1. Data retrievals from our LIS will be done at different timepoints.

Accreditation, Quality Assurance

P0020

SERUM COPPER, SELENIUM AND ZINC STABILITY AFTER 15 DAYS

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BACKGROUND-AIM

Study of the serum concentrations of trace element such as copper, selenium and zinc is important for the screening, diagnosis and follow-up of malnutrition, malabsorption and other metabolic and neurological diseases. It is not unusual the delay in sample analysis due to technical or organizational reasons. Therefore, knowledge of its stability and preservation is an important requisite to inform reliable results in trace element analysis.

METHODS

Prospective study of the concentrations of copper, selenium and zinc after 15 days sample storage at two different temperatures (4ºC and -20ºC) using 3 different types of tubes; polystyrene tube (PST), Eppendorf tube (EP) and translucent polypropylene tube (PPT). 30 samples were studied for each type of tube, of which 15 were stored refrigerated at 4ºC and 15 were stored frozen at -20ºC for 15 days. The results after storage were compared with the initial measurements of the three elements made on the polypropylene tube using the Student's t-test and comparing mean difference with the quality specification of each analyte. Copper, selenium and zinc were measured by inductively-coupled plasma mass spectroscopy (ICP-MS NexION 300X, PerkinElmer) using Sc as internal standard. Quality specifications (as total error) for copper, selenium and zinc were 11.2, 15.51 and 10.98%, respectively.

RESULTS

Only copper and selenium concentrations measured in PST and stored at -20ºC showed a mean difference meeting quality specification: 10.5% and 13.4% respectively. In contrast, zinc results showed a mean difference above the limit in all conditions.

CONCLUSIONS

Upon 15-day delays in trace element measurements, only polystyrene tubes at -20ºC may be used for sample storage to quantify serum copper and selenium by ICP-MS. Storage of serum samples at 4ºC resulted in a significant loss of stability regardless of the type of tube.
As zinc shows poorer stability, reliable results may not be obtained in any of the assayed conditions.

Accreditation, Quality Assurance

P0021

INTERPRETATION OF COMPLETE BLOOD COUNT PARAMETERS DURING NORMAL PREGNANCY- DO WE HAVE APPROPRIATE REFERENCE INTERVALS?

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BACKGROUND-AIM

Due to the complexity of the process of creating reference intervals (RI) and economic reasons, most laboratories adopt harmonized RIs or those recommended from literature sources, but it is mandatory to make a comparability of the analytical system and the corresponding RI. In the absence of harmonized values for pregnant women, literature RIs are most often used to help in the interpretation of laboratory findings, but they are not mentioned on laboratory reports. The aim of this work was verification of literature RIs according to the Clinical Laboratory Standards Institute (CLSI) EP28-A3c protocol.

METHODS

The CLSI protocol recommends checking the RI by analysing a minimum of 20 samples from healthy subjects. The acceptance criteria being that less than 10 % of the obtained results are outside the RI. Therefore, we checked RI for erythrocytes, hemoglobin and leukocytes measured on an ADVIA 2120 analyser (Siemens Healthineers, Erlangen, Germany) in 73 samples of healthy pregnant women in the first trimester of pregnancy and 38 samples of the same pregnant women in the third trimester of pregnancy.

RESULTS

The results of the parameters in the first trimester showed that our population of pregnant women does not meet the reference intervals for any parameter. Outside the RI are 36 % of the results obtained for erythrocyte values and it is similar with the hemoglobin values, where 32 % of the results are outside the RI. Outside the literature RIs are 9.6 % of the measured results for leukocytes, which still makes the recommended RIs for leukocytes acceptable. In the third trimester, the results were in better agreement with the literature reference intervals; all hemoglobin results were within the RI, while for leukocytes only one value was below the RI. However, 10.5 % of the erythrocyte results obtained are outside the RI which would make it unacceptable.

CONCLUSIONS

During pregnancy, the organism changes daily, which leads to different reference intervals compared to the period before pregnancy. By verifying the values of our pregnant women and the literature references, we obtained unsatisfactory results, which is why it is necessary to repeat the verification, and if similar results are obtained again, it is necessary to make national reference intervals in pregnancy.

Accreditation, Quality Assurance

P0022

SELECTING THE RIGHT TEMPERATURE FOR LONG-TERM STORAGE OF HUMAN SERUM SAMPLES CONTAINING SSRI'S.

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BACKGROUND-AIM

Determine temperatures for prolonged storage of patient samples containing Selective Serotonin Reuptake inhibitors (Citalopram, Desmethylcitalopram, Paroxetine, Fluvoxamine, Sertraline, Fluoxetine, and Norfuoxetine) are not widely available. We conducted a long term stability study where spiked human serum were stored at -80°C, -20°C, 5°C and 25°C for up to 180 days.

METHODS

Samples were analyzed in five replicas for each temperature on each day, and the SSRi's were extracted from serum by SPE and measured on LC-MS/MS. Samples were analyzed on day 0, 2, 4, 8, 14, 17, 23, 30, 60 or 180.

RESULTS

Samples were stable for up to 30 days at 5°C, and up to 180 days at -80°C. The highest CV was found for Paroxetine at 25°C and the lowest for Certraline at -80°C. All had recovery on 100% +/- 10. Except for Paroxetine and Norfluoxetine with 121% and 123% respectively after 180 days at -20°C.

CONCLUSIONS

We found excellent recovery's at -80C after 180 days for all analytes. Our recommendation is; store samples at -80°C if samples are to be stored for more than 60 days. For short term 5°C is adequate up to 30 days.

Accreditation, Quality Assurance

P0023

EVALUATION OF INTERNAL AND EXTERNAL QUALITY CONTROLS OBTAINED BY ATELLICA IM 1600: TWENTY-TWO MONTHS OF MONITORING

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BACKGROUND-AIM

The confidence in the results provided by the laboratory is based on the assessment of daily internal quality controls (iQC) in combination with external quality controls (eQC). The aim of this study was to evaluate the internal and external quality control for anaemia tests (vitamin B12, ferritin, folic acid) and hormones cortisol, estradiol (eE2), FSH, free thyroxine (FT4), insulin, LH, progesterone(PRGE), prolactin, sex hormone-binding globulin, human chorionic gonadotropin (ThCG) and T3 (TSH3UL) measured in the Atellica Solution analyser (Siemens).

METHODS

For the assessment of iQC, we have daily analysed three levels of IntelIQ Immunoassay Plus Control (Bio-Rad) in three different Atellica analysers during 22 months. We used three different lots of controls (41000T, 85220T and 85230T). A pool of coefficients of variation (CV) was calculated by combining the imprecision from the analysers and different lots. The CV obtained was compared with the target CV provided by Siemens.
eQC was evaluated using the Fundació pels Controls de Qualitat dels Laboratoris Clínics program, comparing standard deviation indices (S) with the peer group and the same instrument. We accepted ±3 as the maximum limit of S for eQC. The Atellica assays evaluated are competitive or two-site sandwich immunoassays based on chemiluminescence with acridinium ester technology.

RESULTS

For all iQC measurements, the CV obtained was lower than the target CV. The majority of CVs were below 5%. Only the following tests had a CV between 5 to 10%: three levels of cortisol, three levels of vitamin B12, levels two and three of folic acid, and levels one of PRGE, T3, eE2 and ThCG. Level one of folic acid had a CV between 10-15%. The CV of level one of some tests is slightly higher respect to the other levels, this is due to the fact that levels one have lower target concentrations, so a minor variation produce a major impact.
Furthermore, eQC S was lower than 3 in 329 out of 330 evaluations. Only one FT4 measurement had an S value higher than 3 (-4.3) in June 2020.

CONCLUSIONS

Since this study has been conducted over a long period of time, we can confirm that the results obtained by Atellica Solution Analysers are robust and accurate and that fulfil both iQC and eQC requirements.

Accreditation, Quality Assurance

P0024

ACCURACY STUDY OF ABBOTT'S SIGMA STRONG REAGENTS

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BACKGROUND-AIM

The sigma STRONG (σSTRONG) reagents are marketed by Abbott with a new formulation that aims to improve stability and calibration issues; but they differ in technical specifications. The ISO 15189 standard for the accreditation of clinical laboratories requires a verification of the veracity of the measurement procedures before clinical use and whenever they have undergone any modification.
The aim of the study is to compare the intraserial and intralaboartory accuracy of the σSTRONG techniques with the traditional ones.

METHODS

Three analyzers (Alinity C) loaded with classic reagents and six analyzers with σSTRONG reagents were used to determine: uric acid, albumin, alanine aminotransferase (ALT), amylase, aspartate aminotransferase (AST), total bilirubin (BT), cholesterol, creatinine, alkaline phosphatase, gammaglutamyltransferase (GGT), iron, lactate dehydrogenase (LDH), protein and triglycerides.
For intraserial imprecision, a series of 10 measurements of a serum or urine sample was performed on each analyzer. For intralaboratory imprecision, 20 results were collected from one control level processed on consecutive days.
For the statistical study, the mean (X) and standard deviation (SD) of the intra and interseries coefficients of variation (CV) were calculated of each analyzer. The X+2SD was assumed to be the maximum intralaboratory CV obtained for each presentation. The CV of σSTRONG was compared with the classic presentation using Chi-square and a statistical significance of $p<0.005$.

RESULTS

Uric acid, ALT, amylase, BT, creatinine and LDH reagents presented significantly different CVs than those observed in the classic presentations.
The CV of amylase was lower in the σSTRONG presentation. However, BT and creatinine CVs were significantly higher, at the limit of laboratory quality specifications. ALT CV presented a high interinstrumental variability, with intraserial CVs of 1.9-7.7%, which orients to a high sensitivity to the analyzer status. Differences in LDH and uric acid were less pronounced.

CONCLUSIONS

New formulations should be tested before use in clinical practice to assess their accuracy. The reagents that showed the greatest differences were ALT, amylase, BT and creatinine, so they require special attention in their implementation and follow-up.

Accreditation, Quality Assurance

P0025

REAGENT LOT-TO-LOT DIFFERENCES FOR D-DIMER

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BACKGROUND-AIM

D-dimer measurement is recommended as part of clinical algorithms to exclude venous thromboembolism (VTE). A common decision limit for exclusion of VTE is <0.5 mg/L fibrinogen equivalent units (FEU). Therefore, for appropriate medical decisions to be made, D-dimer results should be consistent over time regardless of reagent lot number. The aim was to present the results obtained from a national surveillance program for lot-to-lot evaluation for D-dimer.

METHODS

Noklus developed a national surveillance program for lot-to-lot evaluation for several analytes, among them D-dimer. An excel template was provided to Norwegian hospital laboratories with a standardised procedure for how to perform the lot changes. Each laboratory made a pool of patient plasma (D-dimer level 0.4-1.0 mg/L FEU) and analysed 12 replicates with the current and new reagent lot. Mean percent difference between the two reagent lots was calculated together with the 90% confidence interval (CI).
Data from 15 Norwegian hospital laboratories with 51 D-dimer lot-changes were collected from November 2019 to December 2022. Four different measurement procedures (MPs) were in use: Hemosil D-dimer HS, Instrumentation Laboratory, Bedford, MA, USA; Innovance D-dimer, Siemens Healthineers, Erlangen, Germany; STA-Liatest D-dimer, Diagnostica Stago, Paris, France; and Cobas Tinaquant D-dimer, Roche Diagnostics, Mannheim, Germany.

RESULTS

Mean absolute percent difference between reagent lots (min-max, number (n) of lot changes) for Hemosil was 3.8% (1.1-7.1%, n=8), for Innovance 4.7% (0.3-10.7, n=21), Cobas Tinaquant 5.7% (0.0-12.0, n=10) and STA-Liatest 7.9% (1.8-19.3, n=12). All mean differences including 90% CIs between two lots, except two individual results from Liatest, were within the acceptance criterion of ±20%.

CONCLUSIONS

Results from three years collection of reagent lot-to-lot differences for D-dimer in Norwegian hospitals show that lot-to-lot variations varies considerably for the various MPs on the market. Knowledge of this variation is useful in the evaluation of each new lot in the routine laboratory, but also, e.g., when selecting new instruments for D-dimer in the laboratory.

Accreditation, Quality Assurance

P0026

RELIABILITY OF A REDUCED BRACKETED CONTROL CONCEPT FOR AUTOMATED BIOCHEMISTRY ANALYZERS

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BACKGROUND-AIM

In Clinical Biochemistry, internal quality control samples (IQC) are used to ensure analytical quality. Traditionally, IQC's were included in the beginning and end of each analytical series and evaluated prior to the release of patient results. Today, most tests are processed on automated analyzers in a continuous mode, and IQC protocols often include a "Critical control" (CC) analyzed after daily start-up and a "Bracketed control" (BC) analyzed periodically along with patient samples. Optimally, at each CC or BC all analytes are measured in two levels of IQC. However, since IQC materials and reagents are costly, the BC often includes only one level of IQC and a selection of analytes, covering the testing principles, measuring cells and essential technical parts of the analyzer. This study aimed to investigate whether the BC is a reliable concept to detect clinical relevant analytical errors.

METHODS

On two Cobas 8000 lines each consisting of two ISE-, one c702- and two e602-modules, the BC (9 analytes) was analyzed three times a day; at 18:00 h, 02:00 h and before daily maintenance. When a BC result was outside ±3SD, IQC's in two levels were measured for all tests on the actual analyzer module. Subsequently, reliability of patient results released since the last approved IQC was evaluated by random samples reanalyzed using another analyzer. During eight months we exchanged the BC at 18:00 h with an additional CC to investigate whether analytical problems that were not detected by the BC was revealed.

RESULTS

A total of 1,440,674 patient results were produced for the 65 tests performed on our two Cobas 8000 lines. The BC and CC at 18:00 h resulted in 28 and 84 occasions respectively, where patient samples (n=996 vs n=1669) were reanalyzed due to an IQC result outside ±3SD. On 14 and 30 occasions respectively, patient results (n=222 vs n=311) were subsequently corrected. Thus, using the BC concept we might have overlooked 89 (0.062 ‰) patient results, which according to our accept criteria were erroneous. Of the 89 corrected results, 3 were judged of clinical importance. The annual extra costs for identifying these errors is approximately 220,000 €.

CONCLUSIONS

Reduced BC overlooks only very few errors and has a substantial lower cost compared to CC.

Accreditation, Quality Assurance

P0027

COMPARISON OF PATIENT MEDIANS CAN BE A USEFUL TOOL FOR SURVEILLANCE OF GLOBAL HARMONISATION EFFORTS

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BACKGROUND-AIM

Post market surveillance of the performance of laboratory tests is important and should be performed during the entire life cycle of an instrument. Noklus (The Norwegian organization for Quality Improvement of Laboratory Examinations) offers laboratories worldwide to participate in a program called “the Percentiler” where daily calculated patient medians from an out-patient population are reported. The core concept is that patient medians are normally stable over time.

METHODS

When patient medians are grouped according to measurement procedures, comparison of different groups can be a useful tool to identify problem areas in need of harmonisation efforts, as well as assessing the effect of ongoing harmonisation and standardisation projects. Differences between measurement procedures based on patient medians must be interpreted in the context of the analyte in question and known variation between patient populations.

RESULTS

Results for common analytes as creatinine, chloride, ALT and FT4 are all analytes showing differences between measurement procedures over time. As an example; the median for chloride in serum/plasma for one year in the Percentiler-program for the Siemens group (Atellica and Dimension) is 106.0 mmol/L, the Abbott group (Architect and Alinity) 105.0 mmol/L and the Roche group (Cobas) 102.4 mmol/L.

CONCLUSIONS

Comparison of patient medians for different instruments groups reported from routine laboratories is a useful tool for surveillance of global harmonisation efforts. Results are updated daily in the program, and patient samples are by definition commutable. These are important advantages compared to EQA-programs especially where non-commutable control materials are used.
Noklus will later this year (2023) launch an updated version of the program with the new name “Noklus Patient Median” program (NOPAM). New features in the updated program will include the possibility to group by method information and geography. This will improve the quality of the program and give a better overview of analytical differences between routine laboratories and measuring systems. NOPAM will also be available for EQA providers.

Accreditation, Quality Assurance

P0028

ACCURACY OF PO2 – A 20 YEAR OVERVIEW OF BLOOD GAS PERFORMANCE

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BACKGROUND-AIM

Over the last 2 decades industry has provided us with an increasing number of smaller, portable analysers, utilising single or multi-use cartridges for Point of Care (POCT) Blood Gas analysis. Most EQA Providers distribute aqueous material for their performance assessment, however annual studies conducted by Weqas using tonometered haemolysate have identified significant matrix issues with aqueous material especially for pO 2. The aim of this retrospective study was to assess the performance of Laboratory and POCT analysers for pO 2 using both fresh haemolysate and aqueous material.

METHODS

Tonometered blood haemolysate with oxygen saturation kinetics identical to that of fresh blood was distributed on an annual basis to all participants in the Weqas Blood Gas Scheme over a 20-year period. The performance for pO 2, expressed as coefficient of variation (CV) and bias against the All Method Average was calculated for each analyser for the haemolysate and concentration matched aqueous samples.

RESULTS

An increase in the use of POCT analysers was observed over this period, representing 87%, 43%and 8% of analysers in 2021, 2012 and 2001 respectively. There was little change in the overall precision profile from 2000 to 2021 however a much lower CV was observed at a pO 2 < 15 kPa prior to 2000. At low pO 2 concentration there was a significant improvement in the interlaboratory variation and bias for the haemolysate material compared with aqueous material, CV=10.6%, bias = 1kPa; CV=17.3%, bias = 6kPa respectively. The CV for each analyser varied greatly; in 2021 a CV of 8.8% and 14.9% at a pO2 of 8.4kPa was observed for a Laboratory and POCT analyser respectively.

CONCLUSIONS

POCT Blood gas analysis continues to grow, with a wide variation in performance for these analysers. Aqueous material has a low buffer capacity and poor ability to dissolve gases compared with fresh whole blood. It is extremely sensitive to changes of oxygen pressure due to contamination by atmospheric air, especially at low pO 2. EQA providers using aqueous material alone need to consider these pre-analytical effects in their interpretation of analytical performance. The use of fresh tonometered haemolysate provides commutable material that overcomes this issue.

Accreditation, Quality Assurance

P0029

APPLICABILITY FMEA (FAILURE MODE, EFFECT AND ANALYSIS) IN THE MAPPING OF QUALITY RISK MANAGEMENT IN THE CLINICAL LABORATORY

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BACKGROUND-AIM

Quality risk management is a fundamental process in the accreditation of clinical laboratories. Mapping of quality risk, begins with quality risk assessment followed by quality risk control. To ensure proper functioning of this mapping, it is necessary to carry out periodic reviews.
Multiple tools can be applied, among the most useful and well-known is FMEA (Failure Mode, Effect and Analysis). FMEA, identifies potential defects, evaluates them, and identifies possible causes. This process qualifies a risk according to the effect and the probability that a result affected by a cause can reach a patient. At the end, it defines preventive and/or corrective actions that minimize this impact.

METHODS

FMEA uses a decision tree that breaks down the process into different phases.
In the first phase, it identifies the potential failure mode. In the second phase, it describes the potential effect of the failure and assesses the severity index (S) or seriousness. The third phase, identifies the cause of the failure mode and assesses the rate of occurrence (O) or the cause. In the fourth phase, he identifies and assesses the detection systems (D). In the fifth phase, the Risk Priority Number (RPN) is calculated using the formula RPN = SxOxD. In the sixth phase, actions are proposed to minimize the risk and reduce the RPN to calculate a new criticality index.

RESULTS

RPN evaluates FMEA results at 3 levels by using a risk matrix that classifies risks according to colors and severity. Unacceptable risk (red), which must be reduced; major risk (yellow) in which the risk must be reduced to the minimum possible; Minor risk (green) which is considered acceptable and its reduction will depend on the benefit/cost ratio.

CONCLUSIONS

FMEA is a very useful tool used in the clinical laboratory for the identification of potential failures in any phase of the analytical process (pre-analytical, analytical, post-analytical) in the mapping of quality risk management. FMEA allows to reduce these risks through the application of corrective and/or preventive actions aimed at improving the quality of the processes of a clinical laboratory.

Accreditation, Quality Assurance

P0030

PATTERN OF CHANGES OBSERVED IN ALINITY HQ ANALYZER WITH DENGUE INFECTION

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BACKGROUND-AIM

The Abbott Alinity hq analyzer uses advanced optical technology to identify unique patterns consistent with different types of infection and hematopoietic neoplasms. In the context of Dengue, unique morphologic changes are seen under the microscope and patterns are identified in the flow scattergrams.

METHODS

Samples obtained from individual with known Dengue infection was run on the Abbott hq hematology analyzer. Cells counts were analyzed and specific patterns on the scatterplots were identified. In addition, the specimen was reviewed as a peripheral blood smear under the microscope.

RESULTS

This patient presented with absolute and relative neutropenia, relative lymphocytosis and thrombocytopenia. The VAR LYM flag was triggered, and lymphocyte, monocyte and basophil counts were labelled as suspect.
Review of the Alinity hq scatterplots revealed a predominant lymphocyte population (cyan) that had an unusual pattern showing 2 subpopulations of cells (IAS vs ALL) on the scatterplots. The lymphocyte population also extends into the monocyte population (purple) (ALL vs PSS) on the scatterplots.
Peripheral smear review showed a high number of plasmacytoid reactive lymphocytes with irregular nuclei and abundant basophilic cytoplasm. In addition, there was a visible decrease in the number of platelets and occasional presence of large platelets correlating with the CBC result showing thrombocytopenia. Based on the clinical presentation and laboratory findings, the patient was diagnosed as having dengue hemorrhagic fever (DHF).

CONCLUSIONS

DHF is caused by the dengue virus, which belongs to the Flavivirus family. Humans are infected by the bite of the infective Aedes aegypti mosquito (Gubler). According to the World Health Organization, DHF is defined by fever, hemorrhagic manifestations (such as petechiae/purpura, epistaxis, menorrhagia and gastrointestinal bleeding thrombocytopenia and evidence of increased vascular permeability (Gubler, CDC). The diagnosis of DHF is based on clinical, epidemiological and laboratory data. Laboratory findings include neutropenia, lymphocytosis and presence of atypical lymphocytes which are seen in up to 73% of dengue infections (Tanaka). In severe cases, DHF patients can experience sudden deterioration of symptoms.

Accreditation, Quality Assurance

P0031

THE CDC CLINICAL STANDARDIZATION PROGRAMS (CDC CSP) - IMPROVING THE QUALITY OF DISEASE BIOMARKER MEASUREMENTS IN PATIENT CARE AND RESEARCH

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BACKGROUND-AIM

CDC's Clinical Standardization Programs (CDC CSP) assists researchers and laboratories with assessing and improving the analytical performance of biomarker tests performed in patient care, public health, and research. CDC CSP develops and applies reference methods, materials, and protocols to consistently calibrate biomarker tests across instruments and laboratories and to assess and improve other analytical performance characteristics, such as selectivity. In addition to providing assistance with assay calibration, CDC CSP helps clinical and research laboratories monitor the accuracy and reliability of tests over time. Furthermore, CDC CSP collaborates with researchers on the development of reference intervals and on using new and emerging biomarkers in patient care and public health.

METHODS

CDC CSP provides comprehensive programs for traditional blood lipids, testosterone, estradiol, and vitamin D. Notable improvements in assay performances have been observed with assays that are standardized by CDC CSP. Free thyroxine (FT4) was recently introduced as a new standardization program analyte. Programs for apolipoproteins, free testosterone, parathyroid hormone, and angiotensin peptides are being developed.

RESULTS

Prior to the launch of the new programs, CDC CSP conducted interlaboratory comparison studies to assess current performance of FT4 and lipoprotein(a) [Lp(a)] assays. FT4 measurements showed a high variability in calibration accuracy among assays, with some assays reporting values up to 50% lower than the reference value. It is anticipated that assay recalibration to a common standard will notably improve assay variability. Lp(a) showed inter-assay variability (CV of 3.3 % to 69.1 %) that increased at higher Lp(a) concentrations that was not isoform dependent.

CONCLUSIONS

The interlaboratory comparison studies demonstrated a clear need for standardization of FT4 and Lp(a) assays. To assist with recalibration and verification of FT4 and Lp(a) assays, CDC CSP provides laboratories and assay manufacturers with single-donor/pooled sera value assigned by a reference method for FT4 and by a mass spectrometry method for Lp(a).

Accreditation, Quality Assurance

P0032

QUALITY MANAGEMENT IN BIOBANKING

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BACKGROUND-AIM

Bank of Biological Material of Masaryk Memorial Cancer Institute (BBM MOÚ) is the coordinator of the Czech national node of biobanks - BBMRI.cz, which has been part of the European Research Infrastructure Biobanking and Biomolecular resources Research Infrastructure (BBMRI-ERIC) since 2013.

METHODS

BBM MOÚ is focused on long-term storage of frozen or otherwise processed tissue and other human biological material of oncology patients and clients of the Prevention Center of MOÚ. This biological material, including related data, is provided primarily for research purposes.

RESULTS

The goal of biobanks Quality management is to provide biological material and related data for research and development in a minimum standardized quality in order to strengthen mutual interoperability across several EU countries. The introduction of a Quality management system (QMS) is a surefire way how to prove a flawless operation of the given biobank. Accreditation of biobanks in the Czech Republic will be carried out according to the ISO 20387:2021 Biotechnology-Biobanks standard.

CONCLUSIONS

In 2022, BM MOÚ participated in the ČIA pilot project to assess the implementation of the Quality management system (QMS) according to the standard ISO 20387:2021, and based on the assessment of the established SMK and the activities carried out in BBM MOÚ, the compliance with the requirements of this standard has been met. Due to the fact that the ISO 20387 standard is already harmonized, BBM MOU will be the 1st biobank in the Czech Republic that will be accredited according to this standard.

Accreditation, Quality Assurance

P0033

VERIFICATION OF HAEMATOLOGY ANALYSER MINDRAY BC-5390 CRP AND COMPARISON WITH SYSMEX XN-550

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BACKGROUND-AIM

A verification study must be a first step when introducing a new anaylser to your laboratory. In this study the aim was to assess analytical performance of haematology analyser BC-5390 CRP (Mindray, Shenzhen, China), prior to its routine implementation.

METHODS

Evaluation of analytical performance for parameters leukocytes (WBC), erythrocytes (RBC), haemoglobin (Hgb), platelets (PLT), mean corpuscular volume (MCV) and mean platelet volumen (MPV) included: precision (within-run and within-lab, 5 replicates for 5 days) and trueness for which three levels of the commercial control material (BC-5D Hematology Control, Low (L1), Normal (L2), High (L3)) were used. Patient leftover samples were used for within-run precision estimation (1 random sample, 20 replicates in a serie) and 40 samples for method comparison with XN-550 (Sysmex, Kobe, Japan). Coefficients of variation (%) and biases (%) were calculated in User Verification of Precision and Estimation of Bias Workbook (EP15-Ed3-WB) and for comparison study MedCalc was used (Passing-Bablok regression analysis). Acceptance criteria for WBC, RBC, Hgb, MCV, PLT and MPV were as follows: a) within-run precision: 2%, 1.5%, 1.5%, 1%, 4%, 4% (manufacturer technical specifications), b) within-lab precision: 5.4%, 1.3%, 1.4%, 0.4%, 2.8% and 1.1% (European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Biological Variation Database, Desirable Specification (EuBIVAS DES); c) trueness: 5%, 2%, 2%, 3% and 8%, no data (manufacturer technical specifications), respectively.

RESULTS

Within-run precision was within acceptance criteria for patient sample while for control material criteria were only not met for PLT (6.7%) and MPV (4.9%) for L1. Within-lab precision criteria were not met for L1 for PLT (6.7%), MPV (5.1%), Hgb (1.5%) and for all three levels for MCV (0.8%, 0.7% and 0.8%). Estimated bias was within the acceptance criteria for all parameters except for RBC, L1 (2.9%). Passing-Bablok regression analysis showed only proportional difference for WBC (y=-0.16(95% CI:-0.48 to 0.06) + 1.04(95% CI:1.02 to 1.08)x).

CONCLUSIONS

The performed analytical evaluation confirmed Mindray BC-5390 CRP as a reliable analyser regarding precision, trueness and method comparison with Sysmex XN-550.

Accreditation, Quality Assurance

P0034

ESTABLISHING REPORTABLE INTERVAL FOR CLINICAL LABORATORY TESTS THROUGH RETROSPECTIVE DATASETS

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BACKGROUND-AIM

For the objectives of meeting the quality requirements, reducing errors, and minimizing patient risk, the reportable interval of clinical laboratory results has to be established. This interval lies between the limits for incompatibility with life, so any lab result values beyond these limits are impossible to belong to a live patient and consequently should be held from being reported. The methodology for establishing the reportable interval for lab tests is still challenging. Clinical evidence is extremely rare about these limits due to the inherent limitation in defining result values that are incompatible with life in a live patient population. However, the reportable interval can be established through statistical tools, which can estimate the unlikely lab result values regardless of their clinical implication. In this study, we aimed to establish the reportable interval of some laboratory tests through data analysis of retrospective clinical laboratory datasets.

METHODS

The publicly available Medical Information Mart for Intensive Care (MIMIC)-IV v2.0 dataset was used for establishing their reportable interval by applying Dixon's test, which is a statistical test for assessing the homogeneity of the data and detecting outliers. Only lab tests with more than 10,000 quantitative results of non-fraction units were selected. The results of each test were first checked by Dixon's test to detect any outliers present. The interval was then got established by inferring high and low hypothetical outlier values from the highest and lowest non-outlier result values in the dataset. The INTEGO dataset, which is a primary care Flemish dataset, was used to apply the established intervals for detecting implausible records.

RESULTS

The reportable intervals of 154 lab tests were established by analyzing ~85.5 million lab result records. The established intervals got then validated by laboratory medicine experts. The intervals were then applied to 174 million lab result records of the INTEGO dataset.

CONCLUSIONS

Retrospective clinical laboratory datasets can be used to establish the reportable interval of lab tests, which helps in reducing errors by holding results out of this interval, therefore minimizing patient risk, and enhancing the quality of the clinical laboratory services.

Accreditation, Quality Assurance

P0035

COMMUTABILITY ASSESSMENT OF FOUR CANDIDATE REFERENCE MATERIALS FOR ASPARTATE AMINOTRANSFERASE (AST)

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BACKGROUND-AIM

Measurement standardisation of the catalytic concentration of AST in serum is based on three pillars: the primary reference measurement procedure (PRMP), reference laboratories, and suitable certified reference materials (CRMs). The existing AST CRM (ERM-AD457/IFCC) is intended as trueness control material for the PRMP and, in the upcoming years, will be replaced by a new CRM. Proven commutability of the new CRM would allow an extension of the intended use to trueness control of both the PRMP and the routine measurement procedures (MPs).

METHODS

The JRC performed a commutability study with four candidate RMs for AST and 30 serum pools. Two of the candidate RMs contained purified AST from human tissue and the other two contained recombinant human AST expressed in E. coli. All candidate RM were prepared in a buffer solution with various compositions.
We used the IFCC primary reference measurement procedure (PRMP) and five different IVD routine MPs. These MPs have been selected according to its extensive use for the AST determination, and are the following: Abbott (Alinity c), Beckman (Coulter AU5800), BioSystems (BA400), Roche (Cobas c 702) and Siemens (Dimension Vista 1500).
The data were analysed using the "difference in bias" approach (recommended by the IFCC Working Group on Commutability), which is based on the difference in bias between a RM and serum pools, when measured with the routine MP versus the PRMP.

RESULTS

The commutability profile of the four candidate RMs was variable and one of these materials, based on a recombinant form of human AST, showed a better commutability profile. The composition of this candidate RM will be selected for the production of the new AST CRM.

CONCLUSIONS

A CRM for AST in an artificial matrix can be commutable for several routine MPs and the origin of the AST material (human recombinant form expressed in E. coli or purified from human tissue) has not shown to be a critical factor.

Accreditation, Quality Assurance

P0036

EVALUATION OF REQUESTS WITH AST AND ALT IN AMBULANT PATIENTS IN HEALTH AREA 2 OF THE REGION OF MURCIA. SPAIN.

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BACKGROUND-AIM

Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST) enzymes are measured in the clinical laboratory for diagnosis and monitoring of liver disease, usually together in the same request. ALT is more liver specific than AST for diagnosis and monitoring of liver disease so in ambulatory patients it is the magnitude of choice. We want to evaluate the demand for these enzymes in ambulatory patients.

METHODS

The evaluation has been carried out with the requests of ambulant patients, neither hospitalized nor from the Emergency Department of the central laboratory of Area 2 (289512 inhabitants) of Santa Lucía Hospital, Servicio Murciano de Salud, Region of Murcia, Spain during the year 2021. The determinations were performed in Cobas 702 automatic analyzer of the Cobas 8000 platform (Roche Diagnostic) by molecular absorption spectrometry for the methods: Aspartate Aminotransferase acc. to IFCC without pyridoxal phosphate activation Alanine Aminotransferase acc. to IFCC without pyridoxal phosphate activation, respectively.

RESULTS

There were 200725 requests involving ALT or AST, of which 167794 were from outpatients, not admitted or emergency department patients.
With both enzymes there were 155916, of which 142623 with ALT below the cut-off point (91 %). Ninety-eight percent of the AST results of the requests with ALT below the cut-off point were below the cut-off point (men 40 U/L, women 32 U/L), the rest of the values above the cut-off point had a median of 45 U/L for men and 36 U/L for women.

CONCLUSIONS

The results obtained show that, by managing the requests of outpatients, by performing only the ALT, 98% of the AST could be missed, in our case it would be 142623 determinations in a year. The 2% of AST above the cut-off point is not significant, since the enzyme is not the most specific for the liver and the values are very close to the cut-off point. We have to reach a consensus with the requesting clinicians that in outpatients only ALT activity will be measured and in case of being above the cut-off point, AST activity will be measured. This step would be very beneficial for the demand management of our laboratory.

Accreditation, Quality Assurance

P0037

ERROR DETECTION TO IMPROVE PATIENT SAFETY & CLINICAL OUTCOMES: EVALUATING ANALYTES SPECIFIC THRESHOLD LIMITS (TLS)

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BACKGROUND-AIM

Aim was to devise a mechanism to contain such typographical errors. An error detection system based on TLs was devised, where traps were set in the Lab Information System (LIS) whereby an alarm or notification was triggered when a result falls outside limit.

METHODS

This quality improvement project (QIP) was conducted at the Section of Clinical Chemistry from Oct 2021 - Jun 2022.
Plan: A QIP team comprising of Chemical Pathologist, QC Officers, Information technology (IT) analyst and laboratory manager was formed. Team defined core activities to define TLs, implement it in LIS and evaluate its impact.
Do: The team identified maximum and minimum TLs for 225 analytes based on analytical measurement range (AMR), extended analytical measurement range (EAMR) and/or maximum dilution, keeping in view the maximum reported result in the previous six months and the medical decision point for each analyte. These TLs were first simulated by applying on the Service Line system (a mirror system of LIS) to identify and correct any arising issue and then applied on LIS.
Check: An 'Error detection Policy' was developed and corrective action mechanism for result beyond TLs was defined, educational interventions done to train staff, faculty, residents of the TLs process, how to define, simulate and implement TL for an analyte, and corrective actions to be taken.
Act: QIP team reviewed the process and recommended to include this in the 'New Test' introduction checklist and review the TLs after introduction, discontinuation, change in methodology or kit/assay for any analyte.

RESULTS

Entire test menu for quantitative analytes at section of clinical chemistry was reviewed (n=221). The TLs were applied based on AMR in 46.15% (n=102), EAMR 45.24% (n=100), previously reported patient results or medical decision point 8.59% (n=19). The CE course was implemented and attempted by staff (n=49), faculty (n=5) and residents (n=3).
Prior to implementation during a period of 2 years (n=2) complaints were received for the results received beyond TLs. However, none were received after TL implementation.

CONCLUSIONS

Findings suggest that the TLs improved the error detection and will prove beneficial in reducing post analytical errors and for best laboratory practices.

Accreditation, Quality Assurance

P0038

USAGE PATIENT POOL SAMPLES AS INTERNAL QUALITY – COMPARISON OF FIVE COMMERCIAL TOTAL 25(OH) VITAMIN D ASSAY IN PATIENT POOL SAMPLES AND IN COMMERCIAL QC SAMPLES TOGETHER WITH LCMS MEASUREMENT

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BACKGROUND-AIM

Determination of Total 25 (OH) Vitamin D (25OHD) has become a routinely measured parameter. Although most manufacturers have adopted arbitrary reference limits, the levels of Total Vitamin D in commercially available control materials vary significantly between manufacturers. Mainly thanks to the so far unsuccessful attempt to standardize the method. This study evaluates the benefits of using mixed patient samples for internal quality control.

METHODS

Mixed samples of patients at levels of 40 nmol/l (sample 1) and 110 nmol/l (sample 2) were prepared for the study. For comparison, control materials LiquichekTM Specialty Immunoassay Control from Biorad (Level 1 – QC1, Level 2 – QC2) were used. Intermediate precision and repeatability were determined on Beckman Coulter DxI 800, Roche Cobas e801, Abbott Alinity and Diasorin Liaison XL analyzers. The values were compared and evaluated with respect to the characteristics of the kits listed in the package leaflets. Repeatability was supplemented by measurements on a Siemens Advia Centaur analyzer and samples were measured by the LCMS method traceable to NIST SRM 972a on two LCMS systems. All samples were measured for 1,25 (OH)2 Vitamin D on a Diasorin Liaison XL analyzer.

RESULTS

Intermediate precision and repeatability results are comparable for patient pooled samples and commercial controls, and consistent with manufacturer's instructions for use. The 25OHD level in sample 1 shows bias to LCMS from -7.5% to 45%, in sample 2 from -13.8% to 6.3%. 25OHD level in QC1 shows bias to LCMS of -15.9% to 446%, in QC2 from -46.6% to 247.5%. LCMS determination of commercial controls has shown a high level of 25(OH)Vitamin D2 (25OHD2). These levels are significantly higher than in patient samples. The other metabolites of Vitamin D (24,25 (OH)2 Vitamin D3; 1,25 (OH)2 Vitamin D3 and 3epi 25 (OH) Vitamin D3 correspond to the ratios in patient samples and do not affect the different values determined by individual systems as much.

CONCLUSIONS

Commercially available control materials often achieve the declared levels of 25OHD by the isomers spiking. However, these do not reflect the ratios of isomers in normal patient samples and therefore we consider the use of pooled serum a to be advantageous.

Accreditation, Quality Assurance

P0039

PATIENT BASED REAL-TIME QUALITY CONTROL (PBRTQC) -IDENTIFICATION OF APPROPRIATE DELINEATIVE MARKERS FOR SERUM SODIUM USING BIG DATA

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BACKGROUND-AIM

Patient-based real-time quality control (PBRTQC) procedures make use of shifts in the trend of statistical measures of spread in laboratory results to identify possible bias in analytical methods. Owing to the challenges experienced with traditional internal quality control practices, PBRTQC is gaining popularity in clinical laboratories with its integration requiring some statistical groundwork. In this study we aimed to compare and optimize various PBRTQC procedures for serum sodium using bias detection and validation curves to ultimately select the optimal algorithm that can be implemented.

METHODS

We extracted and analysed serum sodium results (>280 000) over a period of two years from the laboratory information system. Various PBRTQC procedures were evaluated by data analysis. Different inclusion criteria, quality control procedures (moving mean and moving median), batch sizes, data truncation limits and control limits were tested. The ability of the procedure to detect bias was the criterion used to select the optimal procedure. After optimization, validation of the selected procedures was done. The results were displayed using bias detection and validation graphs.

RESULTS

We identified that the PBRTQC method which performed optimally required a block size of 25 consecutive patient results; the moving average quality control procedure; no truncation of the data; and control limits set to the reference change value.

CONCLUSIONS

We demonstrate for the first time the application of real-life data from serum sodium results in the PBRTQC process. This study illustrates the ability of a public sector tertiary laboratory in South Africa to use existing patient data to investigate and identify the optimal PBRTQC procedure for a specific analyte. Implementation of PBRTQC will be of substantial value in resource-limited environments eg. developing countries with limited availability of quality control materials and will inevitably enrich current laboratory quality control practices resulting in the production of high quality results.

Accreditation, Quality Assurance

P0040

PERFORMANCE NOTIFICATIONS DECREASE REACTION TIMES TO EQA REPORTS

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BACKGROUND-AIM

Labquality organizes over 900 external quality assessment (EQA) rounds yearly. We publish client performance reports as soon as possible after the closing date. For almost ten years, the participating laboratories have received emails when all final reports with expert comments have been published. Since 2020, we have sent automatic performance notifications based on the calculated difference of the participants' results from the target values, target areas and acceptable performance. In case the participant exceeds the target areas or has other notifications to their performance, a warning is shown in the email title and body text. The performance is also indicated in our IT-platform LabScala with a graphical element on the dashboard and in the report folder view.

METHODS

We extracted the dates of the Report ready -emails and compared them to the dates of report opening of the participant specific reports to investigate the effect of the emails and perfomance notifications on the reaction times.

RESULTS

In 2019, the median reaction time after the Report ready -emails was 8 days and it has decreased as the report performance notifications were introduced in 2020. We now have performance notifications for 50 % of our reports and in 2022 the reaction time median was 6 days for participants who opened the reports after receiving the Report ready -email. For the reports with a poor performance, the median reaction time was 5 days. Some participants open their reports before the email is sent. The overall reaction times have decreased from 8 to 7 days from 2019 to 2022 and there is a statistical difference ($P < 0.0001$). The reaction times of reports having a warning compared to reports not having a warning, differ statistically in 2022 ($p<0.001$).

CONCLUSIONS

The overall participant reaction time to their EQA reports drops yearly. A statistical difference between the reaction times in opening reports containing information of poor performance compared to reports with acceptable performance was noted. This indicates that changing the Report ready -emails to include a performance notification in the email title, body text and LabScala has been a valuable improvement for the laboratories.

Accreditation, Quality Assurance

P0041

ANALYTICAL PERFORMANCE EVALUATION OF THE ABBOTT 25-OH VITAMIN D ASSAY ON THE ARCHITECT I1000SR ANALYZER

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BACKGROUND-AIM

Within the last several years, frequency of vitamin D testing has multiplied substantially all over the world, since it has been shown to have an important role in many diseases and conditions.
In order to ensure the quality of the obtained results we evaluated the analytical performance of the Abbott 25-OH vitamin D (VitD25-OH) Chemiluminescent Microparticle Immunoassay (CMIA) on the Architect i1000SR analyzer.

METHODS

Repeatibility, between run, within-laboratory precision and trueness were determined using the commercial control samples for 5 secutive days in triplicate. The coefficients of variation were calculated (at low, medium and high control levels, N=15) and compared to the acceptance criteria declared by the manufacturer (within-laboratory total CV at 50/100/187,5 nmol/L <3,6/<3,2/<4,1%). The bias was calculated and compared to the acceptance criteria declared by the Riqas External Quality Assessment Scheme (22,6%). Additionally, concentration of VitD25-OH was compared with the VitD25-OH on the analyzer Architect i2000SR in an accredited laboratory, for 40 patient samples in the range from 9,1 to 161,7 nmol/L. The results are statistically processed in the MedCalc program (v.17.9.2) by Passing-Bablok regression.

RESULTS

Satisfactory results were obtained for repeatibility, between run and within-laboratory precision; the coefficients of variation were at 50 nmol/L 2,2%, 1,5%, 2,3%, at 100 nmol/L 3,0%, 0,6%, 2,6% and at 187,5 nmol/L 1,9%, 0,6%, 1,7%. The deviation from the declared value of VitD25-OH in the control sample showed satisfactory accuracy: bias was -1,5%, 2,0% and 1,2%. Passing-Bablok regression analysis showed that there is no constant or proportional deviation between the analyzers i1000SR and i2000SR: Y= -0.24(-1,55 - 0.76) + 0,98 (0.94 - 1.00)X.

CONCLUSIONS

We conclude that the Abbott VitD25-OH CMIA method on the Architect i1000SR analyzer is a reliable, accurate and precise. It shows a good comparison with the VitD25-OH on the analyzer Architect i2000SR and could be implemented in a routine laboratory work.

Accreditation, Quality Assurance

P0042

A COMPARATIVE STUDY OF ERYTHROCYTE SEDIMENTATION RATE BY AUTOMATED ESR ANALYSER ALIFAX AND MANUAL WESTERGREN'S METHOD

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BACKGROUND-AIM

The erythrocyte sedimentation rate (ESR) is a widely used simple,inexpensive ,nonspecific screening test to assess an inflammatory or acute phase response. ESR can be effective in determining prognosis in chronic diseases like Hodgkin's disease ,Rheumatoid arthritis or prostatic cancer .The most satisfactory method of performing the test was introduced by Westergrens in 1921 and it is recommended by International Council for Standardization in Hematology.Alifax Instrument has a fully automated ESR system and engineered to respect Clinical Laboratory Standards Institute (CLSI) requirements.It just needs 150 ul blood per sample in EDTA and you can have the results in just 20 seconds.
Aim :To compare the performance of the Automated ESR Analyzer Alifax with the Gold Standard manual Westergren Method.

METHODS

The present study is a comparative study which is done on routine haemogram samples in Genius Laboratory Network for a period of a week in November 2022. Samples were collected from both male and female patients of all age groups. From the time of blood collection all the 158 patients samples were processed within 2 hours of collection.ESR of each patient was evaluated by Westergren method and Alifax instrument.The linear regression and Bland and Altman data analysis were used to measure the agreement between the two methods.

RESULTS

The ESR measured by Westergren method ranged from 2 mm/1st hour. to 99 mm/1st hour, with a mean of 18.44 mm/1st hour. while ESR measured by automated method ranged from 2 mm/1st hour. to 120 mm/1st hr , with a mean of 18.78 mm/1st hour. The regression analysis showed a good correlation between the two methods(r=0.92)The Bland and Altman statistical analysis showed a wide degree of scatter between results by the two ESR techniques.72.15% of differences between the two methods were $\leq$ 5.and 15.19% were $\leq$ 10.
Similar results were observed across all ages, and gender patients

CONCLUSIONS

The results of the present study determined good correlation between the two methods.
In laboratories with high-sample load where manual measurement may be tedious,the automated method of ESR measurement can safely replace the Westergren method for Low-ESR values.While for high-ESR values,validation by the standart Westergren method may be needed.

Accreditation, Quality Assurance

P0043

LABORATORY QUALITY MANAGEMENT AND ACCREDITATION

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BACKGROUND-AIM

A quality management system (QMS) is a vehicle to deliver a quality service. The importance of quality in the functioning of health care laboratories is well recognized globally. The poor quality of laboratory results can lead to inappropriate interventions, adversely affect the credibility of the laboratory and may also invite legal action. The QMS defines the organizational structure, responsibilities, policies, procedures, standards and resources required. The laboratory quality system essentials are: Organization; Facilities; Personnel; Equipment; Purchasing and Inventory. The work quality system essentials are: Process control; Documents and Records and Information management. The measurement quality system essentials are: Occurrence management; Assessments: external and internal; Customer service and Process improvement.
Laboratories not implementing a good quality management system are guaranteed that there will be many errors and problems occurring that may go undetected.
Implementing a quality management system may not guarantee an error-free laboratory, but it does yield a high-quality laboratory that detects errors and prevents them from recurring.

METHODS

We analyzed the process of implementation of laboratory quality system and accreditation of medical laboratories in Republic of North Macedonia.

RESULTS

Medical laboratories have pioneered quality control and quality assurance in health care. The introduction of the accreditation program of medical laboratories in R. North Macedonia is one of the key professional and ethical responsibilities of diagnostic professions. Accreditation may not only facilitate quality improvement of laboratory services, but also the development of a quality-based purchasing and reimbursement policy of the health insurance fund. Accreditation of laboratories in our country is in varying phases of development. Some laboratories have established accreditation systems; others are still in the planning phase. Till January 2023, fourteen medical laboratories have been accredited according to MKS EN ISO 15189:2013.

CONCLUSIONS

Accreditation of medical laboratories is a mark of quality and is objective proof that a laboratory is not only competent, but safe, patient-focused, efficient and reliable.

Accreditation, Quality Assurance

P0044

THE ROAD TO ACCREDITATION IN LATIN AMERICA, DIFFICULTIES AND OPPORTUNITIES.

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BACKGROUND-AIM

The Latin American Confederation of Clinical Biochemistry, COLABIOCLI, had established a Working Group on Accreditation Management (WG-AM) since 2020 with the aim to improve the accreditation process and its implementation in the medical laboratories of Latin America (LATAM). There was regional interest in establishing the international standard, promoting the collaboration between the national accreditation bodies, metrology institutes and medical laboratories.

METHODS

The COLABIOCLI WG-AM included an agenda with a data base of LATAM regulatory national standards, provided continuing education activities, and distributed an important survey to COLABIOCLI affiliated member societies to learn about the level of implementation from good laboratory practices (GLP) to accreditation ISO 15189.

RESULTS

LATAM is a very heterogeneous region, with differences in economy, equipment and resources. ISO 15189 implementation varies from country to country. In some countries, local programs with similar requirements to ISO 15189 are helping medical laboratories moving forward. However, it is not a mandatory standard, it is expensive to implement, and auditors and assessors have different criteria. Nevertheless, based on the results of the survey from 2022, we know that medical labs in LATAM can achieve accreditation, many complies with some of the requirements, and others are accredited already, even that number compared with the total of medical labs in the region are not too many. On the other hand, no reimbursement neither recognition are obtained after implementing ISO 15189. Therefore medical laboratories do not get any feedback neither there is access to other national or international markets. Then the results from the survey provided a better understanding of how medical laboratories are managing the accreditation process.

CONCLUSIONS

The COLABIOCLI WG-AM is an instrumental resource to help medical labs achieving accreditation, the group is offering tutorial courses and advice on laboratory accreditation. In 2022, the fourth version of ISO 15189 was realized. And In 2023, a Spanish version is available. The COLABIOCLI WG is compromised with the medical laboratories from LATAM to provide resources and tools to accomplish the standard.

Accreditation, Quality Assurance

P0045

DEMYSTIFYING THE ROLE OF IQC AND EQAS IN SIX SIGMA APPROACH BACKGROUND

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BACKGROUND-AIM

Sigma metrics is a strategy that provides an intuitive, encompassing, snapshot of method performance suitable for use in quality management planning. In clinical laboratory sigma seeks to improve assay quality by identifying bias and /or imprecise assay so that appropriate quality monitoring strategies can be used and assay performance can be addressed. Most Sigma benchmarking happens through the "counting" approach – simply counting up how many defects occur in a given sample, convert that into a % error rate and then a defects per million rate (DPM), and then consult a Six Sigma table to match that DPM with the corresponding Sigma metric. With most of our Quality Indicators, we can convert them into DPM and then Sigma-metrics. However, for analytical methods, the task is harder. Clinicians and technicians simply don't know when a test result has a medically significant error present – when all that is present is one number. So, the counting approach for Six Sigma benchmarking isn't available as a way to determine analytical quality.

METHODS

The authenticity of any report from a lab depends on its Quality Policy & Quality system. Now to have a good report Good Laboratory Practices as well as good processes are extremely required. Routine QC and routine statistics are okay but deploying sigma analysis to lab segment will take the lab to next level of Quality. Lab quality can be benchmarked by sigma tools.
In our laboratory the six sigma metrics was calculated for all parameters. Thereafter, the parameters with low sigma were analyzed in detail for quality improvement.

RESULTS

A higher Sigma metric value means fewer analytical errors and fewer questionable test results are accepted and reported, and fewer acceptable test results are falsely rejected and not reported. In turn it will actually help clinicians to take their decision firmly and hence benefit patient care and management.

CONCLUSIONS

Six Sigma metrics or Sigma metrics, have been used to measure quality in an objective and quantitative manner, combining the three traditional elements used to evaluate assay performance: the allowable total error (TEa), bias and precision. Implementation of the Sigma metrics approach, leads to reduced operational defects in the laboratory and/ or quantitation of test performance quality.

Accreditation, Quality Assurance

P0046

AN EVALUATION OF MEASUREMENT UNCERTAINTY VALUES AMONG BECKMAN COULTER AU SERIES AND DXC700AU ANALYZER USERS USING STANDLAB IQS

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BACKGROUND-AIM

The determination of Measurement Uncertainty (MU) as an accuracy value of a performed measurement is not a common practice in Poland.
The StandLab IQs software collects results from daily control measurements and uses them to calculate statistical indicators for quality control. A comparative analysis is also performed within the control materials with the same LOT number. Additionally, it uses a modified CLSI-based Top-Down method to determine MU.

METHODS

Beckman Coulter analyzed the MUs obtained in medical laboratories equipped with its AU series analyzers using StandLab IQs. Due to potential interpretive ambiguities surrounding MU, all calculations in StandLab used relative error rates expressed as a percentage. The analysis was based on data obtained between May and November 2022. 21 laboratories met the criteria for the number of control results. For each of them, an expanded MU, k=2, was estimated for basic biochemical parameters. The results of measurements performed on control materials with normal and pathological values were used.
From the whole group of tests, the means and medians for each value level were determined and compared with the requirements of the manufacturer and the LabQuality (LQ) external QC program.

RESULTS

For 22 parameters, the difference in MU values obtained for different levels of analyte was analyzed, and statistically significant differences were observed for both normal and pathological levels for TBIL, CREA, and Fe.
Mean and median values were also calculated from the MUs obtained from completed quality control tests. The average values of the expanded MU and median values were higher than the LQ requirements for only the measurements of sodium and calcium levels.
The widths of the MAX-MIN and Q3-Q1 intervals were analyzed for the MUs of measurement results obtained in all tested analyzers. The MAX-MIN values exceeded 10% only for the CRP measurements, while the Q3-Q1 values remained below 10% for all measured parameters.

CONCLUSIONS

The analysis indicates that the results obtained are highly consistent and can be used for uncertainty estimation in laboratories. All tests performed gave results in accordance with the requirements of the manufacturers of control materials.

Accreditation, Quality Assurance

P0047

QUALITY INDICATORS IN THE POST-ANALYTICAL PHASE, TURNAROUND TIME (TAT), AND NOTIFICATION OF CRITICAL RESULTS – ARE WE GOOD ENOUGH?

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BACKGROUND-AIM

Quality indicators (QI) in the post-analytical phase of a laboratory accredited to ISO 15189 as turnaround times (TATs) and notification of critical values to the clinicians are crucial for the benefit of patients. This study aims to assess the TATs of emergency analytes and critical value notifications during the year 2021. and 2022. and to present specific requirements of the laboratory for better performance.

METHODS

In the Clinical Department of Laboratory Diagnostics, University Hospital Dubrava, according to ISO 15189 requirements, TATs are gathered monthly through the laboratory information system (LIS), whereas the critical values notified by telephone are still manually written down in the paper form. TATs for emergency samples and critical values for leukocytes (WBC), hemoglobin (Hb), prothrombin time (PT, PT INR), potassium (K), and high sensitivity troponin I (hsTnI) in years 2021. and 2022. were compared. The calculation for sigma metrics was done with an online calculator from Westgard.

RESULTS

Test demands increased in 2022. compared to 2021. for WBC (36.1 %) and Hb (36.1 %), PT, PT INR (29.3 %), K (25,9 %), and hsTnI (50.6 %). Sigma metrics showed similar values for year 2021. and 2022. for WBC (3.8; 3.9), Hb (3.8; 3.9), PT, PT INR (2.8; 3.0), K (2.8; 2.8), and hsTnI (2.9; 2.9), respectively. Notifications of critical values were done in 30 minutes after validation of results, where WBC, Hb, PT, PT INR, K, and hsTnI share 46.2 % (2268/1047) in 2021. and 44.7 % (3603/1611) in 2022.

CONCLUSIONS

Continuous monitoring of QI serves to identify places for improvement of the overall laboratory process. Regardless of the increase in test demands, TATs for our laboratory remained almost the same. Autovalidation should be implemented in the laboratory for faster TATs. TAT monitoring and manual writing of critical values notification to the ward is time but also labor-consuming. Notification of TAT expiration in real-time during the analytical process and critical value notification recording should be a part of the LIS.

Accreditation, Quality Assurance

P0048

A SEVEN-YEAR EXPERIENCE OF EXTERNAL QUALITY ASSESSMENT PROGRAM FOR RHD FETAL GENOTYPING

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BACKGROUND-AIM

Non-invasive fetal RHD genotype helps the practitioners to greatly improve patient monitoring in RH1 negative women. A positive RHD fetal genotyping diagnoses a RH1 feto-maternal incompatibility for the anti-RH1 allo-immunized pregnant women. For the non-immunized ones, a negative test will avoid injection of IgRH. Since the RHD fetal genotyping became a key to the monitoring of RH1 negative pregnant women, an increasing number of laboratories performed such test. In 2010, it appeared essential for the CNRHP, and part of its missions, to propose to laboratories an external quality assessment. The CNRHP can rely on more than twenty years experience in the fetal RHD genotyping to establish such control. In 2015, we transfered EQC program conducted by the CNRHP to ASQUALAB. The aim of this presentation is to review the EQC program seven years after its launch.

METHODS

Positive control specimen were prepared from RH1 negative plasma donors spiked with various concentration of RH1 positive plasma in order to reflect RH1 positive fetuses at different gestational ages. Negative control specimen, made also from RH1 negative plasma donors. After the initial CNRHP analysis, the samples were conveyed to the participating laboratories with a feedback form where they had to state 1) the material and methods used and 2) the results and the clinical biological interpretation in the context of a clinical case.

RESULTS

14 assessments were conducted since 2015 with an increasing number of laboratories from 7 to 16 in 2022. Each year, we achieved a 100 % response rate. The EQC results were most of the time conform to those expected although the laboratories use different extraction and amplification protocols. Some laboratories made erroneous clinical interpretations despite right analytical results.

CONCLUSIONS

the presented EQC meets the criteria required to evaluate the practices of laboratories performing noninvasive fetal RHD genotyping. The extension of the field from analytical process to postanalytical process including results interpretation and biological advices was important to improve national harmonization of the results of this specialized examination and to highlight the labs giving clinical advices to help prevention of fetal or newborn anemia.

Accreditation, Quality Assurance

P0049

ESTABLISHMENT OF REFERENCE INTERVALS FOR FREE LIGHT CHAINS AND IMMUNOGLOBULINS IN SAUDI POPULATION

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BACKGROUND-AIM

Testing serum free kappa (FK), free lambda (FL) and K/L ratio is considered as part of the International Myeloma Working Group guidelines for the diagnosis and management of monoclonal gammopathies. Therefore, reliable diagnosis and management are based on reliable reference intervals (RIs) in each population. This study was dedicated to study the RIs for free kappa (FK), free Lambda (FL), K/L ratio in addition to immunoglobulins (IgG, IgM, IgA) for the Saudi population using the Freelite reagents from Binding Site.

METHODS

A total of 180 apparently healthy individuals aged ≥18 years were recruited from western, central and eastern regions of Saudi Arabia using the IFCC reference interval committee and decision limits protocol specified for the global study. All serum specimens were measured using Freelite reagents from Binding Site. Multiple regression analysis (MRA) was performed to explore sources of variation of each analyte. The variation in reference values attributable to sex, age, BMI and region was calculated by ANOVA as a standard deviation ratio (SDR). RIs were derived by the parametric method.

RESULTS

MRA revealed that region, BMI, smoking and exercise were not relevant sources of variation for any analyte. Based on SDR cutoff value (>0.4), between-sex partition RIs was not required for all analytes except IgM. Both FK and FL were highly associated with IgA ($r = 0.73$, $r = 0.41$; $p<0.001$) respectively.

CONCLUSIONS

RIs for free light chains (FK, FL, K/L ratio) and immunoglobulins analytes specific for Saudi Arabians were established in careful consideration of various factors. The ranges were different from those provided by the manufacturer and from other countries.

Accreditation, Quality Assurance

P0050

EXTERNAL QUALITY ASSESSMENT PROGRAM FOR ANTI-RED BLOOD CELL ANTIBODIES TITRATION : HETEROGENEOUS RESULTS FOR ANTI-M TITERS

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BACKGROUND-AIM

Anti-red blood cells (RBC) titration with indirect antiglobulin test allows to quantitate maternal antibodies during pregnancy and to assess the risk for hemolytic disease of the fetus and newborn. In 2019, The French National Reference Center in Perinatal Hemobiology decided to launch an external quality assessment program for anti-RBC antibodies titration with ASQUALAB, distributing 2 samples per year per participant and proposing clinical cases and questions to answer.

METHODS

ASQUALAB send twice a year a plasma sample with a clinical case study prepared by CNRHP.

RESULTS

Since 2019, 5 exercises have been proposed. For exercises with anti-D (RH1) (n=2), with anti-c (RH4) (n=1) and with anti-K (KEL1) (n=1), 7 laboratories/7 have found a result inside the expected titer range, with adapted advices associated for the biological follow-up and for the clinical (ultrasound) monitoring of the pregnancy. For the exercise with anti-M (MNS1), the found titer values varied between <1 and 16 with the saline tube method. The advice given with the results were different, depending not only on the titer value but also on the global consideration for the hemolytic risk related to anti-M, due to different concern based on literature and their own experimental data.

CONCLUSIONS

These results underline the good interlaboratory standardization of the titration methods used in France, concerning the RH and the KEL antibody specificities, as well as homogeneous results interpretations and advices for pregnancy management. But they show that important differences could exist with other antibody specificities like anti-M, for which there is variable individual antigenic expression and for which the risk for fetus and newborn hemolytic disease could be difficult to evaluate.

Accreditation, Quality Assurance

P0051

ESTABLISHMENT OF REFERENCE INTERVAL FOR HEMOGLOBIN A1C AND OTHER HEMOGLOBIN VARIANTS FOR HEALTHY ADULTS IN THE WESTERN REGION OF SAUDI ARABIA

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BACKGROUND-AIM

The glycated hemoglobin (A1c) is commonly measured by the principle of high-pressure liquid chromatography (HPLC). Other hemoglobin variants (A1A, A1B, F, LA1c, and A0) are measured simultaneously for detecting any abnormalities in the variants. Due to lack of locally derived reference intervals (RIs) for such parameters; laboratories use RIs derived from the manufacturer and other populations. Therefore, the RIs for such parameters must be established for proper diagnosis and follow up of DM and for detecting any abnormalities in the level of different hemoglobin variants which may have a potential effect on A1c level.

METHODS

Cross sectional study was conducted in Saudi Arabia as part of the IFCC global multicenter study. 409 healthy adult subjects (>18 years, BMI 28.3 ± 6 Kg/m2) were recruited, and their blood samples were tested for A1c by Tosoh G8 HPLC analyzer. Complete blood count and other tests of biochemistry were tested simultaneously on the same samples. The needs for RIs partitioned by sex and age was based on standard deviation ratio (SDR) based on 3-level nested ANOVA. RIs were derived parametrically with/without application of latent abnormal values exclusion method (LAVE).

RESULTS

Based on thresholds of SDR≥0.4 and/or Bias Ratio (BR)≥0.57, RIs for A1c and other Hb variants were not partitioned by sex or BMI but partitioned by age for A1c, LA1c+, A1B and A0. The multiple regression value (MRV) for A1c was noted to be significantly increased with metabolic parameters of Uric acid and GGT in females (rp = 0.36; rp = 0.39) more than males (rp = -0.02; rp = 0.16) respectively.

CONCLUSIONS

This study showed that RIs for A1c and other Hb variants applied on healthy adult Saudis can be significantly affected by age. The obtained outcomes will improve the interpretation and the clinical decision of Hemoglobin A1c and other hemoglobin variants results using the HPLC method.

Accreditation, Quality Assurance

P0052

IMPLEMENTING ANTI-RH1 MICROTITRATION EXTERNAL QUALITY CONTROL PROGRAM (EQC); A FRENCH EXPERIENCE

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BACKGROUND-AIM

Microtitration of anti-RH1, an indirect haemagglutination gel diffusion test, allows quantification of low concentrations of anti-RH1. It is suitable for passive anti-RH1 following the injection of IgRh in anti-RH1 prophylaxis. With the prospect of wider use of this technique thanks to automation and with the legal obligation for French laboratories to be accredited came the need for an EQC.

METHODS

The CNRHP and ASQUALAB has set up one and send twice a year, a plasma sample with a clinical case study.

RESULTS

Since 2019, 3 exchanges were proposed with about fifteen participants. The majority of laboratories use a manual technique on papainized red blood cells. More than 90% of them had a correct result. The 2 erroneous results correspond to a not returned result and a negative result, an inappropriate term for an anti-RH1 whose concentration was below the detection threshold of the method. The interpretation on the passive or immune nature of anti-RH1 was correct for all the laboratories. Nevertheless, differences in practice can be observed for anti-RH1 prophylaxis advice, which is not carried out by all.

CONCLUSIONS

Microtitration technique is simple, generally well mastered by all the participants and a valuable aid in the monitoring and management of RH1 negative pregnant women.

Accreditation, Quality Assurance

P0053

EVALUATING ASSAY PRECISION FOR IMMUNE- CHEMILUMINISCENT METOD FOR NGAL (NEUTROPHIL GELATINASE ASSOCIATED LIPOCALIN)

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BACKGROUND-AIM

According to the needs of ISO 15189, part of the process of validation and verification of the method is evaluating the test precision. For this purpose, we need to asses the repeatability and total within run laboratory precision.

METHODS

According to the CLSI EP 15-A2 recommendations every user of the test should undertake the measurements of the analyte in at least two level, running three replicates over five days. In our work we have estimated the assay precision of quantification of NGAL (Neutrophil gelatinase associated lipocalin) immune chemiluminescent method by estimating the repeatability and within- laboratory precision as well as to evaluate obtained results.
In our study we have used two pools of urine. P1 derived from 30 healthy patients, and P2 derived from 30 patients on hemodialysis. All samples were run in duplicate as three replicates during five days using ABBOT urine NGAL kit.

RESULTS

The repeatability value for P! was 2.44 ng/ml and for P2 5.29 ng/ml. Evaluated repeatability verification value for P1 and P2 was lower than the claimed manufacturers verification value (3.1 and 6.4). Estimated within-laboratory precision was for P1 18.87 ng/ml and for P2 23.003 ng/ml.
Evaluated within-laboratory precision verification value for P1 was 0.059 and for P2 was 0.092 that is less than manufacturers claimed verification value (0.067 and 0.098 respectively)

CONCLUSIONS

Our data have confirmed that the method is suitable for the purposes of ISO15189 and that repeatability and within-laboratory precision verification values are consistent with the manufacturers claims.

Accreditation, Quality Assurance

P0054

THE UNI EN ISO 15189 ACCREDITATION OF THE GENETICS AND MOLECULAR BIOLOGY LABORATORY: GROWTH PATH BETWEEN CONFIRMATIONS AND CRITICALITIES

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BACKGROUND-AIM

The standard iso 15189 accreditation ensures high standards of operation in diagnostic laboratories. This takes place through the verification of the skills of the laboratory staff, the adequacy of the performance of the results and the appropriateness of the instruments and methods used for the analyses. The purpose of this work was to evaluate the major criticalities encountered in the accreditation process of the medical genetic laboratory and the consequent strategies implemented to overcome them.

METHODS

Our laboratory requested accreditation for 37 genetic examination procedures divided into 31 flexible field procedures and 6 fixed field procedures.

RESULTS

we applied a standard validation method to a genetic assay, measuring reliability (comparing results with gold standard or with other CE-IVD method, evaluating results of known genotype), precision and reproducibility repeating same sample in the same and different conditions where possible (different instrument, different lot of the reagents, different operator, extraction of the same sample), defining limit of detection diluting the amount of DNA and limit of sequencing (region of the gene analysed), robustness and analytical sensitivity and specificity. Finally in the validation we add some specific genetic evaluation, as comparison of the variant allelic frequency compared with online database, and specific QCmetric (such as area peak, coverage of reading). On the other hand, the verification of qualitative or quantitative method followed the performance reported by the provider of the kit but in many cases the main difficulties was the lack of certified sample for rare mutation. Sensitivity and specificity of qualitative method was evaluated analysing VEQ and CQI results and analysing concordance of repeated analysis. In quantitative assays (where % of mutation is quantified) is necessary to evaluate the limit of detection possibly with a certified sample, otherwise in the majority of cases such certified sample are not available, so we utilised dilution of control sample provided in the kit.

CONCLUSIONS

Our work suggests that for the accreditation of the genetics and molecular biology laboratory new guidelines are needed to define parameter that properly could be applied to the genetic field.

Accreditation, Quality Assurance

P0055

STUDY OF THE RELATIONSHIP BETWEEN 25 (OH) VITAMIN D AND LEPTIN IN INDIVIDUALS WITH INSULIN RESISTANCE

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BACKGROUND-AIM

Aim: Studies have shown that the Mediterranean population, as well as Albania, have low levels of vitamin D. Even the Mediterranean population with diabetes has shown low levels of vitamin D. It is unclear if this low level of vitamin D is associated with high levels to leptin.. Also, it has not been ascertained whether this relationship is different in those with and without insulin resistance. The present study aims to study the relationship between 25-hydroxy vitamin D [25(OH) vitamin D] and leptin in individuals with and without insulin resistance.

METHODS

Methods: Fifty-two individuals were included in two study groups (n =26 each group). The first group included individuals with insulin resistance (homeostasis model assessment of insulin resistance [HOMA-IR] ≥2.0). The second group included those without insulin resistance (HOMA-IR <2.0). Comparison of 25(OH) vitamin D, leptin, anthropometry and biochemical parameters was made between two groups and correlations between 25(OH) vitamin D, leptin and HOMA-IR were studied.

RESULTS

Results: People with insulin resistance had the same age (38.6 ± 5.2 years) and body mass index (24.3 ± 3.1 kg/m2) as those without (39.4 ± 5.1 years and 23.4 ± 3.1 kg/m2). Individuals with insulin resistance presented significantly lower 25(OH) vitamin D levels (17.7 ± 7.2 vs. 22.2 ± 11.5 ng/mL, P = 0.03) and significantly higher levels of leptin (16.8± 15.7 vs. 9.5± 9.2 ng/mL = .09) compared to those without insulin resistance. A significant negative correlation was observed between 25(OH) vitamin D levels and overall leptin (r = -0.2, P = .007). HOMA-IR showed a significant negative correlation with 25(OH) vitamin D levels in subjects with insulin resistance (r = -0.32, P = .026).

CONCLUSIONS

Conclusions: The study revealed higher levels of circulating leptin and lower levels of vitamin D 25(OH) in subjects with insulin resistance. 25(OH) vitamin D levels were inversely related to leptin levels, especially in women.
Key words: Vitamin D, Hyperleptinemia, insulin resistance, HOMA.

Accreditation, Quality Assurance

P0056

THE STUDY OF THE POSSIBILITY OF USING MAGNETIC NANOPARTICLES IN THE TECHNOLOGY OF ISOLATION AND PURIFICATION OF BLOOD COAGULATION FACTOR VIII

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BACKGROUND-AIM

Magnetic nanoparticles (MNPs) are a special class of nanoparticles that can be controlled using a magnetic field. Such particles usually consist of two components: a magnetic core (iron, nickel or cobalt) and a chemical shell (starch, dextran, silica gel, etc.). By choosing an appropriate method of synthesis and fractionation, the size, shape, surface coverage, and colloidal stability of MNPs can be controlled.
Aim: to investigate the possibility of using MNPs in the technology of isolation and purification of blood coagulation factor VIII (FVIII).

METHODS

In the work were studied: MNP-COOH-500 nm; MNP-PEG-COOH-300 nm; MNP-NH2-250 nm; MNP-NH2-130 nm; MNP-NH2-80 nm; MNP-OH-250 nm. The activity of factors VIII was determined using one-stage clotting methods. For fractionation of MNPs a tripod with a constant field neodymium magnet (0.24 T; Sphere Sim, Lviv) was used.

RESULTS

A study of the influence of MNPs on FVIII activity was conducted. The initial concentration of FVIII was 1.0 IU/ml. FVIII activity was determined immediately upon addition of MNPs (up to a final concentration of 50 μg/ml); after 15 min of incubation and after the action of a constant field neodymium magnet. The activity of FVIII was established: MNP-COOH-500 nm: when applied - 1.0 IU/ml, after 15 min - 1.0 IU/ml, after the magnet - 1.0 IU/ml; MNP-PEG-COOH-300 nm: when applied - 1.5 IU/ml, after 15 minutes - 1.45 IU/ml, after magnet action - 0.6 IU/ml; MNP-NH2-250 nm: when applied - 0.55 IU/ml, after 15 minutes - 0.5 IU/ml, after the action of the magnet - 0.5 IU/ml; MNP-NH2-130 nm: when applied - 1.55 IU/ml, after 15 minutes - 1.45 IU/ml, after the magnet - 1.0 IU/ml; MNP-NH2-80 nm: when applied - 1.55 IU/ml, after 15 minutes - 1.7 IU/ml, after the magnet - 0.5 IU/ml; MNP-OH-250 nm: when applied - 0.5 IU/ml, after 15 minutes - 1.0 IU/ml, after the magnet - 0.45 IU/ml.

CONCLUSIONS

It was established that the activity in the FVIII solution was reduced by two times after the action of the magnet using the following MNPs: MNP-PEG-COOH-300 nm; MNP-NH2-250 nm; MNP-NH2-80 nm and MNP-OH-250 nm.

Accreditation, Quality Assurance

P0057

TO REDUCE SWEAT REJECTION RATE, USING SIX SIGMA METHODOLOGY

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BACKGROUND-AIM

Sweat testing serves as a standard method for diagnosis of cystic fibrosis. The sweat testing procedure involves sweat stimulation, collection, and analysis. The Section of clinical chemistry had 15 % average monthly sweat rejection rate by the end of 2021, which was leading to excess staff time, reagent consumption & cost. Aim was to reduce the failure rate in sweat production to <5.0 %, staff time & cost by the end of year 2022 also aimed to meet the benchmark required by the CAP (college of American pathology) and increasing six-sigma level.

METHODS

Six sigma methodology (DMAIC) was applied to conduct this project from Jan 2021 to Dec 2022. Define: Defined core activities to identify root cause and take respective corrective actions. Formed a process flow & value stream map. Measure: Identified fundamentals reasons behind increased failure using the fish bone tool. Measured the current process sigma scale & selected the data collection plan used pareto to prioritize the problem. Analyse: Theories were tested for selected remedies. Improve: Implemented selected corrective actions. Control: Control plan matrix used & mistake proofing techniques added, like: Reviewed patient assessment questionnaire and identified need for corrections necessary to rule out hydration status of patients. Reviewed and updated patient information material with required amendments. Conducted awareness sessions for new rotating residents along with respective technologists provided teachings. Team reviewed the processes and recommended to defer dehydrated patients along with strict monitoring of sweat production indicator on daily basis by sub-section supervisor and respective assigned resident to attain the benchmark and reduce additional cost

RESULTS

Significant differences obtained comparing statistics before and after interventions, wastage of staff time has been reduced from 120 minutes/month to 20 minutes/month. Additional cost reduced to PKR 6000/month from PKR 18000/ month. Rise in sigma level from 2.4 to 3.6 and the rejection rate for sweat came out to be 2.2% from 15%.

CONCLUSIONS

Six sigma methodology not only reduced the cost while improved the accuracy of testing which subsequently increasing patient satisfaction level, and also helped to meet the benchmark required by the CAP.

Accreditation, Quality Assurance

P0058

CERTIFICATION PROCESS OF THE ANDALUSIAN AGENCY FOR HEALTHCARE QUALITY IN THE LABORATORY

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BACKGROUND-AIM

The certification by the Andalusian Agency fot Healthcare Quality (ACSA) is based on the compliance with the Laboratory Manual of Standards with 5 blocks:
I. The person, center of Healthcare System: The user as an active agent. Accessibility and continuity of health care. Clinical information
II. Organization of the activity focused on the person: Process Management. Promotion and prevention of health and environment. Strategic direction and planning
III. Professionals
IV. Support processes: Structure, equipment and suppliers. Systems and information technologies
V. Continuous improvement: Quality and safety tools. Results
The 103 standards are divided into 3 groups:
I) vested rights of persons, quality of life, ethical principles and safety of users and professionals:59 with 40 required
II) elements associated to a higher development of the organization:28
III) innovation and development for the society:16
Based on the compliance: Advanced level (>70% group I including the required), Optimal (100% group I and >40% group II) and Excellent (100% group I and II and >40% group III) with 5 years of validity.

METHODS

A request for the project is made on November 2021 with a period of one year.
The self-evaluation process starts on the platform "ME_jora C" and, implementing the cycle PDCA of Deming, the positive evidences are given to each standard through supporting documents. A work group composed of 7 professionals is established with a timeline of the distribution of the standards and assigned tasks to achieve the legitimacy of compliance, and in the case of detecting shortcomings, to establish the improvement areas.

RESULTS

On November 2022, the audit team carries out a visit. It consists of three simultaneous routes through circuit of management, care and support.
The provided evidences are thoroughly checked to be correlated with the daily practice, allowing to detect strengths and weaknesses.
On December 2022, the Optimal certification is granted, and the possibility of promotion to the Excellent level.

CONCLUSIONS

The certification process is a useful methodological tool to check if the activities are carried out in accordance with the quality standards, providing by the external evaluation a public and clear recognition of the institution and professionals who accomplish with it

Accreditation, Quality Assurance

P0059

THE FIRST SCOPE OF ACCREDITATION IN THE FIELD OF POINT-OF-CARE TESTING (POCT) IN SERBIA

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BACKGROUND-AIM

Center for Medical Biochemistry of the University Clinical Centre of Serbia (CMB UCCS) is the largest, tertiary healthcare institution in Serbia in the field of laboratory diagnostics and from 2009 is the first accredited laboratory according ISO 15189. It has 200 healthcare workers employed in 13 CMB laboratories. The UCCS POCT instruments multisite network, supervised by CMB, has been growing in the last 25 years in order to provide rapid results to clinicians 24 h/day. With the aim to improve confidence in POCT results, and following the developed countries that have POCT in the accreditation scope, CMB UCCS laboratory management gave an initiative for introducing a structured POCT program at UCCS, to ensure compliance with ISO 22870 that provides specific requirements applicable to POCT and which is strongly related to ISO 15189.

METHODS

The initial step in our accreditation process was appointment of POCT Director, POCT Coordinator and multidisciplinary POCT committee consisted of the laboratory staff, physicians and nurses, administration and IT service staff, and POCT policies and procedures preparation. Verification of the analytical performances of the methods according to the ISO 22870 requirements was performed.

RESULTS

Currently, more than 800 trained operators are trained for using 15 blood gas analysers (13 ABL90 Flex (Radiometer®, Denmark) and 2 GEM Premier 5000 (Instrumentation Laboratory (Werfen, USA)), performing more than 150.000 tests/year. Except internal quality assurance, external proficiency testing program was introduced. Control of staff training and competence assessment, policies, procedures and quality assurance, are now under the guidance/oversight of CMB UCCS. In July 2022, Accreditation Body of Serbia made a decision to extend the scope of accreditation of the accredited conformity assessment body CMB UCCS for the POCT according to the standard SRPS EN ISO 15189 and SRPS EN ISO 22870.

CONCLUSIONS

After this first step, we plan to select and implement key performance indicators monitoring, continuously improve the quality and value of laboratory services, supporting medical decision making and contributing better and safer patient care.

Accreditation, Quality Assurance

P0060

FERRITIN REPORTING: AN EXTERNAL QUALITY ASSESSMENT PROGRAM PERSPECTIVE

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BACKGROUND-AIM

The serum ferritin test provides an indication of body iron stores. Elevated ferritin levels can indicate an iron storage disorder such as hemochromatosis or a chronic disease process, whereas low levels are associated with iron deficiency anemia. The Institute for Quality Management in Healthcare (IQMH) provides ISO 17043:2010 accredited Proficiency Testing programs including ferritin. The IQMH Endocrinology Committee sought to understand how laboratories manage reference intervals and post-analytical reporting of ferritin, recognizing that population-based reference intervals (RIs) may reduce the clinical utility of ferritin testing, particularly for iron deficiency.

METHODS

An online survey was distributed during February to March 2022 to 101 participants including 88 Ontario laboratories currently licensed for ferritin, and 13 additional laboratories currently participating in the IQMH Endocrinology A survey. Statistics were calculated from the per cent of laboratories that responded to each question. If a participant did not reply to a question, they were not included.

RESULTS

A total of 97 participants responded representing users of the five major testing platforms. The majority of laboratories provide sex- and age-specific RIs (89% and 61%, respectively), while few provided a single RI without age or sex partitions (9%). The sources of RIs were primarily from the manufacturer's instructions for use (64%) and/or internal reference interval validation (51%). Considerable variation in RIs was noted. In addition to RIs, inclusion of interpretative comments regarding iron deficiency anemia (14%) or iron overload or inflammation (5%) with clinical cutoffs was much lower. The low clinical cutoffs ranged from 5-100 μg/L (median = 15 μg/L), while high clinical cutoffs ranged from 300-100,000 μg/L (median = 600 μg/L). Despite the lack of standardization of ferritin assays, the WHO has recommended cutoff values for detection of iron deficiency and excess.

CONCLUSIONS

A lack of consistency exists in the interpretation of ferritin levels among laboratories, even when using the same platform. Ferritin RIs on their own may not accurately reflect clinical decision limits. These findings should prompt laboratories to review their RIs and consider interpretation comments, particularly for iron deficiency.

Accreditation, Quality Assurance

P0061

DEVISING ANALYTE-SPECIFIC QUALITY GOALS FOR LDL CHOLESTEROL FROM CLINICAL GUIDELINES: CONVERGENCE OF LABORATORY GOALS AND CLINICAL REQUIREMENT

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BACKGROUND-AIM

The quality goals of a laboratory can be expressed in terms of total allowable error which includes both imprecision and bias. Clinical outcomes, biological variation, and state-of-the-art models are various approaches that may guide laboratories in deciding quality goals. Among the three approaches, the one based on clinical outcomes is considered to be the ideal approach. LDL Cholesterol (LDL-C) is a known risk factor for atherosclerotic cardiovascular disease. Various societies have brought forth guidelines that decide treatment strategies based on LDL-C levels. In this study, we assessed the principle of devising imprecision goals of LDL-C based on the prevailing guidelines such that there is minimal misclassification.

METHODS

For the study, we focussed on determining the coefficient of variation for LDL-C, as an indicator of imprecision, based on the clinical guidelines. We took three guidelines with their respective cut-offs: 2018 American College of Cardiology (190 mg/dL and 70 mg/dL), 2019 European Society of Cardiology (190 mg/dL, 116 mg/dL, 100 mg/dL and 70 mg/dL) and 2012 Canadian Cardiovascular Society Guidelines (130 mg/dL and 75 mg/dL). We plotted the Coefficient of variation (CV) on the X-axis and LDL-C on the Y-axis. A lateral funnel graph was drawn with both arms of the funnel plotting the higher (mean +2SD) and lower ranges (mean-2SD). The intersection of arms of the funnel for different cut-offs was identified as the maximum permissible CV while the respective guidelines are being used.

RESULTS

From the analysis, we obtained the maximum permissible CV that would prevent the overlap between two classes and thus leading to misclassification while various guidelines are used. For the American College of Cardiology Guideline, we observed that the maximum permissible CV of 23% prevents overlap. For the Canadian Cardiovascular Society Guidelines, 13% was the maximum permissible CV and for the European Society of Cardiology Guidelines, the maximum permissible CV was 9%, 5%, and 12% for various cut-offs.

CONCLUSIONS

The current study brings forth the necessity of determining the coefficient of variation of a parameter in the laboratory based on the prevailing clinical guidelines to prevent the misclassification of individuals.

Accreditation, Quality Assurance

P0062

MULTI-TARGET METHOD IN CLINICAL TOXICOLOGY: A NEW CHALLENGE FOR QUALITY IN LABORATORY MEDICINE

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BACKGROUND-AIM

Multi-target methods are increasingly used in laboratory medicine, allowing the simultaneous identification and/or quantification of a growing number of analytes. In the context of quality management and the accreditation process, there are few concrete international guidelines for the validation of such methods. Based on the identification of at least 200 distinct molecules, analytical toxicology and clinical biological French associations have established recommendations for the accreditation of toxicological screening methods according to the ISO 15189 standard. This work aims to apply these recommendations to a liquid chromatography coupled with high resolution mass spectrometry (LC-HRMS) screening method in serum.

METHODS

Using this LC-HRMS toxicological screening method, 155 analytes were tested from serum panels chosen based on their various therapeutic or chemical classes, distribution throughout the chromatogram, and broad mass/charge ratio distribution. The validation parameters included limit of identification (LOI), repeatability, intermediate precision, inter-sample contamination, and stability.

RESULTS

The analytical performance showed high repeatability, with a coefficient of variation (CV) of less than 20% for all compounds tested at two concentration levels (n = 5). The intermediate precision was validated for 88% and 92% of the tested analytes at the lowest and highest levels respectively, at the 20% CV threshold, and 123 LOI values were established. The stability of almost all analytes was confirmed after 14 days of storage. No sample-to-sample cross-contamination was observed.

CONCLUSIONS

Based on national recommendations, the validation of the multi-target method met pre-specified analytical performance criteria for more than 120 analytes in serum. Given the large number of compounds detectable and the variety of matrices, the validation of the toxicological screening is based on an initial validation of a restricted field of analytes and progressively extending to other matrices and compounds. International agreement concerning validation guidelines for multi-target methods, adapted to the complexity of a large number of compounds and clinical expectations, would help in the accreditation process according to the ISO 15189 standard.

Accreditation, Quality Assurance

P0063

DYNAMIC REFERENCE CHANGE VALUE (DRCV) AS A MONITORING TOOL FOR THE STEADY STATE OF MONOCLONAL COMPONENT IN PATIENTS DIAGNOSED WITH MONOCLONAL GAMMOPATHY OF UNCERTAIN SIGNIFICANCE

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BACKGROUND-AIM

Monoclonal gammopathy of uncertain significance (MGUS) is a common dyscrasia characterized by the presence of a monoclonal protein without any evidence of tissue damage. MGUS can progress to symptomatic forms such as multiple myeloma. MGUS is diagnosed by the presence of a monoclonal component (MC) and do not develop clinical manifestations. Thus, the determination of the MC concentration is crucial for the diagnosis and monitoring of this pathology, being stable over time. The reference change value (RCV) is a tool that allows us to determine if the difference between two consecutive values of a magnitude presents significant changes. But when it is necessary to assess this difference in more than two consecutive values, the classic formulas for estimating the RCV are not adequate. Lund et al have developed a strategy to be able to compare more than two consecutive results using the dynamic RCV (dRCV). Thus, the objective of this work is to apply the dRCV in the follow-up of the MC in patients diagnosed with MGUS to determine the steady state of the MC.

METHODS

Retrospective study (2010-2020) selecting 118 patients diagnosed with MGUS. The study included patients with a variation of less than 5 g/L in the MC (stability condition based on the literature), who did not meet the criteria for progression, not received treatment, and had more than four consecutives determinations. The MC values and isotype were collected. To calculate the dRCV value, the method proposed by Lund et al was used. This method allows to assess the steady state of a magnitude using more than two consecutive values.

RESULTS

Of the patients studied, 20 were not in a steady state situation throughout the entire period studied. No differences were observed between the different isotypes studied.

CONCLUSIONS

Setting a variation amount of 5g/L to determine the MC steady state presents limitations. The use of the dRCV represents an objective tool to assess the steady state of the MC in patients with MGUS with better performance than the value of 5g/L of variation. The 20 patients who were not in steady state based on dCVR would require increased monitoring due to the risk of disease progression. dRCV can help us to anticipate the progression to multiple myeloma.

Accreditation, Quality Assurance

P0064

PRACTICAL CONSEQUENCES AND PATIENT SAFETY IMPLICATIONS OF USING HARD CUT-OFFS IN TREATMENT ALGORITHMS, WHICH ARE FURTHER EXACERBATED BY METHOD BIAS DIFFERENCES

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BACKGROUND-AIM

Laboratory results are routinely reviewed in conjunction with Reference Ranges which are often method specific. National and International Guidelines are widely used which often have specific concentration cut-offs and are usually method independent. These 'hard' cut-offs aid in decision making for patient treatment, but misclassification can be very costly both financially and to patient outcomes.
The example of creatinine is shown here. The clinical utility has expanded since it was first introduced and it is now routinely used in many algorithmic tests/pathways, including eGFR and AKI. EQA data consistently shows that there are manufacturer differences in bias, neither these, nor the impact of interferents are taken into consideration in clinical pathways.

METHODS

The AKI element of the UK NEQAS for Acute and Chronic Kidney Disease Scheme has over 350 participants. In 2022, two specific scenarios were probed 1) can methods identify a 26 umol/L difference in creatinine between specimens? and 2) what is the spread of creatinine results at 354 umol/L? Serum specimens were designed to investigate these areas and distributed to all participants within the Scheme.

RESULTS

Both the KDIGO AKI Guidelines and the NHS England AKI Algorithm require laboratories to be able to differentiate a creatinine difference of 26 umol/L. To allow for the tolerances in measurement, we factored-in a bias of 7.5% — our regular allowable error — onto what we added as a 'spike', so we added 28 umol/L creatinine into our base specimen. Of 363 laboratories, including all Abbott Architect and all Abbott Alinity Jaffe users, 18% measured the difference between the two specimens to be less than 26 umol/L.
Another 'hard' cut-off in the algorithm is a creatinine concentration of 354 umol/L, which classifies a patient as AKI Stage 3. A specimen was designed to have a concentration of 354 umol/L (confirmed by reference method analysis as 354.92 umol/L). 46% of 359 laboratories measured a creatinine >354 umol/L with a range of results from 320 – 390 umol/L.

CONCLUSIONS

As laboratory medicine improves and the clinical utility of existing assays is extended, verification is required to ensure that the performance of assays are fit for purpose across all manufacturers for their extended roles.

Accreditation, Quality Assurance

P0065

PROTEINURIA EXPLORATION: EXTERNAL QUALITY ASSESSMENT

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BACKGROUND-AIM

Proteinuria exploration including specific urinary proteins measurement or and urinary proteins electrophoresis, allows medical diagnosis orientation for typing renal diseases or gammopathies. Participation in External quality assessment (EQA) is required for laboratories accreditation according to ISO15189 to provide proof for reliability of the results.

METHODS

The program implemented by Asqualab included 3 surveys per year including 2 different samples. These samples are prepared from fresh urines according to pathological criteria, and pooled according to CLSI EP 37-A procedure. After urinary protein electrophoresis and specific urinary protein measurements, pooled samples are divided into aliquots and lyophilized, to ensure stability. The absence of urinary proteins degradation after lyophilization has been checked before shipping of the samples to the laboratories.

RESULTS

In 2022, 29 medical laboratories participated in the EQA program. All of them provided results for total proteinuria measurement and 15 for urinary protein electrophoresis and albuminuria measurement. Only 2 to 6 laboratories, according to the sample, measured specific urinary proteins (immunoglobulin G, transferrin, retinol binding protein, alpha1microglobulin, beta2microglobulin). All participants associated comments of their results, chosen within a list of 18 proposals. Comments were classified as appropriate if they fulfil the expected one given by the referent laboratory, acceptable if they did not impact the diagnosis or therapeutic attitude and inappropriate if they could compromise the diagnosis or therapeutic attitude.
Total proteinuria measured by pyrogallol red colorimetric method showed results higher than those measured by benzethonium chloride (differences ranging from 15% to 32%, according to the protein composition of the samples). Comments were appropriate for 56%, 17%, 26% and 59% of the responses for samples 1,2,3 and 4, respectively.

CONCLUSIONS

The results of this program showed a great heterogeneity in the comments for interpretation of the results of urinary protein exploration. This can be explained by the large number of used methods and by the large number of controversial references related to these explorations due to the lack of recommendation by the scientific authorities.

Accreditation, Quality Assurance

P0066

STANDARDS FOR REPORTING BIOLOGICAL VARIATION STUDIES.

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BACKGROUND-AIM

Biological variation data (BVD) are reference data. The data have many important clinical and laboratory applications. Published Biological Variation studies often lack key metadata required to enable the assessment of the veracity of the BVD that they contain. This means that well-executed studies might deliver data that are devalued and non-translatable because of deficiencies in reporting. The development of an initiative similar to that used to improve the quality of reporting of diagnostic accuracy studies, the Standards for Reporting Diagnostic Accuracy (STARD), may provide a solution to this problem. This will require adoption of a consensus view of appropriate structure and content.

METHODS

The EFLM Biological Variation working groups, and task groups, have undertaken work that enables the description of the current state-of-the-art of the classical prospective experimental approach to the delivery of BVD that enables the definition of a candidate model to address this need. Research and knowledge gained from the processes of setting up the EFLM Biological Variation database, development of tools such as the biological variation critical appraisal checklist (BIVAC), delivery of the multicentre European Biological Variation Study (EuBIVAS), and delivery of systematic reviews underpin the proposed model.

RESULTS

A distillation of the work has been made available online to enable the development of a standard for the design and publication of BV studies that enables delivery of a STARD-like approach applicable to BVD studies. It has been brought together in the form of an interactive mind-map that can be navigated by users and providers of BVD. (https://biologicalvariation.eu/Publication_Structure_V2_0.html).

CONCLUSIONS

A resource has been developed to enable users to check that existing and future studies reporting BVD comply with a proposed structure, reporting a considered minimum data set and compliant with the embedded BIVAC. The use of such a resource parallels that of the STARD initiative, here addressing quality issues with the reporting of BVD. As the field develops, further iterations of the mind-map will be required in response to the development of new approaches to delivery of biological variation data (e.g., big data approaches).

Accreditation, Quality Assurance

P0067

DEVELOPMENT AND VALIDATION OF CE-IVD KIT FOR MONITORING MONOCLONAL ANTIBODIES USING MASS SPECTROMETRY

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BACKGROUND-AIM

Mass spectrometry is a technology widely used in the clinical lab, for monitoring a wide range of compounds, such as antibiotics, immunosuppressants, etc. More recently, this technology has been used successfully to develop methods for quantifying large molecules, such as antibody therapeutics, which are now widely used as treatments for various diseases. However, the implementation of biologics monitoring assays is not so easy, even for staff skilled with mass spectrometry. One major difficulty is the sample preparation step, which is really complex compared to what is done for small molecules.

METHODS

In order to facilitate the implementation of such approaches and the possibility for clinicians to have access to therapeutic monitoring of monoclonal antibodies, we have developed ready-to-use kits, based on mass spectrometry. On a technical point of view, the solution was evaluated in several clinical labs and gives satisfaction. To accompany the diffusion of such an approach, it was really important also to consider the regulated environment. Indeed, over the last ten years, there has been a evolution in regulations, standards and protocols on this instrumentation (EMA, ISO, CLSI, etc.), up to the implementation of the recent European Regulation 2017/746 (IVDR).

RESULTS

In this poster, we describe how we have managed and how we managed the development of our innovative commercial solutions for TDM of mAbs in this IVDR context, from the early-stage phase until the submission of the technical dossier to the notified body for obtaining the CE label.

CONCLUSIONS

The mAbXmise kits are robust and easy bioanalytical solutions, meeting regulatory requirements, developed for being implemented in clinical lab by pharmacologists who are willing to propose TDM for mAbs.

Accreditation, Quality Assurance

P0068

REFERENCE VERSUS CONSENSUS VALUES IN PROFICIENCY TESTING OF CLINICAL CHEMISTRY: A COMPARISON BASED ON LABORATORIES' RESULTS IN PALESTINE

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BACKGROUND-AIM

Proficiency testing (PT), or external quality control provides additional means to ensure the quality of the results of laboratory testing. The most applied methods of achieving this objective are the comparison of laboratory results with reference values (RVs) or consensus values (CVs). The Center for Quality in Medical Laboratories (CQML) – Al-Quds University is the only Palestinian provider of PT. The results of participants at the CQML are compared with CVs calculated based on Algorithm A of ISO 13528. Given the wide range of equipment and reagents employed in laboratories, it might be risky to make conclusions based on CVs exclusively. In this work, we compare CVs obtained from data collected by the CQML for 11 analytes corresponding to clinical chemistry with certified RVs and compare PT results obtained under both criteria (CV and RV).

METHODS

A lyophilized human serum sample was prepared and tested in a certified laboratory to determine RVs. Two samples were distributed to the Palestinian laboratories participating in the CQML. CVs and the allowable limits of performance (ALP) were calculated from the obtained data based on Algorithm A of ISO 13528 and the standards provided by the certified laboratory. The deviation between CVs and RVs was calculated for each analyte using the formula [(consensus mean − reference mean) X 100/reference value]. The percentage of laboratories that met the ALP criteria was then compared using both criteria for each analyte.

RESULTS

The deviation between CVs and RVs for the evaluated analytes ranged from -0.56% for Calcium to -14.3% for Aspartate Aminotransferase. The percentage of laboratories that met the allowable limits of performance ranged between 69.3-91.7% when CVs were used for comparison, whereas the range was 59.6-89.5% when using RVs.

CONCLUSIONS

The deviation between CV and RV could vary depending on the analytes under investigation. The adoption of a combined approach of these schemes in PT should be considered as a more practical approach to evaluating the performance of laboratories in Palestine.

Accreditation, Quality Assurance

P0069

PREPARATION AND PRELIMINARY CHARACTERIZATION OF CANDIDATE CERTIFIED REFERENCE MATERIALS FOR ASPARTATE TRANSAMINASE

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BACKGROUND-AIM

Aspartate transaminase (AST) or Aspartate aminotransferase (ASAT) (EC 2.6.1.1) is an enzyme involved in amino acid metabolism that catalyzes the conversion of aspartate and 2-oxoglutarate to oxaloacetate and glutamate. The catalytic activity of AST is commonly measured as a biomarker for liver damage, although it is also increased as a consequence of heart, muscle and kidney damage. The reference system for AST determination is essential for the standardisation of AST measurements and the comparability of patient results over time and place, and comprises the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) reference procedure and certified reference materials (CRM). Here we prepared two candidate CRMs for AST and preliminarily evaluated their stability, homogeneity and catalytic activity concentration.

METHODS

The candidate CRMs for AST have been produced from either AST purified from human liver or a recombinant AST from human liver expressed in Escherichia coli, in a buffer containing bovine serum albumin, and have been lyophilised. The homogeneity and stability of the materials have been tested, and the catalytic activity concentration has been estimated using an automated procedure that is traceable to the IFCC reference procedure for determination of AST at 37 ºC.

RESULTS

The estimated catalytic activity concentrations obtained were 96.2 U/L and 94.5 U/L for the candidate CRMs prepared with purified AST or recombinant AST, respectively, lying well within the range defined for the target concentration (50-150 U/L). The homogeneity of each material was evaluated by measuring the catalytic activity concentration of AST in ten vials taken randomly and analysed in duplicate. Acceptable homogeneity results were obtained. The stability studies showed that the materials are stable in the different conditions studied including accelerated stability studies on the lyophilised materials as well as stability studies on the reconstituted materials.

CONCLUSIONS

Two stable and homogeneous candidate CRMs have been prepared to be used primarily as a control for the IFCC reference procedure for determination of AST at 37 ºC. These materials will be subject to further evaluation to assess their suitability as potential CRM.

Accreditation, Quality Assurance

P0070

QUALITY ASSESSMENT OF MEDICAL LABORATORIES UNDER THE AUSPICES OF CZECH MEDICAL ASSOCIATION: 20 YEARS OF EDUCATION AND AUDITING

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BACKGROUND-AIM

Quality assessment of medical laboratories in the Czech Republic is provided by the Czech Accreditation Institute (CAI) and the National Authorisation Body for Clinical Laboratories (NASKL), a part of the Czech Medical Association of J.E.Purkinje (CzMA). The aim is to describe the history and future targeting of NASKL.

METHODS

Qualitative and quantitative description of NASKL and CzMA activities.

RESULTS

In 2001, the forthcoming ISO 15189 (FDIS: Quality management in the clinical laboratory, 2000-08-18) was selected as a suitable target for education and auditing of medical laboratories. A first set of standards compatible with ISO 15189 was published in 2003 and the National Registry of Clinical Laboratories was founded in the same year. NASKL was established in 2004, first audits appeared in 2006. Scientific societies under CzMA (clinical chemistry, hematology, microbiology, immunology, etc.) defined audited unit (a scientific laboratory discipline acting at postal address) and a rule „one branch one auditor" has been used till today. The auditor (qualified expert, approved by the respective scientific society) verifies compliance with the recommendations issued by the societies of CzMA and compliance with NASKL Guidelines, based on ISO 15189. In 2022, 353 audited units were registered, mainly clinical chemistry (115), hematology (65), pathology and cytology (56), microbiology (47), transfusion medicine (35), immunology (23) and others (12). There were 274 audits (disciplines at postal address) during 2021 and 2022. Certificate of laboratory quality is valid for 3 years with occasional checks during this period. In 2023, changes in NASKL Guidelines will be published to incorporate changes in ISO 15189. Also, new guidelines with respect to IVD-R 746/2017 are under preparation. Development of scientific recommendations of scientific societies represents a continuous process.

CONCLUSIONS

The two systems of quality proof (accreditation by CAI or audits by CzMA) are interchangeable, both based on ISO 15189 and accepted by health insurance payers. The main feature of NASKL is flexibility in the adoption of scientific recommendations and co-operation of scientific bodies under the umbrella of CzMA.

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Accreditation, Quality Assurance

P0071

VERIFICATION OF TWO AUTOMATED COAGULATION ANALYSERS FOR ROUTINE COAGULATION TESTS

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BACKGROUND-AIM

According to the international standards for clinical laboratories, methods which have been validated by the manufacturer and are implemented without modification must have verified precision and accuracy. We performed verification according to CLSI guideline (EP15-A2) for prothrombin time (PT) and fibrinogen and compared results from two coagulation analysers.

METHODS

Two levels of commercial control plasmas, Control Plasma N (CPN) and Control Plasma P (CPP) (Siemens, Germany) were analysed over 5 days in triplicate on two coagulation analysers BCS XP (Siemens, Germany). One analyser was purchased in 2011 and the other in 2022, and verification of PT and fibrinogen was done on both analysers after their purchase. Results are presented as coefficient of variation (CV), bias and total error (TE). The verification results were compared with the acceptance criteria according to manufacturer's claims and biological variation.

RESULTS

On the older analyser, the bias for inaccuracy for PT was 4.6% for the CPN and 1% for the CPP, while in both controls on the newer analyser it was less than 1%. Likewise, the imprecision in the series and from day to day met the manufacturer's criteria only on the newer analyser. The bias of inaccuracy for fibrinogen on both analysers was less than 1% in both controls. By measuring the imprecision in the series on the older analyser, unsatisfactory CV were obtained, while on the new one, CV met manufacturer's criteria. The results obtained on the newer analyser also met the analytically desirable precision derived from biological variation and desirable value for TE for both; PT (CV < 1.9%, TE < 1,43) and fibrinogen (CV < 7.7%, TE < 13,44), while on the older analyser these criteria were not met.

CONCLUSIONS

The verification of the recently introduced coagulation analyser in routine operation showed a much better performance compared to the verification of the analyser from 2011 although the manufacturer claims that the analysers are the same, i.e. that there were no changes that could affect the precision and the accuracy of the analyser. Therefore, verification should be done not only when new methods and analysers are introduced, but also periodically due to changes in the lots of reagents and calibrators, and in analysers' performance.

Accreditation, Quality Assurance

P0072

EVALUATION AND IMPROVEMENT OF LABORATORY REPORT QUALITY IN RELATION TO HEMOLYSIS MANAGEMENT BY APPLYING THE CONTINUOUS IMPROVEMENT CYCLE TOOL

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BACKGROUND-AIM

Hemolysis interference is a real problem faced by clinical laboratories. With the increasing demand for analytical requests the management of this type of interference manually is becoming more and more laborious.
The objective of this work is to evaluate and improve the quality of the laboratory report by automated management of interferences due to hemolysis, through the implementation of a cycle of evaluation and quality improvement.

METHODS

Pre-post design to evaluate with a qualitative-quantitative approach through a cycle of improvement, the "quality in the laboratory report managing in an automated way the interferences due to hemolysis, problem selected after the identification of improvement opportunities and their prioritization, using tools such as the nominal group technique, decisional matrix and cause and effect analysis.
The causes that could influence the problem were analyzed and 2 valid and reliable criteria were elaborated (1-Analytical report with a hemolysis index ≥800 should be annulled. 2-Analytical report with parameters interfered by hemolysis (between 15 and 799) should specify comments of such interference).
The dimension studied was scientific-technical quality. The laboratory computer system was used to obtain data on compliance with the criteria.
For the first evaluation, the time frame was 01/01/2017 to 30/06/2017. The degree of compliance with the evaluated criteria was estimated and the quality defects and prioritization of the intervention were analyzed using the affinity diagram and Gantt tools. Six months after implementation, a re-evaluation was carried out, establishing the time frame as 01/10/2017 to 30/03/2018. The sample frame was all samples with hemolysis index during the indicated time frames (309062 reports in the evaluation and 309398 in the re-evaluation).

RESULTS

In the first evaluation, criterion 1 presented a compliance rate of 84.4% and criterion 2 a compliance rate of only 0.28%. In the second evaluation, after the application of the interventions, the average compliance was 100% for both criteria.

CONCLUSIONS

The completion of the improvement cycle has managed to improve the quality in the issuance of the laboratory report. It is necessary to implement a monitoring plan to ensure that the improvements achieved are maintained over time.

Accreditation, Quality Assurance

P0073

WORK CLIMATE SURVEY AS A TOOL FOR CONTINUOUS IMPROVEMENT IN THE CLINICAL LABORATORY

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BACKGROUND-AIM

The ISO 15189 proposes to carry out satisfaction surveys to detect possible improvement actions for the better functioning of the service. Therefore, in order to promote the continuous improvement of our Laboratory, a questionnaire of professional quality of life is carried out to the personnel of the Service, which allows to evaluate the strengths and weaknesses of the same in aspects such as work environment, training and communication.

METHODS

97 professionals participated in the study, who evaluated both the training received and the work environment. To this end, they were asked to rate each of the aspects studied from 1 to 5, with 1 being not at all satisfied and 5 totally satisfied. It was considered that all those aspects whose score was lower than 3 should be studied in order to carry out improvement actions.

RESULTS

The aspects that obtained a lower score in the study were:
- Knowledge of the staff welcome manual (2.5 points).
- Being informed about new developments and the status of the Service (2.9 points).
- Receiving continuous training (3 points).

Once the aspects to be improved were known, different corrective actions were taken. With regard to the improvement in the communication of results, the establishment of periodic meetings between the technical and medical staff was proposed and a distribution list was created in the corporate mailing list in which all the staff of the Service was included. Finally, to improve the training aspects, the personnel welcome manual was digitalized and made available to the workers, and continuous training courses were programmed for laboratory technicians and physicians, which will be given by the service personnel.

CONCLUSIONS

The work environment is closely related to the behavior of employees, directly affecting their work performance. This is why it is essential to implement models for the evaluation of the work environment within organizations, since this makes it possible to detect the causes of the various internal problems and the reasons for job dissatisfaction. However, it is not enough to recognize these problems; it is essential to implement action plans to reverse the problems detected.

Accreditation, Quality Assurance

P0074

RESULTS OF EXTERNAL QUALITY ASSESSMENT (EQA) PROGRAM OF URINE SEDIMENT

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BACKGROUND-AIM

The Coordination Regional Center for Laboratory Medicine of Lombardy Region (Center) provides the External Quality Assessment (EQA) scheme of urine sediment evaluation with the aim to verify the inter-laboratory reproducibility of the morphological identification of urine particles.
Here we evaluate the concordance between the results obtained in two different exercises involving the same images proposed at different times.

METHODS

The EQA material consists of urine particles digitalized images, proposed both in phase contrast and in bright field microscopy. Each participant has to recognize the element present in each couple of images and has to suggest the most appropriate clinical condition that is more frequently correlated to the identified element. The answers are compared by the Center with the expected results assigned by consensus of a panel of experts.
In July 2021 and in June 2022 the same images containing red blood cells (RBC) were proposed. The recognition of acanthocytes, isomorphic, dysmorphic and ghost RBC was requested.

RESULTS

In the first exercise acanthocytes were correctly recognized by 73% of participants compared to 84% (+11%) of the second one and even the correct association of the clinical condition increased from 62% in the first one to 71% (+9%) of the second one.
90% of participants in the first exercise and 92% (+2%) in the second one recognised isomorphic RBC but the correct clinical association decreased from 95% to 88% (-7%) in the second one.
Identification of dysmorphic RBC was correct in 80% of cases in the first exercise and in 86% (+6%) in the second one; the relevant clinical condition association increased from 70% to 78% (+8%) in the second exercise.
Ghost RBC identification were slightly better in the second exercise 89% vs 87% (+2%) but the relevant clinical condition decreased to 68% vs 77% (-9%).

CONCLUSIONS

EQA scheme of urinary sediment evaluation has been very helpful to verify and strengthen basic skills for the recognition of urinary sediment particles.
Through the proposal of the same images at different times, the percentage of correct recognition has increased for all elements, although some laboratories have correctly identified the element only in the first exercise.

Accreditation, Quality Assurance

P0075

WORK CLIMATE SURVEY AS A TOOL FOR CONTINUOUS IMPROVEMENT IN THE CLINICAL LABORATORY

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BACKGROUND-AIM

The ISO 15189 proposes to carry out satisfaction surveys to detect possible improvement actions for the better functioning of the service. Therefore, in order to promote the continuous improvement of our Laboratory, a questionnaire of professional quality of life is carried out to the personnel of the Service, which allows to evaluate the strengths and weaknesses of the same in aspects such as work environment, training and communication.

METHODS

A total of 97 professionals participated in the study, who evaluated both the training received and the work environment. To this end, they were asked to rate each of the aspects studied from 1 to 5, with 1 being not at all satisfied and 5 totally satisfied. It was considered that all those aspects whose score was lower than 3 should be studied in order to carry out improvement actions.

RESULTS

The aspects that obtained a lower score in the study were:
- Knowledge of the staff welcome manual, which should be given to all new staff (2.5 points),
- Being informed about new developments and the status of the Service (2.9 points).
- Receiving continuous training (3 points).

Once the aspects to be improved in the Service were known, different corrective actions were taken. With regard to the improvement in the communication of results, the establishment of periodic meetings between the technical and medical staff was proposed and a distribution list was created in the corporate mailing list in which all the staff of the Service was included. Finally, to improve the training aspects, the personnel welcome manual was digitalized and made available to the workers, and continuous training courses were programmed for laboratory technicians and physicians, which will be given by the service personnel.

CONCLUSIONS

The work environment is closely related to the behavior of employees, directly affecting their work performance. This is why it is essential to implement models for the evaluation of the work environment within organizations, since this makes it possible to detect the causes of the various internal problems and the reasons for job dissatisfaction. However, it is not enough to recognize these problems; it is essential to implement action plans to reverse the problems detected.

Accreditation, Quality Assurance

P0076

USE OF DIGITAL TOOLS FOR THE TRAINING OF LABORATORY PERSONNEL

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BACKGROUND-AIM

The ISO-15189 standard is intended to ensure the quality and technical competence of clinical laboratories. In its subsection 5.1 "Personnel", it requires that laboratory management must document the qualification of personnel for each work position. For this purpose, demonstrated training evaluations to perform the relevant activities must be recorded.
In a laboratory service of a tertiary hospital, there are a large number of workers with diverse functions involved in the analysis process. The classic paper-based evaluation model is cumbersome and impractical in an organization of this size. Therefore, the digital transformation of these trainings is proposed in order to optimize the process.

METHODS

To carry out this digitalization we have used the Microsoft Forms platform. Through it, the person in charge of each section responsible for the corresponding training can add the items that characterize the training for a job or laboratory equipment and edit them easily. All the data is stored in the platform and can be simply accessed to review or update a training. In addition, it allows exporting to Excel the list of all training for a given activity with the different items that compose it. On the other hand, the access to the platform requires the user and password of the corporate e-mail, which also increases the protection of the data handled.

RESULTS

We have been working for a year with digital training in our laboratory, which has improved its quality. As they are more convenient to complete, the time for filling out these documents has decreased, and they are now easier to locate when they are needed. In addition, being able to export the results of all the professionals trained for the same function has allowed us to create statistics from which we can extract the weak points of personnel for a given activity, thus seeing where training needs to be reinforced more.

CONCLUSIONS

The use of digital tools allows training to be carried out in a more accessible, organized and secure way, in addition to the great savings in paper that it entails. In this way, the progressive digitization of documents brings a great improvement in the management of laboratory information.

Accreditation, Quality Assurance

P0077

BIOLOGIE HABILITATION, A NEW TOOL FOR POINT-OF-CARE TESTING OPERATORS TRAINING AND ACCREDITATION

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BACKGROUND-AIM

Risk analysis of point-of-care testing (POCT) shows that of staff training-accreditations management is a critical point difficult to control. Indeed, training, empowering and maintaining the skills of POCT operators is a challenge, especially with night staff on a remote site from the laboratory.
Usual POCT middleware offers to manage operators' authorizations (renewal date, quiz…) but does not control the entire process allowing a POCT coordinator to be sure that an operator is competent to realize all the phases of the analysis.

METHODS

"Biologie Habilitation" from Biologie e-learning is an innovative solution that allows training-accreditation and maintenance of skills for POCT operators, paperless and without travel. We experienced it at the Saint-Antoine hospital.

RESULTS

This very flexible solution makes it possible to adapt to different organizations. Thus, the evaluator can carry out the training-accreditation on site or remotely.
The operator validates his initial training through e-learning modules (courses, procedures, tutorials) prepared by the laboratory that can be viewed on computer, tablet or mobile. He validates his theoretical evaluation by answering a quiz and his practical evaluation by sending a video of his practice filmed by himself, making it possible to check all the steps carried out, as well as other proofs (ticket device result) to the evaluator. As the evaluator can be a person from outside the laboratory (staff from the clinical unit or supplier), the POC quality insurance manager can appoint a biologist responsible for validating each step of the accreditation.
To maintain their skills and thus retain their access rights to the device, the operator must acknowledge reading of the communications sent by the laboratory and meet new defined criteria (validate a skills maintenance quiz at regular intervals, carry out a minimum number of analyzes over a given period…). All data is stored in Biologie Habilitation in compliance with the General Data Protection evaluation.

CONCLUSIONS

Biologie Habilitation therefore allows close remote control of the training-habilitation-maintenance of operator skills throughout the process with tangible proof of their technical skills.

Accreditation, Quality Assurance

P0078

COMPARISON OF CORRECTED CALCIUM: STANDARD FORMULA VERSUS POPULATION-ADJUSTED FORMULA

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BACKGROUND-AIM

Under normal conditions, calcium(Ca)circulates in plasma in various forms: about 40%is bound to albumin(Alb),about 15%forms complexes with other proteins such as globulins,and the remaining 45%is in free ionic form(Ca2+),which is biologically active
The Ca correction equation for Alb,Cacorrected=[Catotal]+0.8[4-Alb], is standard and historically used,however,it has limitations.Varied in population groups and the methdos to assess the standard formula are no longer the same in modern laboratories.Therefore,it is advisable to obtain a population-adjusted Ca by Alb correction equation and specific analytical methods to provide a more clinically reliable and quality-assured result

METHODS

Using MODULAB as a statistical tool, data on calcium, creatinine, magnesium, vitamin D, parathyroid hormone, albumin, transaminases and alkaline phosphatase were collected from 5736 patients from our hospital (primary and specialised care)
Using Excel 2016, the results were filtered to include only patients with parameters within the reference values established in our laboratory.A total of 1055 patients considered as healthy population were obtained to obtain the corrected Ca equation.Linear regression yields an equation of the form y=ax+b, where a is the slope (pte) and b is the intercept (Ordo).Finally we compared the data obtained by the formula found and the standard formula and assess the clinical significance of the change.For our population a Pte=0.5574 and Ordo=7.1661 were obtained and used to derive the new adjusted equation,Cacorrected=Catotalmeasured-(pte*Alb)+(Camean-Ordo)

RESULTS

Comparing this with the standard equation used in the laboratory [Catotal]+0.8[4-Alb] and taking as reference interval 8-10.8mg/dL for the Cacorrected resulted in: 123 vs 102 cases of hypercalcaemia and 119 vs 102 cases of hypocalcaemia, for the new adjusted equation and the standard equation respectively. The adjusted equation is able to identify 2% of hyper and hypocalcaemia compared to previous standard practice

CONCLUSIONS

The equation adjusted to the local population of our hospital is able to identify 2% of hyper and hypocalcaemias with respect to previous standard practice. It is therefore more accurate in classifying our patients

Accreditation, Quality Assurance

P0079

BILIRUBIN MEASUREMENTS IN WHOLE BLOOD USING EXTERNAL QUALITY ASSESSMENT SAMPLES: ANALYTICAL PERFORMANCE OF BENCHTOP POINT-OF-CARE INSTRUMENTS

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BACKGROUND-AIM

Accurate measurement of total serum bilirubin (TSB) in newborns is essential for the diagnosis and treatment of neonatal hyperbilirubinemia. Variation in terms of bias and imprecision in TSB measurements affect clinical decision making. Harmonization of TSB results is endorsed by external quality assessment (EQA) programs. Benchtop point-of-care (POC) instruments using whole blood samples are increasingly being used for bilirubin quantification, but data on analytical performance of POC devices in EQA programs are currently not available. We aim to evaluate analytical performance of four commonly used point-of-care instruments for quantifying bilirubin in whole blood.

METHODS

We set up an EQA program with participation of twenty-three Dutch hospital laboratories evaluating four commonly used POC methods (Radiometer ABL 90, Siemens Rapid Point 500, IL GEM Premier 4000 and 5000) for measurement of whole blood bilirubin. The EQA consisted of two samples with a bilirubin concentration between 100 μmol/L - 500 μmol/L. The EQA samples were prepared from heparinized adult blood was spiked with different concentrations of synthetic bilirubin (B4126, Sigma-Aldrich, St.Louis, USA). The EQA samples were sent three-monthly to participating hospitals, i.e., six times, from January 2021 until June 2022.

RESULTS

The data contained 202 bilirubin measurements on four POC devices: 152 using Radiometer ABL 90; 32 using Siemens Rapid Point; 8 using IL GEM Premier 4000 and 10 using IL GEM 5000, respectively. The POC bilirubin concentrations were compared to the target bilirubin concentrations. Mean POC bilirubin concentrations were higher than the target bilirubin concentration (+55% at 100 μmol/L; +5% at 200 μmol/L; +6% at 300 μmol/L and +24% at 400μmol/L) or lower (-3% at 500 μmol/L). Coefficients of variation (CVs) varied significantly between the four POC methods. Mean CVs of POC bilirubin measurements were similar at all target bilirubin concentrations: 5.5% at 100 μmol/L, 6.6% at 200 μmol/L, 5.4% at 300 μmol/L, 4.7% at 400μmol/L, and 6.9% at 500μmol/L, respectively.

CONCLUSIONS

This EQA pilot study demonstrates considerable bias and imprecision for measurements of whole blood bilirubin on benchtop POC devices. Further research is needed to study (pre)analytical factors, potentially involved herein.

Accreditation, Quality Assurance

P0080

ENSURING RELIABILITY OF THE DETECTION OF DPD DEFICIENCY AND SEVERE TOXICITY OF FLUOROPYRIMIDINES-BASED CHEMOTHERAPY THROUGH EXTERNAL QUALITY ASSESSMENT PROGRAM: FIVE YEARS OUTCOME

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BACKGROUND-AIM

Pretherapeutic evaluation of the risk for severe toxicity of fluoropyrimidines (FP) before chemotherapy, mandatory in France since 2018, consists in pre-emptive screening for dihydropyrimidine dehydrogenase (DPD) deficiency based on DPD phenotyping using plasma uracil measurement (U). Contraindication is decided in case of complete DPD deficiency (0.08% of patients FP toxic deaths) where U≥150µg/L and adaptation of FP dosage for patients with partial DPD deficiency (9% of patients) for 16< [U] >150 µg/L.
Participation of the medical laboratories (ML) in an External Quality Assessment program (EQAP) for evaluation of U measurement is necessary to insure accuracy of the results and appropriate interpretation.

METHODS

An EQAP was organized by ASQUALAB since 2018 including 3 surveys, 6 plasma samples per year. Control materials were prepared by spiking human dialyzed plasma with different known concentrations of U, and lyophilized. All participating ML used liquid chromatography (n=45) with mass spectrometry (84%) or UV detection (12%), 2 ML did not specify the method involved.
The results provided as U concentrations were compared to the weighted target value, to the general mean and pair group mean according to acceptable limits (+/-20%) as well.

RESULTS

In 2018, 13 French laboratories took part to the evaluation, they were 47 European ML in 2022.
The results provided were assessed against expected results defined by the reference laboratory.
For normal samples, 100 % of the results provided in 2022 were found with no DPD deficiency, as expected. In 2020, they were 94% (34/37).
For samples allowing to conclude to partial deficiency, 83 to 97% of participants (39 to 43/47) get U>16µg/L, depending on the concentration level of the samples, especially those with values close to 16µg/L.
For samples associated with complete deficiency, 90% of the participants found U >150µg/L (42/47), they were 84% in 2019 (21/25), showing an Improvement of the evaluation given by the ML.

CONCLUSIONS

The number of participating ML in EQAP greatly increased in Europe within 5 years. Data presented demonstrate the important role of EQAP for harmonization and improvement of the medical decision for the detection of fluoropyrimidines toxicity due to chemotherapy.

Accreditation, Quality Assurance

P0081

ACCREDITATION AND CERTIFICATION OF LABS IN THE FEDERATION OF BOSNIA AND HERZEGOVINA

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BACKGROUND-AIM

Accreditation of labs is a procedure that reviews the quality of laboratory work, and represents a measure of quality in health care systems. The difference between accreditation and certification is that accreditation proves the competence to perform certain tests, measurements, certification or inspection, and certification provides a confirmation (certificate) about the compliance of the management system, products or people with a certain standard or technical specification. The aim of the research is to show the criteria for the accreditation of labs in the Federation of Bosnia and Herzegovina.

METHODS

The relevant articles for this review were searched from online data sources, including legal procedures of Bosnia and Herzegovina.

RESULTS

Accreditation of medical labs is carried out in European Union countries according to the International Standard for Medical Laboratories ISO 15189 and is legally mandatory. Given that Bosnia and Herzegovina is not yet in the European Union, medical labs are not legally obliged to carry out accreditation according to ISO 15189. The Quality and Accreditation in Healthcare Agency in the Federation of Bosnia and Herzegovina is the only competent authority in the field of quality improvement. and safety of health services and accreditation of health institutions in the Federation of Bosnia and Herzegovina. The agency was established on the basis of the Law on the System of Quality Improvement, Safety and Accreditation in Healthcare. When it comes to lab diagnostics, the standards for accreditation differ in relation to the level of health care, so medical labs in primary health care must meet 21 certification criteria and 4 accreditation criteria, medical labs in polyclinics 20 certification criteria and 2 accreditation criteria, and in hospitals 27 certification and 9 accreditation criteria to be certified and accredited.

CONCLUSIONS

Regulated processes of lab diagnostics and certified and accredited labs ensure safety for patients, and therefore it is necessary that they are carried out as much as possible within the Quality and Accreditation Agency, as well as with the introduction of ISO standards as a legal obligation.

Accreditation, Quality Assurance

P0082

EVALUATION OF OSMOLALITY IN A "POINT OF CARE TESTING" EQUIPMENT

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BACKGROUND-AIM

Osmolality is the amount of osmotically active particles dissolved in 1 kilogram of solvent (Osm/Kg). Its determination provides information on the hydroelectrolytic balance, the hyperosmolar state, the degree of hydration/dehydration, the acid-base balance and the function of antidiuretic hormone (ADH). The point of care testing (POCT) equipment is a widely used device due to its speed, reliability, small size and ease of use.

METHODS

Through the laboratory computer system (SIL), Modulab (Werfen), the data of those patients who requested venous gasometry and biochemical analysis with glucose (Glu), urea (Ure), sodium (Na) and potassium (K) together, were compiled in a retrospective way (6 months). The samples were processed in parallel in ABL 90 Flex (Radiometer) and Alinity c (Abbot) gas equipment. The osmolality parameter obtained through the ABL 90 Flex equipment is a calculated parameter that does not take urea into account. The osmolarity formula calculated by SIL and used to determine the theoretical osmolarity of patients from biochemical data was: (1.98*Na)+(Glu/18)+(Ure/6)+9. The data have been analyzed calculating the linear correlation coefficients and using the Passing-Bablok regression method with the MedCalc version 19 program.

RESULTS

588 patients were studied, initially the Pearson correlation coefficients were calculated assuming normal distribution and Sperman (non-normal distribution) obtaining 0.619 and 0.436 respectively. The osmolality calculated from the biochemistry was assigned as variable "x" and the osmolarity obtained by the POCT equipment as variable "y". The data obtained with their corresponding 95% confidence interval (CI) were: Regression line: y = 92.157258 + 0.661290 x. Sorted Origin: 92.16 (95% CI: 71.1 to 112.0). Slope: 0.66 (95% CI: 0.59 to 0.73).

CONCLUSIONS

The results show that there is no correlation between the value provided by the POCT team and the calculated theoretical value. Due to the fact that this equipment is used in critical places and far from the laboratory, this determination should be deactivated in the report since it can lead to errors in patient assessment. The biggest differences between results have been found in those samples with urea values higher than 100 mg/dL where the difference between both values is 10% on average.

Accreditation, Quality Assurance

P0083

INCREASE IN VITAMIN D POISONINGS IN OUR HEALTH AREA

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BACKGROUND-AIM

The main function of Vitamin D is the regulation of phospho-calcium metabolism. Recent studies have linked low levels of this vitamin with a higher incidence of allergies, autoimmune diseases and certain types of cancer. Vitamin D poisoning occurs from excessive intake of supplements, never from diet or sun exposure. The consequences of poisoning cause increased bone resorption and intestinal absorption of calcium, leading to hypercalcemia that can cause nausea, vomiting, weakness, bone pain, and kidney problems due to the formation of calcium stones. The objetives are to study how the determinations of this hormone have evolved, the cases of intoxication by vitamin D and to identify patterns.

METHODS

Vitamin D levels were determined using the 25-hydroxy-Vitamin D analyte (main circulating form) using the paramagnetic particle chemiluminescent immunoassay technique in a DxI unit (Beckman Coulter). High values are considered from 80 ng/mL and the upper safety limit, from which it can cause toxicity, above 100 ng/mL. The data for the years 2018-2021 were obtained retrospectively through the SIL laboratory Modulab (Werfen).

RESULTS

In 2018, 1099 determinations and 3 cases of poisoning (>100) were made; in 2019, 2110 and 5; in 2020, 2580 and 5, and in 2021, 4470 and 10, respectively. In 2020, there was a stabilization probably due to the pandemic (Covid-19). From 2018 to 2021, the determinations made of vitamin D have increased remarkably, reaching 4,470 in 2021 (4 times more than in 2018). The cases of poisoning have also increased, going from 3 in 2018 to 10 cases in 2021. 78.2% of the cases of poisoning occurred in women, and according to the age range, 91% of the cases were older than 43 years.

CONCLUSIONS

The treatment of intoxication consists of the suspension of vitamin D intake, dietary calcium restriction, restoration of the intravascular volume deficit and, if severe, administration of corticosteroids or bisphosphonates. This increase in the number of determinations could be due to the administration of vitamin supplements. Almost 80% of the poisonings occurred in women and in adult patients (one case in adolescents and none in minors).

Accreditation, Quality Assurance

P0084

COMMUTABILITY OF NINE BLOOD MATERIALS FOR HEMOGLOBIN A1C TESTING

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BACKGROUND-AIM

Commutability hemoglobin A_{1C} blood materials for laboratory comparisons is necessary to ensure the quality of HbA_{1C} results. The aim of this study was to investigate the commutability of nine processed blood materials (PBMs) prepared by different methods and HbA_{1c} values.

METHODS

The nine blood materials were one less modified blood material, three processed blood materials (PBMs) from in vitro glycation, two commercial PBMs, and three unprocessed blood materials (UBMs). The samples consisted of twenty-five clinical blood samples and nine blood materials analyzed by two immunoassays in a certified NGSP Level 1 reference laboratory, two immunoassays in clinical laboratories, and two point-of-care devices. The commutability of nine blood materials was evaluated according to CLSI-EP14.

RESULTS

Unprocessed blood material and less modified blood material showed higher commutability than PBMs. Mean differences of $HbA_{1C} \leq 0.2\%$ between blood materials were more commutable than mean differences of $HbA_{1C} > 0.2\%$. Hemoglobin A_{1C} in blood materials with values $\leq 6.0\%$ showed greater commutability than the > 6.0%.

CONCLUSIONS

The commutability of HbA_{1C} in blood materials showed variance and dependence on preparation methods, HbA_{1C} value and measurement principles.

Accreditation, Quality Assurance

P0085

ATELLICA® CI 1900 SAMPLE CARRYOVER PERFORMANCE EVALUATION

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BACKGROUND-AIM

The Atellica® CI 1900 Analyzer uses independent integration and random-access sampling to process chemistry (CH) and immunoassay (IM) tests. A single-use, disposable sample tip is used for IM assays, whereas a reusable dilution probe is used for CH assays. When a sample tube is first accessed by the CH dilution probe to process CH assays, then accessed by the IM disposable tip to process IM assays, there is the potential for sample carryover that could affect IM assay results. The purpose of this investigation was to evaluate sample-to-sample carryover performance on the Atellica® CI 1900 Analyzer.

METHODS

Hepatitis B surface antigen (HBsAg) was selected as the test analyte, given the extreme HBsAg concentrations that can exist in clinical samples. High HBsAg pools ranging from 25 to 55 million Index values were prepared by spiking purified HBsAg into serum. Eleven low (L) samples containing 600 µL of HBsAg-negative control QC and 10 high (H) samples containing 300 µL of the high HBsAg serum pool were created. The samples were first processed with one replicate per sample with the Atellica® CH ALT assay on the Atellica® CI 1900 Analyzer so that the CH dilution probe would aspirate 50 µL of sample. Sample-to-sample carryover testing was performed in a defined high (H)- and low (L)-sample consecutive sequence: L1, L2, L3, H1, H2, L4, H3, H4, L5, L6, L7, L8, H5, H6, L9, H7, H8, L10, H9, H10, L11. All low (L) samples were next assayed for HBsAg using the Atellica® CI 1900 Analyzer. The sample carryover study was conducted on three Atellica® CI 1900 Analyzers. Carryover in parts per million (ppm) was determined by multiplying the difference of the “high-low” mean (L4, L5, L9, L10, L11) and “low-low” mean (L2, L3, L6, L7, L8) by 1,000,000 and dividing by the high HBsAg sample concentration.

RESULTS

The measured sample carryover results were 0.00, 0.00, and 0.00 ppm. All three Atellica® CI 1900 Analyzers produced sample-to-sample carryover of <0.1 ppm using HBsAg as the analyte.

CONCLUSIONS

The Atellica® CI 1900 Analyzer demonstrated the capability to ensure sample-to-sample carryover of <0.1 ppm into primary sample containers with a minimum of 600 µL sample volume.
*Not available for sale in the US. Product availability varies by country.

Accreditation, Quality Assurance

P0086

METHODOLOGY EMPLOYED FOR FLEXIBLE SCOPE ACCREDITATION ACCORDING TO ISO15189 OF A HEREDITARY CANCER GENE PANEL USING NEXT GENERATION SEQUENCING (NGS).

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BACKGROUND-AIM

Due to the constant evolution of clinical laboratories and the availability of large panel of NGS genes,it is necessary to describe a methodology in order to accredit these studies for flexible scope according to ISO15189,allowing to include in the accreditation the study of new genes without prior approval by ENAC.
The aim of this study is the verification of a NGS panel of 70 genes related to hereditary cancer and the interchangeability study between NGS sequencers (single virtual device).

METHODS

Interchangeability study between MiSeq and NextSeq sequencers (Illumina):sequencing of 24 samples in both platforms and comparison of the variants obtained using Sophia DDM analysis software.
Verification study of the Hereditary Cancer Solution panel(Sophia Genetics):sequencing of 24 samples (clinical and reference (SeraSeq))were analyzed in two different MiSeq runs in different days.Read quality and variant detection capacity were verified.

RESULTS

Interchangeability study:6884/7026 variants were replicate.Therefore,the remaining 142 variants were identified in one of the platforms.The non-replicated variants were visualized in Integrative Genomics Viewer,located in regions of low complexity,defined them as artifacts or false positives.
Verification study:
Verification of reading quality:%Mapped readings and coverage 200x exceed 99%(%desired≥95% and ≥90%,respectively).
Evaluation of the detection capability of SNVs and INDELs:samples containing genetic alterations previously characterized by Sanger sequencing and MLPA were used.100% of SNVs and 96% of INDELs were detected (a threshold of >95% has been established).

CONCLUSIONS

Regarding the interchangeability study, since both sequencers detect 98% of the variants and all possible artifacts were detected with a warning,we can conclude that both sequencers are interchangeable and constitute a single virtual device. As for the verification of the panel,it has been carried out satisfactorily, since it complies with all the requirements stipulated by the laboratory. These results corresponding to the analytical part,together with the completion of a check list where changes in the pre-analytical, post-analytical and Laboratory Information System (LIS) were revised,allowed us to define a systematic for a flexible scope accreditation according to ISO15189.

Accreditation, Quality Assurance

P0087

EVALUATION OF THE URINARY DIPSTICK TEST THROUGH RESULTS OF AN EXTERNAL QUALITY ASSESSMENT PROGRAM

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BACKGROUND-AIM

Urine dipsticks (UD) are the most used method in urinalysis laboratory practice due to their low cost and feasibility. Aim of the study was to assess the degree of harmonization of the most used UD in Italy comparing the results provided by participants to the External Quality Assessment Program (EQAP) managed by the Centre of Biomedical Research (CRB), over the last 7 years (2016-2022).

METHODS

The EQAP, set up in 2001, consists of 4 surveys/year of 2 lyophilized control samples (cs) each, specially manufactured for CRB. Results of 56 cs, for a total of 103870, were evaluated grouping them in a categorized scale with a consistent assignment of UD categories to the respective concentration ranges of the analytes.
For glucose (GLU), total proteins (TP), albumin (ALB) and creatinine (CR) the values obtained by clinical chemistry instruments at the laboratory of the University-Hospital of Padova were utilized as a reference.
We calculated: the percentage of results with a value corresponding to the mode (value that occurs most frequently) for each parameter and cs; the median and percentiles of results belonging to the same category; Cohen's Kappa (K).

RESULTS

The agreement between the values provided by the various types of UD was excellent for nitrites (K= 0.981), good (K 0.61-0.80) for pH and specific gravity (K=0.688 and 0.610 respectively) and moderate (K 0.41-0.60) for GLU, PT, hemoglobin (Hb), leukocyte esterase and ketones with K for positive cs = 0.550; 0.588; 0.497; 0.594 and 0.458 respectively.
A concordance ranging between 89% and 99% was observed for negative cs but where the measurand was present "in traces" false negative results were found, e.g.: the 24% (11-41%) for cs with 0.3–0.5 g/L of GLU and the 10% (9-23%) for cs with 0.1-0.3 mg/L of Hb.
For PT, cs with concentrations between 0.2 and 0.7 g/L and ALB <5 mg/L, the 97% (96-98%) of UD gave negative results. Moreover, in 10 cs with a Protein/Creatinine ratio (PCR) of ~180 mg/g the 20% (17-59%) of UD provided a normal PCR. The agreement of ALB results obtained with Dasit, Meditape UC-11A strips was good (K= 0.626) but in cs with ~20 mg/g of ACR the 28% (10-77%) provided a normal ratio.

CONCLUSIONS

The EQAP could be a valid tool in providing a reliable view of the degree of harmonization among results of different types of UD.

Accreditation, Quality Assurance

P0088

A MODEL FOR MANAGING QUALITY CONTROL FOR A GROUP OF AUTOMATED HEMATOLOGY ANALYZERS

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BACKGROUND-AIM

We present a robust method for Monitoring Quality Control for a laboratory with multiple analyzers measuring the same analyte based on the detection of medically important out-of-control error conditions. This approach used to build control charts with an independently assessed, fixed mean and CV common to a group of equivalent analyzers in separate geographical sites.

METHODS

Quality control data were collected from a total of fifteen identical analytical modules (Sysmex XN).
Statistical and clinical tests were used to assess the reliability and robustness of the peer group data. Single Levey-Jennings control charts were designed using peer group reference mean and control limits for hemoglobin (Hb), leukocytes (WC) et platelets (Pl) in a network of fifteen analyzers in two distinct geographical sites. Both statistical and clinical assessments of significance were used to the evaluate detection of medically important out-of-control error conditions.

RESULTS

The confidence interval of the mean of the group of peers is less than the decimal of rendering the result. The peer group parameters are stable when evaluated statistically or using biological variation. The average biases of Internal quality controls (IQC) for Hb, WC, and platelet do not include any significant real bias. The actual pooled CVs of the beta testing laboratories are comparable to the CV90 for Hb and WC. The CV90 of the Pl is significantly higher than the pooled CV. The expected rate of unreliable results when estimating the performance of methods with the CV90 is less than 0.1% for the three parameters studied. Among the fifteen analyzers none presented an IQC result outside Maximum Allowable measurement Uncertainty (MAU) and a non-compliant External quality controls (EQA) result during the months analyzed.

CONCLUSIONS

Averages from Sysmex outsourcing data are reliable, robust and stable. The CV90s are not statistically or clinicaly different from the actual pooled CVs for Hemoglobin and leukocyte. The CV90 is significantly higher than the pooled CV for platelets. Nevertheless, this CV90 remains much lower than MAU. The model successfully reduces risk by managing multiple instruments to well-defined performance goals. The system is readily implemented.

Accreditation, Quality Assurance

P0089

EVALUATION OF THE CONCORDANCE OF GLYCATED HEMOGLOBIN VALUES BETWEEN THE HPLC (BIO-RAD D10) AND CAPILLARY ELECTROPHORESIS (CAPILLARYS FLEX PIERCING) SYSTEMS.

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BACKGROUND-AIM

At present, more than 20 different assay methods are being used to measure the level of HbA1c in clinical laboratories. These methods are based on different analytical principles, such as immune turbidimetry, cation-exchange chromatography, and high-performance liquid chromatography (HPLC). HPLC and electrophoresis are known for being first type methodologies. Meanwhile, several studies have shown significant differences between the different methods to measure HbA1c levels.
The aim of our study is to evaluate the performance of two systems: D-10® (Biorad) method that uses ion exchange HPLC and Capillarys Flex Piercing® (Sebia)based on capillary electrophoresis method and to assess the agreement between the results of the two systems.

METHODS

To evaluate the performance of the two above-mentioned methods, two levels of internal quality control materials were used (Physiological and pathological levels) . Within run (n = 30) and between run (n =30) coefficient of variation (CV) were determined for each test. Then, we have processed random samples from 107 patients coming to our laboratory for HbA1C analysis on both the analyzers Bio-rad D10 and capillarys Flex piercing. The correlation and the comparison studies were conducted using the Linear regression analysis and Bland–Altman plots.

RESULTS

The results of our study have shown good precision (within and between run) for both levels with all the CVs for physiological and pathological samples were less than 3% of required CV for analytic reproducibility for the two systems.
The comparison study has found an excellent correlation between the two systems with a R coefficient of 0.976 ($p < 0.001$). The difference diagram according to Bland and Altman have shown that ninety-five percent of the differences are between - 0.895% and + 0.79%.

CONCLUSIONS

Our study has demonstrated the existence of differences that does not allow a transferability between the two systems which requires the follow-up of patients with the same technique.

Accreditation, Quality Assurance

P0090

MICROALBUMIN ASSAY: VERIFICATION AND COMPARISON OF METHODS BETWEEN ALINITY® AND ARCHITECT CI-8200® ABBOTT

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BACKGROUND-AIM

The verification of analytical methods is a requirement of the International Organization for Standardization ISO 15189. It consists of evaluating the performance of an analytical method according to a well-defined protocol and then comparing it with pre-established analytical objectives. Through this work we present the results of the microalbumin verification protocol by comparing two automats: Alinity® and Architect ci-8200® Abbott. This work constitutes an elementary basis for the implementation of an accreditation procedure, which is part of the quality process to which our laboratory is committed.

METHODS

The working methodology adapted by our study is based on the recommendations of the protocol of the technical guide of accreditation of COFRAC. The verification of the method focused on the determination of microalbumin on the Alinity® automaton by immuno-turbidimetric method in order to evaluate the analytical performances in terms of repeatability and intermediate fidelity carried out from samples of patients hospitalized at the University Hospital and from internal quality controls. A comparison of methods was also carried out between the two automata Alinity® and Architect ci-8200®. The statistical processing of the data was performed using the middleware module of the BYG® software.

RESULTS

The results obtained for the different verification criteria of the microalbumin assay show a satisfactory repeatability for both levels (1: low / 2: high) with respectively CV1=1.04%, CV2=1.11%. The intra-laboratory reproducibility was satisfactory for both levels with respectively CV1=3.98%, CV2=3.01%. By comparing these results with the CV retained by the French Society of Clinical Biology SFBC, we note that the results are in conformity and below the tolerated limits. The Bland-Altman diagram shows that the average bias between the two automata is about 2.50%, with a linear regression equation Y=1.01X+1.11. The mean of the differences is 2.59 mg/l and the standard deviation of the differences is 3.402 mg/l.

CONCLUSIONS

The results of our study allowed us to verify the performance of the microalbumin assay method and to compare it to the analytical objectives set in the accreditation process to which our laboratory is committed. Thus, the two automated systems Alinity® and Architect ci-8200® are comparable.

Accreditation, Quality Assurance

P0091

IMPROVING ERROR REDUCTION IN THE POST ANALYTICAL PHASE OF THE LABORATORY USING LEAN 6 SIGMA AND BENCHMARKING TOOLS

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BACKGROUND-AIM

The aim of this study is to demonstrate the application of benchmarking and lean 6 sigma tools to improve the post-analytical phase reducing the incorrect laboratory reports in a public tertiary hospital laboratory.

METHODS

This project was carried out between 2021/January- 2022/August. The study was divided into 5 phases according to the DMAIC (Define-Measurement-Analyze-Improvement-Control) methodology. The monthly % of laboratory reports with corrections was considered as a critical success factor for patient safety. The formula used to monitor this indicator in the Laboratory Indicators and Benchmarking Program (PBIL) was (incorrect reports issue by the lab / total number of reports issue by the lab)*100. The PBIL results were considered in sigma metric. The root causes were grouped into clerical errors, technical errors involving personnel, errors related to methodology. An action plan was implemented to achieve sigma metric greater than 5.0 (less than 233 defects per million opportunities). This plan was monitored and controlled in accordance with defined criteria. The results were analyzed.

RESULTS

The documents were updated and the collaborators involved were trained. The report rectification policy was defined, communicated and trained for all collaborators. A training program was implemented with 8 hours in the studied period. The root cause results were classified as methodology (38.0%), technical (32.5%), clerical(29.5%). The incorrect reports were reduced (initial sigma = 4.95) and the final sigma was between (5.26 – 5.34). The laboratory's position in the ranking improved among laboratories with the best results in PBIL for this indicator (from 5th to 3rd quintiles).

CONCLUSIONS

The applied tools were useful in the continuous improvement of the observed quality, add value and increased the level of patient safety in the clinical pathology.

Accreditation, Quality Assurance

P0092

IMPROVING ERROR REDUCTION IN THE POST ANALYTICAL PHASE OF THE LABORATORY USING LEAN 6 SIGMA AND BENCHMARKING TOOLS

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BACKGROUND-AIM

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METHODS

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CONCLUSIONS

The applied tools were useful in the continuous improvement of the observed quality, add value and increased the level of patient safety in the clinical pathology.

Accreditation, Quality Assurance

P0093

ACCREDITATION: BRIDGING THE GAP BETWEEN RESEARCH AND CLINICAL LABORATORIES TO IMPLEMENT TOTAL PRECISION DIAGNOSIS AND PERSONALIZED MEDICAL CARE

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BACKGROUND-AIM

The Sidra Medicine Clinical Genomics Laboratory (CGL) offers genetic services which includes library preparation and sequencing methods employing a wide range of Illumina platforms and Hamilton robotics. The CGL team delivers a cost-effective, rapid, robust and very cost-effective sequencing solutions such as Whole Genome (WGS) / Whole Exome (WES) sequencing that support research initiatives in Qatar. The Pathology Genetics (PG) division is required to provide in-house WES and WGS diagnostic testing to patients. PG has limited analytical platforms to perform such services hence clinical samples are being sent out to reference laboratories abroad which are expensive with longer processing times. In order to perform patient testing in-house, the CGL workflow and processes must comply with requirements of the College of American Pathologists (CAP), the accreditation body of Clinical Pathology department.

METHODS

A designated quality personnel was identified to establish the quality management system (QMS), to lead the preparation for accreditation and to promote quality within practice amongst the staff. An internal audit was performed to determine the available protocols and records in CGL services to identify the gaps for CAP accreditation. All aspects of clinical testing are considered in the Illumina NovaSeq 6000, the main equipment for sequencing, including pre and post analysis equipment used to complete the process.

RESULTS

A quality manual was written to define the whole QMS and to establish the quality policies and objectives. CGL protocols are transferred to PG templates for standardization and uploaded to Q-pulse document control system. Internal quality procedures are utilized for sample library preparation, sequencing and data analysis. Designated CAP proficiency testing surveys are used for external quality assessment. Diagnostic verification and validation plans followed measurable parameters such as repeatability, intermediate precision, reproducibility, robustness and trueness.

CONCLUSIONS

The collaboration between the two departments maximized the available infrastructures of Sidra Medicine as a whole, saved costly genetic send out tests, improved the turnaround time, and fulfilled Sidra Medicine’s vision to provide total precision diagnosis and personalized medical care.

Accreditation, Quality Assurance

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ESTIMATION OF MEASUREMENT UNCERTAINTY OF 42 CLINICAL CHEMISTRY MEASURANDS USING INTERNAL QUALITY CONTROL DATA ON ROCHE COBAS 8000 INSTRUMENTS

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BACKGROUND-AIM

The Measurement Uncertainty model (MU) has been proposed as an alternative to Total Error to evaluate the analytical quality of the results. In this work, we calculated MU of clinical chemistry methods performed at the CoreLab of the Spedali Civili of Brescia and compared them with MAu (Maximum allowable uncertainty), the analytical performance specifications (APS) based on biological variability (BV) recently proposed by the EFLM for MU.

METHODS

IQC data generated between H2 2019 and H2 2022 from 3 Roche Cobas c702 modules with third-party controls were used to calculate the coefficient of variation (CV) of 64 measurands over six months. According to ISO 20914:2019, MU was calculated as $2*(u_{cal}^2 + u_{Rw}^2)^{1/2}$, where u_{cal} is the combination of MU of the higher order reference selected by the IVD manufacturer to implement traceability and the MU derived from the calibrator value assignment process (including any bias correction), while u_{Rw} is the CV of the repeated measurements performed on a QC material during a recommended period of 6 months. Finally, MU was compared with MAu.

RESULTS

The lack of u_{cal} and MAu data prevented the analysis of 22 of the 64 measurands made with Cobas instruments. For the remaining 42 measurands, MU exceeded MAu in 21.7% of the cases; the measurands with the highest number of mismatched MU were bicarbonates and sodium (100%), albumin (81%), calcium (75%), chloride and magnesium (67%) and total protein (47%).

CONCLUSIONS

Measurement uncertainty has recently been proposed as a new model for performing IQC. However, this approach raises some critical issues. First, this task requires obtaining metrological traceability data of calibrators from the manufacturer and selecting MU-specific APS, and these data are often lacking. In addition, it remains difficult to verify the accuracy of the transfer of trueness performed by manufacturers by implementing the metrological traceability chain, as this analysis requires the use of commutable materials with a value assigned by the reference method, but their use is difficult to implement in daily practise. For this reason, setting up an IQC system based on measurement uncertainty is a challenging task that needs to be fine-tuned before this model is successful.

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ESTABLISHMENT OF THE QUALITY SPECIFICATION OF ACETAMINOPHEN IN THE LAB.

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BACKGROUND-AIM

Establish the specification of the analytical quality acetaminophen concentration in serum or plasma measured by enzymatic method (EMIT) in the clinical analysis laboratory.

METHODS

At the 2014 Milan Conference three analytical quality specification models (EC) were proposed. However, some measurands cannot be adapted to these three alternatives. The quality specifications of drugs is a difficult issue because there are no biological variation values in [EFLM, 2021] or [SEQC, 2021], and various authors propose different theories to calculate EC.
In the latest Clinical Laboratory Improvement Amendments [CLIA, 2024] publication makes recommendations for determination and interpretation of Tea for acetaminophen establishing a target value (TV) ± 15% or ± 3 mcg/dL (greater). In addition, data from external laboratory quality control (QCE) for the year 2022 (compiled monthly values for a year), and the last 300 internal quality control (CI) values (entered once a day) were collected.
Attached table with the results obtained in the QCE (table 1) and CI (Table 2), respectively.

Months	LAB value	Target Value	Measurement Error %
1	10	11,3	-11,50
2	99,3	105,2	-5,61
3	10,9	11,6	-6,03
4	37	37,2	-0,54
5	98,8	106,1	-6,88
6	37,1	38,3	-3,13
7	8,9	10,4	-14,42
8	11,5	11,2	2,68
9	90,8	106	-14,34
10	37,3	37,1	0,54
11	9,8	11,5	-14,78
12	8,8	10,6	-16,98

Table 1. Data obtained from the external quality program.

Nivel	Middle value	SD	CV %
1	18,9	0,94	4,96
2	46,5	1,64	3,54
3	118,1	5,83	4,93

Table 2. Data obtained from the external quality program.

RESULTS

Bias is calculated from the QCE data as the average of the results of the measurement errors of the laboratory, resulting in 7.6%. If the formula is applied: TEa=|S|+ 1.65 * CV, where TEa is total error as quality specification, |S| is bias (in absolute value) obtained in the QCE and CV is impresicion (CV between series) obtained in the CI. TEa= |7.6|+1.65*4.96 = 15.8%. We take the CV of the first level of internal quality control as it is the highest value (worst prognosis).

CONCLUSIONS

The EC values obtained from different points of view range from 15% to 15,8%. In our opinion, we chose to set the conservative value specification of 15,8% because we propose that EC be a path of continuous improvement starting from the leats demanding.