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Laboratory Management, Accreditation, Quality Assurance

Cod: W014

LABORATORY MANAGEMENT AND STAFF COMPETENCE: KEY ASPECTS OF THE ACCREDITATION PROCESS.

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Background. The ISO15189 Standard, globally recognised as the most important Standard for accreditation of medical laboratories, focuses on two main aspects: the QUALITY MANAGEMENT SYSTEM and STAFF COMPETENCE. Therefore to achieve accreditation, in addition to a well-structured quality system, are needed: a) the experience in laboratory management and even more in the planning of the strategic goals and of the steps for reaching them and b) the technical Knowledge and staff competence.
Aim of this work is to describe the operational steps planned by the Laboratory Medicine of Padua to meet the strategic goal of the Laboratory accreditation.
Methods. In January 2015, Laboratory Management defines as strategic goal to reach by December 2016, the accreditation according to ISO15189. Accreditation scope, medical areas/tests to be accredited were also defined. Operational steps were planned: 1) by February 2015, a training course to all staff, given by Quality Manager, to explain the standard requirements and to identify areas needing improvement; 2) by December 2015, an on-the-job training to all staff divided into groups, to identify requirements to be meet, processes to be harmonized and procedures to be documented/updated; 3) by March 2016, audit of some tests, to verify if all requirements have been meet; 4) by May 2016, the accreditation application.
Results. In July 2016, the central laboratory and 2 satellite laboratories received the accreditation with flexible scope. 55 coherent groups of tests (identical for technical principle) within 4 medical areas (Clinical Biochemistry, Haematology/ Coagulation, Immunology, Molecular Biology) were accredited. The results demonstrate that the planning of operational goals (intermediate and immediate) and operational steps to reach them was effective in achieving the strategic goal. The proposed model has been also effective in achieving more ambitious goals than Accreditation certificate, the full awareness of laboratory staff and the evidence of staff skills, which were indicated in the audit report as good practices.
Conclusion. The Laboratory Medicine of Padua, focused on two main aspects: a) the management skills in planning the activities and in goals achievement and b) the peer-review analysis of the processes to meet the ISO requirements. A strategic planning represents the first point to achieve results, but it closely depends by the staff competence.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W015

THE EVALUATION QUALITY INDICATORS IN LABORATORY OF OUR HOSPITAL UNDER THE NATIONAL LABORATORY ERROR CLASSIFICATION SYSTEM IN TURKEY

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Background: Clinical laboratories play an important role in improving patient care and safety. All phases and activities of testing cycle should be assessed, monitored and improved in order to increase patient's safety. The national laboratory error classification system (LECS) was created for improve the quality processes of laboratory and patient security by the ministry of health in 2015. The aim of this study was to evaluate the total laboratory process and quality indicators (QIs) in biochemistry laboratories according to this class system. It was to contribute to this process.
Materials: This study was made retrospectively. The number and type of rejected samples between 1 October 2015- 30 and December 2016 were obtained by laboratory information system of Balıkesir State Hospital. Laboratory processes was organized according to LECS created by the ministry of health. This system is occurred from four main section, laboratory error type (59 QIS), stage (pre-intra-post analytical process), place of the error (clinical, intensive care, emergency department, policlinic, surgery, blood collection unit, the sample receiving unit, laboratory and other), profession group (Doctors, nurses, interns students, technician of laboratory, medical secretary, transfer personal, patients, relatives of patient and unknown) and time of the error (00:00 - 04:00, 4:00 - 08:00, 08:00 - 12:00, 12:00 - 16:00, 16:00 - 20:00, 20:00 - 23:59 and unknown). The results were evaluated as percentage.
Results: In this study, to 3965 from 639551 samples were made by LECS in laboratory quality processes. Respectively, rates of pre-intra-post analytic were 78 %, 5%, and 17%. Maximum error type was clots (46%). Place of error was the most emergency service (25%). The times error was made between 8 to 12 hours (31%). profession that error was nurse group (65%).
Conclusions: LECS used in our country is occurred from 59 criteria (38 pre-, 13 intra and 7 Post- analytical phase and 1 others) occurs. Additionally, According to this system is included place, time and professional groups. This system can be implemented by coding the sub-parameter. The source of error can be analysis with advanced tracking. According to these data can be observed the result of the improvement. Using a standard method across the country will increase patient safety.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W016

VERIFICATION OF NEWLY INTRODUCED EXAMINATION PROCEDURES ACCORDING TO ISO15189:2012 ACCREDITATION

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Background: The International Standard ISO 15189 describes the requirements for quality and competence for medical laboratories (ML). The verification of examination procedures (EP) is a crucial step for accreditation. Validated EP used without modification shall be subjected to independent verification by ML before being introduced into routine practice. The analytical performances claimed by manufacturer have to be confirmed through objective evidence.
Aim of this study is to propose an operative process to verify the analytical performances of all the newly introduced EP in a medical laboratory.
Methods: After the analysis of the available scientific documents, for the verification procedure the following steps are assessed: a) the typology of EP; b) performance characteristics to verify; c) the workflow; d) criterion for the results acceptability; e) the feasibility.
Results: Quantitative, semi-quantitative and qualitative EP are individuated. For quantitative EP, at least imprecision and trueness are evaluated in terms of CV% and bias%, respectively. The precision verification study consisted of three parts: 1) repeated measurements over five days on patient samples; 2) calculations of repeatability and within-laboratory precision; 3) assessment of consistency with the claims. Trueness is estimated by analysing materials with known concentration and comparing the results to the target values. For qualitative EP, diagnostic accuracy is evaluated, in terms of sensibility and specificity with true negative samples and true positive patient samples. For semi-quantitative EP, imprecision and diagnostic accuracy are assessed.
Conclusions: A model for the verification of newly introduced examination procedures is proposed, considering all kind of methods commonly carried out in a routine medical laboratory, taking into account technological possibilities, risks, costs and assuring the compliance of the fundamental component of result accuracy.
References: ISO 15189:2012 medical laboratories- requirements for quality and competence. Geneva, Switzerland: ISO, 2012. Clinical and laboratory Standard Institute. User verification of precision and estimation of bias; approved guideline-third edition. CLSI document EP15-A3; Wayne, (PA), USA 2014.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W017

THE LABORATORY COST OF POOR QUALITY

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Background: Laboratories are always aware of the quality of their results and services they are providing. Yet some of the laboratory staff is unaware of laboratory's quality cost and financial status, and thinking that staying within budget is the goal. The problem is that laboratory mangers and accountants are only used to see the input costs (quality control, proficiency testing, accreditation…etc.) but they never see the errors or failure cost. Big mistake.
The laboratory errors result in time loss and costs throughout the laboratory testing phases. Many of laboratory costs are hidden and are not always a financial cost. Actually defining all costs as financial diminishes impact, other costs to be consider in addition to money are: time cost, effort cost and energy cost.
This article will provide an overview of the different types of quality costs including prevention, appraisal, and internal and external failure costs with examples, specific to laboratory environments and giving tips to implement a quality cost program in your laboratory.

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Laboratory Management, Accreditation, Quality Assurance

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EQA AS A TOOL TO IMPROVE THE PERFORMANCE: 10 YEARS OF EXPERIENCE PARTICIPATING IN URINE PARTICLES EQA SCHEME

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BACKGROUND. External quality assessment (EQA) schemes are valuable tools to improve laboratory's performance, even in qualitative analysis, such as urine particles identification and evaluation. EQA scheme with expert comments and explanation of results gives additional value to participants. Knowing the fact that phase-contrast microscopy method is not routinely used for urine particles identification in Lithuanian laboratories, our aim was to evaluate experience on urine particles EQA schemes of Lithuanian laboratories compared to other countries.
METHODS. Dataset of 10 years' period (from 2006 up to 2015) from Labquality EQA scheme 'Urine, identification of cells and other particles' (Labquality, Finland) results was used. It comprised of 38 different rounds / clinical cases. In all 152 digital pictures (76 bright-field and 76 phase-contrast microscopies respectively) with 152 different urine cells or particles were analyzed. In average 225 laboratories, of which 18 were Lithuanian, participated per single round. All answers of the participants were classified and then expressed in percentage rates per single round as follows: E – expected/target finding; A – acceptable finding; W – wrong finding.
RESULTS. E category answers rates of Lithuanian laboratories were higher than in other countries in 41.4 % cases, A category rates – higher in 19 % cases, and W category rates – higher in 63.2 % cases. Generally, frequency of erroneous answers was statistically higher than in other countries (n=152, 28.0±24.0 vs. 20.3±18.0; mean square 507.6, F 4.0, $p<0.001$). Trend analysis of W category answers during 10 years revealed positive results: frequency of wrong answers decreased in average from 38 % to 18 % ($y=–0.1327x+38.164$; $r^2=0.0592$). There was no significant difference in W category rates between bright-field and phase-contrast pictures' results ($p=0.814$). Trend analysis of these two microscopy methods did not change in principle ($y=–0.3946x+42.744$; $r^2=0.1279$ vs. $y=–0.1368x+33.738$; $r^2= 0.0161$).
CONCLUSIONS. It was found that competency of Lithuanian laboratories during last decade was doubtful and there is a huge demand of training for laboratory professionals. But despite this there is an obvious improvement in performance of Lithuanian laboratories performing urine particle identification (even in phase-contrast method), which can be explained by an educational aspect of corresponding EQA scheme.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W019

EVALUATING ASSAY PRECISION FOR IMMUNO-CHEMILUMINESCENT METHOD FOR FOLLICLE-STIMULATING HORMONE (FSH)

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Verification process of the methods according to the needs of ISO 17025 Standard includes evaluating the imprecision of the assay(S). For this purpose it is necessary to assess the repeatability (within-run) and total within-run laboratory precision. According to the CLSI EP15-A2 document the user of the test(s) should undertake the measurements of the analyte(s) at at-least two levels, by running of three replicates over five days. The purpose of our work was to estimate the assay precision of the immune-chemiluminiscent method for FSH quantification by estimating of repeatability and within-laboratory precision as well as, to evaluate the obtained results.

Material of our study were control samples, different from those used to ensure that the instrument is in control at the time of the assessment, with two levels (low and high), which were run in duplicate as three replicates for 5 consecutive days using Immulite/Immulite 1000 Simens kits. The repeatability value for the low replicates was 0.30 miU/ml and for the high replicates 2.1 miU/ml. Estimated repeatability value for the high level was less than the manufacturer's verification value claims (2.1 and 2.5 respectively). Estimated repeatability verification value for the low level of replicates is similar to the verification value of the manufacturer's claim (0.3 and 0.27 respectively). Estimated within-laboratory precision for the low replicates was 0.6 miU/ml and for the high 3.32 miU/ml.

Evaluated within-laboratory precision verification value for the low replicates was 0.42 that is less than the manufacturer's claimed verification value of 2.68. For the high level replicates evaluated verification value was 2.67 less than the manufacturer's claim (13.88).

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

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Laboratory Management, Accreditation, Quality Assurance

Cod: W020

DISCREPANT RESULTS OF KOVA VS BD URINE COLLECTION TUBES; IMPORTANCE OF PRE-ANALYTICAL PROCESS VALIDATION

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BACKGROUND
The undisputable elements of a new test validation are the instrument and reagents performance confirmation, as well as validation of calibrators/QC. The pre-analytical elements such as collection tubes, stability of the analate during ground or pneumatic tube system transportation etc. are commonly neglected. The purpose of this abstract is to show the importance of the validation of pre-analytical processes. It is illustrated by our recent validation of urine collection containers.

METHODS
We used 100 urine samples and compared two, BD and KOVA urinalysis collection systems available on the US market. The aim for validation was to replace KOVA containers with BD collection system that might potentially decreased false positive results of urine culture. For this purposes we compared the chemical testing between KOVA and BD tubs, as well as automatic microscopy of both tubes against manual microscopy. The manual microscopy was done by two experienced technologists who were blinded to the previous automatic and manual results.
RESULTS
1. The instrument detected more bacteria than manual and automated KOVA counting. 6 samples with zero bacteria by automated KOVA and by manual microscopy counting were found to be positive by automated BD.
2. The casts were reported from 6 samples by automated KOVA and by manual evaluation, but not by automated BD. In 2 samples the bacteria was detected by an automated BD and manual microscopic but not by automated KOVA tubes.
3. The leucocyte and erythrocyte count by instruments was higher in 28 samples processed by BD and in 5 samples tested by KOVA when compared to the manual count. BD system detected cells in 5 samples in which automated KOVA and manual microscopy have not found ones.
CONCLUSION
1. The discrepancy detected in bacteria testing between BD and KOVA automated results would increase the numbers of reflexing culture by at least 6%.
2. About 6% of the casts will be missed by automated BD what would affect a diagnosis of tubular.
3. The discrepancy in cell counting my lead to a significant misdiagnosis of patients with urinary track symptoms.
4. The validation of pre-analytical processes including the collecting containers should be an integrative part of initial test validation.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W021

MEASUREMENT UNCERTAINTY OF CHOLESTEROL AND TRIGLYCERIDES – IMMPLEMENTATION IN CLINICAL PRAXIS

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Introduction: When implementing ISO 15189, medical laboratories are required to determine measurement uncertainty (MU) for most of tests performed. MU is a number that is added to the laboratory results as ± value representing the dispersion of the test result. Most of clinical laboratories provide test results to their clients (a practitioner and/or patient), without any indication of MU although that there is always a doubt (uncertainty) about result of any measurement.
The aim of our study was to determine MU of total cholesterol and triglycerides tests using "top down" approach (in accordance with GUM) with many sources of uncertainty included, to investigate the correlation to the value of intra individual-biological variation and to explain the benefit for the clinicians and patients.
Material: Control samples with two different levels, samples and data from EQAS and patient samples were used.
Methods: Total cholesterol and triglycerides were determined using standard methods. The estimation of MU included data derived from within-laboratory validation and Quality Control. The overall relative standard deviations of the methods used were calculated from 4 months (CV_a, analytical imprecision, u_a) while the bias uncertainty (u_b) was estimated from four external quality assessment schemes. The obtained uncertainty was related to the within individuals-biological variation (CV_i).
Results: Using the equation $u_c = [(u_a)^2 + (u_b)^2]^{1/2}$ the combined standard MU (u_c) for cholesterol was calculated to be ±4,9%, while this value for triglycerides was ±17.2%. Consulting literary data we found the value of intra individual-biological variation for cholesterol set at 5.95%, and at 19.9% for triglycerides.
Discussion and conclusions: Our results for MU are much less than the values of intra individual-biological variation for both parameters which means good correlation with the desirable quality specifications. MU allows a practitioner to better realize the clinical condition of a patient and could be a benefit especially for the decision about the significance of the difference between two consecutive results of the same patient obtained from the same laboratory. So, MU is one reason more for a good interface with the laboratory.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W022

EFFECT OF PARTICIPATING IN A QUALITY IMPROVEMENT SYSTEM OVER TIME FOR POINT-OF-CARE C-REACTIVE PROTEIN, GLUCOSE, AND HEMOGLOBIN TESTING

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BACKGROUND: Users of Point-of-care testing (POCT) in Norway participate in a quality improvement system that includes education and guidance in safe laboratory management along with participation in external quality assurance schemes (EQAS).
The aim of this study was to identify the effect on the analytical performance of POCT C-reactive protein (CRP), glucose, and hemoglobin (Hb) with the use of a quality improvement system over time and to identify which factors are associated with good performance.
METHODS: Participants' results from 19 EQAS for CRP, glucose, and Hb from 2006 to 2015 along with information on the instruments used and different practice characteristic were analyzed. Logistic regression analysis was used to evaluate the factors associated with good laboratory performance. An instrument evaluation and comparison for CRP determination was performed using commutable EQA material.
RESULTS: The average number of participants in each EQAS was 2134, 2357, and 2271 for CRP, glucose, and Hb, respectively. The percentage of good participant performances increased gradually whereas that of poor performances decreased with participation in a quality improvement system over 9 years for all 3 analytes. Independent factors associated with good performance were type of instrument, the number of times performing EQA, performing internal quality control weekly, performing 10 or more tests weekly, and having laboratory-qualified personnel perform the tests. Considering CRP instrument performance, Afinion and QuikRead exhibited the lowest systematic deviation.
CONCLUSIONS: The analytical quality of CRP, glucose, and Hb testing is improved by systematic participation in a quality improvement system over time.

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Cod: W023

TURNAROUND TIME

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Turnaround time (TAT) is an example of an indicator of the quality of a process in the laboratory. Doctors and other medical personnel often evaluate laboratories according to the speed of providing analysis results. In the same way they evaluate the quality of the laboratory.

TAT can have a direct impact on the time a doctor needs to diagnose, decide on introduction of a therapy, patient's waiting for the diagnostic procedure.

TAT indicator was measured for analysis of urea and creatinine of patients who need CT and do not bring laboratory results. In 2014, 2015 and 2016 we monitored the indicator in January each year. TAT is measured from the time a patient is inscribed in the laboratory information system (LIS) until the final validated results. After validating analysis, we notify the RTG department by telephone about the results of both analysis and we record the time of call in our LIS. Informing on the telephone was introduced in 2015 to eliminate the communication gap.

These two parameters have been monitored in previous years but the RTG department did not have results in an hour. According to our records we had all the results validated in less than an hour. We found that private patients are not enlisted in the hospital information system and the RTG department personnel did not have an insight into the results. The RTG personnel therefore waited for the patient to physically bring the results to the department. Thus the sum of time from the patient being sent from the RTG department until his return with the laboratory results was more than an hour. In order to reduce the time, we studied all the phases of the analysis and improved the communication between the personnel in the pre-analysis phase by specifically marking these patterns.

In 2015 we reduced the time of delivering results for the analysis of urea and creatinine by 6 minutes. Monitoring allowed analysis of where in the procedure one can find a possibility for improvement and better communication.

We found that our TAT for the analysis of urea and creatinine complies with the times set for "urgent" biochemical samples. In the laboratory the entire process is executed in the requisite time. Our evaluation is that the time is lost when delivering the biological sample from the department. The solution is pneumatic tube systems, which would be used to send biological samples to the laboratory.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W024

REASONS OF SAMPLE REJECTING IN LABORATORY AND HOW TO DECREASE THE REJECTION RATES

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Introduction: In biochemistry laboratories, a sample that can not meet the necesarry requirements is not accepted. Rejected samples are reported to the related units by specifying the rejection cause. Frequently faced problems while accepting the samples are; faulty test entry,lack of preparations which is necessary for the test (hunger, smoking etc.), occurance of hemolysis, lipemia, clot, use of wrong sample vessel, taking the sample in the wrong amount(more or less), mislabeling or sample without barcode, faulty collection of 24 hours urine or transferring samples under inappropriate circumstances. Detection of the amount of monthly rejected samples, statistical distrubiton, training the related staff is necessary in order to remove these causes and prevent the victimisation of patients. In this study, we aimed to put forth the efficiency of trainings by analyzing the amount of rejected samples in Yozgat Cıty Hospital.

Method: Taken from hospital information system, rejected sample statistics relating to 16 months
between 07.2015-10.2016 are examined. These datas were compared in itself and to each other. Besides we examined to see if there is a statistically significant difference in terms of rejection rates before and after the date (29.01.2016) on which the related staff is trained.

Result: There was not a statistically significant difference between average patients numbers before and after training ($p>0,05$). However, rejected sample rates were significantly lower in terms of statistics aftertraining ($p=0,0001$).

Discussion: Preanalytic mistakes composes a big part of the laboratory mistakes. Staff training takes a very imtportant place preventing these mistakes. As it can be seen in our study, training helps decreasing rejection rates. It is suggested to schedule more trainings in order to decrease the rates to lower degrees

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Laboratory Management, Accreditation, Quality Assurance

Cod: W025

THE REFERENCE RANGES OF ROUTINE BIOCHEMICAL BLOOD PARAMETERS IN THE ADULT POPULATION OF ALGERIA (REGION OF ORAN).

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BACKGROUND
The correct interpretation of laboratory results needs the determination of accurate clinical laboratory reference values from regional population. In Algeria the reference intervals used are usually based on values derived from populations in the United States or Western Europe.
The aim of this study was to establish indirect reference range in Algerian population living in the region of Oran for 14 biochemical parameters using data from laboratory information system (LIS) during routine laboratory work.

METHODS:
46243 results stored in the laboratory information system (LIS) for three months (1st March- 31st May 2016) were included. The determination of each reference range was according to the recommendations of the CLSI guideline EP28-A3c. Values established in this study were compared with the Western Europe values being used currently by our laboratory as reference values.

RESULTS:
Final sample size for reference data creation was 33748 after exclusion of outliers and a logarithmic transformation of the raw data was done. Non-parametric reference intervals were estimated statistically after visual observation of the distribution using histograms. Indirect reference values were:
ALT [19-69.4 UI/l] ,AST [15-36 UI/l],Total Bilirubin [0.1-1.9 mg/l], Direct Bilirubin [1.6-10.7 mg/l] , Creatinine [6.19-12.70 mg/l], Blood Urea Nitrogen (BUN) [0,14-0,43 g/l].For the Cholesterol [0,56-1,96 g/l], HDL [0,40-0,60 g/l], Triglyceride [0.34-1.45 g/l] ,Glucose [0.75-1.05 g/l], Total serum Protein [64.14-79.92 g/l]. For the Chloride [98-107 mmol/L], Potassium [3.5-5.0 mmol/L], Sodium [136-144 mmol/L].

CONCLUSIONS:
For most biochemical parameters studied established reference values are similar to those of western-derived reference laboratory values except for ALT, AST and creatinine. It is very important to establish locally relevant reference parameters for commonly used biochemical tests that will help in the interpretation of laboratory results for clinical management of patients.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W026

REVIEW OF CRITICAL LABORATORY RESULT COMMUNICATION IN TAN TOCK SENG HOSPITAL

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BACKGROUND
Critical laboratory results / critical values are any test results that may require rapid clinical attention to avert patient harm. Each laboratory should have a process for immediate notification of such results. Tan Tock Seng Hospital (TTSH), an acute care general hospital with over 1,500 beds, implemented a system where clinicians are notified of critical laboratory results by short messaging service (SMS) via mobile phones. This is a review of the challenges encountered and progress of the SMS notification system since 2009.

METHODS
Previously the manual worklflow of informing the clinician of critical results takes about 18 minutes, this involves the Medical Technologist calling the ward nurse, who will then inform the clinician in charge of the patient. With this new workflow, whereby the critical laboratory results flow directly from the Laboratory Information System (LIS) via the Healthcare Messaging System (HMS) to the clinicians' mobile, it takes less than 2 minutes.
Recipient of these messages are required to respond through SMS by selecting either of these 3 options:
1 ~ Right doctor, acting on it
2 ~ Wrong doctor, acting on it
3 ~ Wrong doctor, not acting on it
Critical laboratory result message will be escalated to the next doctor in line if:
~Recipient reply "3"
~Recipient did not reply within 10 mins
~Recipient reply with any other text instead of "1", "2" or "3"
The last escalation is manual intervention by the Call Centre operator, who will connect the doctor and laboratory staff, to convey the critical result verbally

RESULTS
The laboratory monitor and review the critical laboratory result communication indicator on a monthly basis. On average the percentage of critical results communicated and acknowledged electronically or verbally with read-back remains at about 72% in 2016.

CONCLUSIONS
Despite continuous effort to improve the process over the years, the percentage of critical results communicated and acknowledged electronically or verbally with read back remains well below our target of 100%.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W027

DEVELOPMENT OF AN EXTERNAL QUALITY ASSESSMENT SCHEME FOR URINE DRUGS OF ABUSE

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Introduction
External Quality Assessment (EQA) is an essential part of assuring the quality of laboratory diagnostic services, and participation in EQA is a requirement for laboratory accreditation to ISO15189 and Point of Care (PoCT) accreditation to ISO22870. Drugs of Abuse testing is most commonly performed on urine as most drugs and their metabolites are excreted in urine. Urine testing for both prescribed and illicit drugs is increasingly used in both Laboratory and PoCT settings.

The Weqas Urine Drugs of Abuse EQA Scheme caters for both urine screening and confirmatory testing and allows both qualitative and quantitative reporting.

Aim
To develop and validate material for use in an EQA scheme for Urine Drugs of Abuse testing and to assess the stability and commutability of the material.

Method
Urine pools spiked with drugs or their metabolites were assessed for their short-term stability at 4°C and long term stability at -20°C. Comparability of the urine was assessed from EQA returns across Laboratory, PoCT and Mass Spectrometry methods.

Over 60 sites were recruited to take part in the study. Each site was sent 3 samples per month with negative and positive samples covering 16 drugs / metabolites. The majority of users were using Laboratory or PoCT screening methods reporting qualitative results.

Results & Discussion
The majority of spiked drugs appear stable for 14 days at 4°C and for 4 months at -20°C.

Qualitative interpretation was based on the gravimetric value for each drug according to pre-determined cut points, with the gravimetric value provided for quantitative reporting. For most drugs the qualitative results show over 90% positivity for samples, with spiked values above the cut point. For some drugs, specific performance characteristics have been identified where certain methodologies are unable to measure specific metabolites.

Conclusion
An EQA scheme for Urine Drugs of Abuse has been established using stable, comparable material suitable for Laboratory and PoCT methods, for screening and confirmation testing with quantitative and qualitative reporting available.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W028

COMPARISON OF IQC MEANS AS A TEST OF IQC COMMUTABILITY

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Introduction: Best practice is that Internal Quality Control (IQC) materials should be independent of the assay calibrator material to increase the likelihood that changes in patient values that may occur with a new calibrator or reagent lot are detected. Laboratories should also use IQC material similar to or identical with the patient sample matrix to ensure it is fit for purpose. Thus, best practice is that commutability should be assessed when selecting an IQC material.

Aim: The aim of this study was to determine whether potential commutability issues for a given analyser assay pair for CEA can be simply identified prior to using independent IQC material?

Method: The published mean for IQC materials with 3 levels for CEA were obtained directly from literature provided by Thermo Scientific, Bio-Rad and Randox. There were entered into MS Excel and the means plotted to allow an initial visual comparison. To facilitate a standardised mathematical comparison, the mean of the means was derived for each IQC material and level. Subsequently, for each analytical platform and paired immunoassay, the relationship of the published mean to the mean of the means was calculated. Results more than 10% from the mean of the means in absolute terms were deemed to be atypical. To facilitate visual comparison, the published mean to the mean of the means were then plotted on standardised y-axes against the mean of the mean (x-axis) for each IQC material and the points for the 3 levels joined.

Results: The third party data was not consistent between IQC materials for many analyser immunoassay pairs.

Conclusion: While inconsistencies may be due to commutability issues, specificity and lot to lot issues may also be responsible. However, the presence of such inconsistencies in IQC materials is unlikely to be good for patient care.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W029

AUTOMATED URINE MICROSCOPY ACCREDITATION ISO 15189 IN A FRENCH MEDICAL LABORATORY ON IQ200™

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Background
The « Laboratoire des Cèdres », a French clinical accredited laboratory according to ISO 15189:2012 chose iQ200™ analyzer (Beckman Coulter) for automated Urine Microscopy Analysis. Our goal is to expose how the iQ200™ can face accreditation requirements in France and its maintaining.

Method
In order to achieve ISO 15189:2012 accreditation requirements according COFRAC and QUAMIC, we applied our quality management system and our internal procedures used for all analysis we chose in our laboratory.-
Results
The following topics were treated: Repeatability, Reproducibility, Precision, carry-over, reference method comparison, sensibility and validation of staff skills. All tests asked were easily conducted and all results were in accordance with laboratory and reference texts requirements.
Conclusion
Our laboratory quality management system combined to the use of the iQ200™ analyzer who provides faster turnaround times with accurate standardized results fulfilled the accreditation requirements according to ISO 15189:2012 for over 5 years. Moreover, the technology of iQ200™ and the support of Beckman Coulter's team allow us to maintain easily our quality management.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W030

WORKLOAD IN AN EMERGENCIES LABORATORY

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Background. The workload (number of determinations by sample and by analyte), and the total turnaround time (TAT) is important to provide fast communication to the clinician, helping to establish a correct therapeutic indication.
Our goal was to evaluate the workload in an emergencies laboratory after 5 years of implementation of a LabCell (Siemens Healthineers). Our target was to give all results into first 60 minutes.

Methods. We studied samples measured in an autoanalyzer Advia 1800 (Siemens Healthineers), used in our laboratory to run STAT samples. All serum samples were collected for 10 consecutive days in the morning shift (8-15h). Also, samples of three additional days in the afternoon shift (15-20h) and night shift (20-8h) were included.
The TAT was considered from the registration of the request, once registered at the laboratory, to the validation of the last result obtained. Data were obtained from the Laboratory Information System (Servolab, Siemens Healthineers).
Samples with alarms flags (fibrin, insufficient sample or errors autoanalyzer) were descarted.

Results. The average number of samples analyzed per day was 36, 27 and 27 in the morning, afternoon and evening shift, respectively. The average number of determinations per sample was 6, 5 and 5 for the three work shifts, respectively.
Most requested analytes were glucose, creatinine, urea, sodium, potassium and chloride, followed by alanine-aminotransferase and aspartate-aminotransferase, being less ordered creatine-kinase, magnesium and uric acid.
TAT average was 49, 34 and 38 minutes in the morning, afternoon and evening shift, respectively.

Conclusions. It is known that workload in emergencies laboratory is important for the organization of daily work.
There is an increased workload at the early morning, decreasing slightly throughout the day, being lowest in the afternoon and evening. Therefore, the TAT is increased during morning because of the overlap samples arriving from Emergencies Department, inpatients ward and Primary Health Care.
The workload in clinical laboratories has increased in recent years, among other reasons, due to the incorporation of new methodologies, increased automation, and easy access to the laboratory. Because of that, it is essential to redesign the workflow regularly.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W031

STUDY OF THE SAMPLE HEMOLYSIS DEGREE IN DIFFERENT CLINICAL DEPARTMENTS OF A GENERAL HOSPITAL.

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Background: The main goal of clinical laboratories is to obtain results with precision and accuracy. The hemolysis is produced by a wrong sampling and/or an incorrect sample shipment. It also involves the most frequent analytical interference and it is the cause of 60 percent of the rejected samples in the laboratory. As consequence, it produces an alteration of the results, and therefore, a wrong diagnosis or treatment plan may be reached. Our goal is to conduct a detailed study of the hemolysis in the received blood samples for biochemical analysis in our emergency laboratory from different clinical departments of the hospital and to assess the results.

Methods: During 1 year (From February 2015 to January 2016) a total of 54035 samples were studied from different clinical departments of the hospital (Emergency Room, Internal medicine, Operating Room, Neonatology, Intensive Care Unit, Gynecology and Surgery and Traumatology).
The degree of hemolysis was measured by absorbance at Dimension EXL 200 (Siemens) via standardized index HIL (hemolysis, icterus and lipemia) and it was classified into 3 types: non-hemolyzed (NH) <25 mg/dl of hemoglobin, slightly hemolyzed (SH) 25-200 mg/dl of hemoglobin, and heavily hemolyzed (HH) >200 mg/dl of hemoglobin or visible hemolysis.

Results: We observed that the percentage of hemolysis is very different depending on the department that the samples are handled. The highest hemolysis degree is the in neonatology (19.78% SH and 2.25% HH) and in emergency services (21.67% SH and 3.41% HH). On the other hand, we observed a minor ratio of hemolyzed samples from Operating room (3.11% SH and 0.22% HH) and from Surgery and Traumatology (5.03% SH and 0.44% HH).

Conclusions: We believe that the main cause of these differences is the sample extraction. In neonatology, the main cause of the difficulty in the sample extraction is the type of patients, while in emergencies, the difference may be caused by some of these reasons: the extraction by direct venipuncture, the possible lower training and the excessive changes in the staff, the higher quantity of work and the type of patient, among other reasons. On the other hand, we observe less hemolyzed samples from Surgery room and from Traumatology, probably for opposite reasons (as a clearer protocol of sampling, made with more time and accuracy), comparing with the Emergency Department.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W032

TURNAROUND TIME IN AN EMERGENCIES LABORATORY

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Background. Total turnaround time (TAT) is the interval between the arrival of a sample to the laboratory and the clinical validation of it results. It represents an index of laboratory quality, which affects diagnosis and treatment of patients.
Our goal was to evaluate the TAT (minutes) for emergency analytical biochemistry, and turnaround time in different phases of sample processing: preanalytical, analytical, postanalytical and total.

Methods. We analyzed in a biochemical autoanalyzer Advia 1800 (Siemens Healthineers) the data of 280 STAT requests, for 5 days in the morning (periods: 1 (8-10h), 2 (10-12h), 3 (12 -15h), and for two days, also in the afternoons and evenings (periods: 4 (15-20h), 5 (20-8h).
The indicators used included:
- Time between arrival of the sample to the laboratory and it is on board into the autoanalyzer (preanalytical phase).
- Time between on board sample into the autoanalyzer and results are sent to the Laboratory Information System (LIS) (analytical phase).
- Time between the result are avalaible in the LIS and the clinical validation (postanalytical phase).
- Time between the arrival of the sample to the laboratory and validation of results (TAT).
Time between extraction and sample receiving is unknown.
Data were processed with the Excel 2013 program.

Results. There were 29, 44, 97, 59 and 51 samples during periods 1, 2, 3, 4 and 5, respectively. The average number of test per sample was 6, most frequent determinations were glucose, urea, creatinine, sodium, potassium and chloride. The average turnaround time was 23, 14, 8 and 45 minutes for preanalytical, analytical, postanalytical and total phases, respectively. For periods 1, 2, 3, 4 and 5, the TAT was 60, 50, 43, 36 and 40 minutes, respectively.

Conclusions. During periods when our emergency samples were mixed with inpatients samples (8-10h), the TAT was higher, mostly because of a longer time in preanalytical phase. It is necessary to analyze which factors influence this phase and prioritize STAT samples in order to improve health care quality.
Maximum workload occurs between the 12-15h, but this fact does not affect the TAT.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W033

TURNAROUND TIME TROPONIN AND PROCALCITONIN IN AN EMERGENCIES LABORATORY

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Background. Quick results are critical in a Clinical Emergencies Laboratory, which is exacerbated when shared it with routine Laboratory, especially parameters with high processing times. Total turnaround time (TAT) (minutes), is defined as the interval between the arrival of a sample to the laboratory and the clinical validation of it results.
Our goal was to evaluate the TAT, for Troponin I and Procalcitonin, and their turnaround time in different phases of sample processing: preanalytical, analytical, postanalytical and total. Our target was to give all results in to first 80 minutes.

Methods. We analyzed in a immunobiochemical autoanalyzer Centaur XP (Siemens Healthineers) the results of 84 STAT Troponin requests, and 20 STAT Procalcitonin requests, of 5 days, and separating into three periods (1: 8-10 h; 2: 12-15h; 3: 10-12h), and for two days in two periods (4: 15-20h; 5: 20-8h). Data were processed with the Excel 2013 program.

Results. The Troponin samples analyzed for Troponin were 10, 6, 22, 24 and 22 during periods 1, 2, 3, 4 and 5, respectively; for Procalcitonin were 2, 1, 5, 7 and 5, for each of the five periods. The average turnaround time for Troponin in the preanalytical, analytical, postanalytical and total phases was 27, 24, 7 and 67 minutes; and for Procalcitonin was 31, 32, 7 and 80 minutes. TAT in the periods 1, 2, 3, 4 and 5, was for Troponin 83, 68, 52, 43 and 49 minutes, and for Procalcitonin was 125, 49, 66, 65 and 53 minutes.

Conclusions. The average turnaround time was acceptable, although preanalytical phase should be reviewed as the main subject area of improvement.
This information has led several proposals for improvement, such as creating warning flags for exceeded turnaround time into Laboratory Information System in order to take quick actions.
Periodically is necessary to evaluate TAT to monitor processes and implement improvement proposals.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W034

COMPARISON OF TWO IMPORTANT METHODOLOGIES IN RISK MANAGEMENT

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Background
Patient Safety is considered one of the key aspects of the quality policies of Health Systems.
The aims in this study are:
- Calculate the impact of the failure modes in a medical laboratory
- Compare the risk with two risk management tools: Modal Potential Failure Analysis and Effects (FMEA) versus the Registry Errors, Analysis and Corrective Action System (FRACAS)
- Use FMEA to estimate the potential risks and FRACAS to make real errors analysis

Methods
Our study shows the comparison of two important methodologies in risk management: Failure Model and Effects Analysis (FMEA) and Registry Errors, Analysis and Corrective Action System (FRACAS) in medical laboratory.
The failure modes were identified from the literature and a brainstorming conducted among a working group of laboratory professionals.
FMEA allowed identify potential failure modes and estimate risk through a table of three variables: severity, frequency and detection
FRACAS uses only two variables, severity with the same scale table than FMEA and real observed frequency. FRACAS does not use a detection variable, because it is based in real errors detected. The study was made in all laboratory process: strategic, operational (preanalytical, analytical and postanalytical) and support.

Results
The study was made about 90 possible modes of failure detected by the FMEA model applied to laboratory processes.
FMEA
- Strategic: 2,9%
- Operational
o Preanalytical: 34,2%
o Analytical: 26,5%
o Postanalytical: 35,1%
- Support: 1,3%

FRACAS
- Strategic: 2,0%
- Operational
o Preanalytical: 48,4%
o Analytical: 28,2%
o Postanalytical: 17,2%
- Support: 4,2%

Conclusions
Our study allowed the calculation of the potential risk in the preanalytical, analytical and postanalytical processes, as well as strategic and support processes of medical laboratory.
FMEA allows detecting critical points in terms of the patient risk and FRACAS highlights the priorities to control these points and help to select preventive or corrective actions that we should be incorporated in the laboratory improvement planning.
If FMEA is compared versus FRACAS, the difference is that indices of risk priority are higher in FMEA in postanalytical processes, while comparing FRACAS versus FMEA the rates of risk priority are higher in preanalytical processes.
Our results have allowed develop a map risks within the laboratory.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W035

POTENCIAL RISKS IN THREE EMERGENCY LABORATORIES

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Background
The information provided by the emergency laboratory has a direct impact on patient safety.
The aim of this study is to analyse the potential risks in three emergency laboratories in all processes: strategic, operational (pre-preanalytical, preanalytical, analytical, postanalytical and post-postanalytical) and support. There are also to value the impact of these risks in the patient safety.
An improvement in the safety of the various processes brings to light the potential failure modes in the laboratory and try to solve them.

Methods
The study was conducted in three emergency laboratories during the year 2015.
The method used to identification the potential risks is the Failure Analysis and Modal Effects (FMEA). The calculation of the RPN(G*R*D) is performed in each of the possible points of failure, assessing the gravity (G), the incidence (I), and detectability (D) from a table with predefined values ranging from 1 to 10. The results are grouped according to the processes of the Laboratory.
The study was conducted in three emergency laboratories during the year 2015. The FMEA is developed in groups as a function of their work centre.

Results
101 potential risks are identified by FMEA. There are distributed as follow:
Laboratory nº1
Strategic: 8.88%
Pre-Preanalytical: 13.48%
Preanalytical: 33.86%
Analytical: 22.57%
Postanalytical: 11.33%
Post-Postanalytical: 7.50%
Support: 2.39%

Laboratory nº3
Strategic: 12.89%
Pre-Preanalytical: 12.84%
Preanalytical: 31.00%
Analytical: 22.48%
Postanalytical: 11.62%
Post-Postanalytical: 7.74%
Support: 1.42%

Conclusions
FMEA is a subjective method. This method allows us to calculate the points with the greatest potential impact in terms of patient risk. A greater number of potential errors in the Preanalytical and Analytical processes in all groups were detected. These results allowed identifying critical points in all laboratory processes and prioritising the control of these points. Furthermore, it helped to select preventive or corrective action that we should be incorporated in the laboratory improvement planning and risk management. Strategic and support processes contribute to patient risk rate much lower than the operative processes. Our result shows that the risks of strategic processes are much more elevated than those obtained by support processes. It is important to define corrective and preventive actions for improved the strategic processes.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W036

CATEGORY 1 EXTERNAL QUALITY ASSURANCE PROGRAM FOR SERUM ALANINE AMINOTRANSFERASE AND ASPARTATE AMINOTRANSFERASE

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Background
Patient results can be reported from multiple laboratories within a health care system. For this reason the need of analytical methods standardization becomes essential. To participate in a category 1 External Quality Assurance program (EQAP) is a valuable tool to assess the standardization degree.
The Commission of Analytical Quality and the Committee of External Quality Programs of Spanish Society of Laboratory Medicine (SEQC) in collaboration with the Dutch Foundation for the Quality organized the first national category 1 EQAP pilot study.
The aim is to evaluate the standardization/harmonization degree of serum Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST) in the Spanish laboratories through a category 1 external quality assurance program with commutable material and reference method assigned values.

Methods
88 Spanish laboratories were involved in this program in 2015. 6 control samples (measurement range: ALT 15.3-173.5 UI/L and AST 19.2-141.3 UI/L) were sent to the participants and stored at -20ºC over the period of the study. Each day a sample control was measured by duplicate during 6 consecutive days. Total errors, bias and imprecision were calculated. Any deviation greater than the desirable biological variation allowable limits was considered unacceptable.

Results
A total of 990 AST and ALT results were obtained. The laboratories were coded in 4 ALT and 6 AST different methods. Only the methods recommended by IFCC supplemented with pyridoxal-5-phospate (P5P) met results within acceptable limits. Laboratories which used TRIS buffer without (P5P) method get unacceptable results; however, 57% of these laboratories were erroneously coded as IFCC traceable methods or they did not know their methods traceability.

Conclusions
The lack of standardization of AST and ALT methods, evidenced in our country, could potentially lead to errors in interpreting laboratory reports, therefore providers should give clearer and comprehensive information about method traceability and laboratories must actively deep in the knowledge of their methodologies. Moreover, it would be necessary to make efforts to abandon obsolete methods and adopt those recommended by IFCC (supplemented with (P5P).

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Laboratory Management, Accreditation, Quality Assurance

Cod: W037

ANALYTICAL PERFORMANCE FOR PRECISION IN MEDICAL LABORATORIES: STATE-OF-THE-ART IN 2015

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Introduction
Today, estimation of state-of-the-art is difficult due to poor number of recent publications about analytical performances. The knowledge of current performances for the analytical systems used in medical laboratories is useful to update the data on analytical quality specifications. The aim of the study is to evaluate the precision of the methods used for 25 (out of 252 processed) different analytes from data of a large number of laboratories all over the world, as a tool for harmonisation of the criteria for variability acceptance.

Materials and Methods
- More than 2 billion of results obtained in 2015 by at least 20 to 2000 analysers were analysed from Unity inter-laboratory program (Bio-Rad Laboratories, Inc. Hercules, CA, USA) issued of 92 countries around the world.
- Data was collected from internal quality control associated to inter-laboratories evaluation, units have been harmonized.
- Data included the day-to-day precision expressed as coefficient of variation according to the concentration level of the different quality control materials used by the participants.
- Analytes investigated included albumin, ALP, ALT, total bilirubin, Ca, cholesterol, creatinin, CRP, digoxin, ferritin, fibrinogen, glucose, hCG, haemoglobin, HbA1C, lipase, PSA, GGT, NT pro BNP, PO2, K, Na, TSH, Troponin I, Troponin T.
- Medians of CVs were calculated for respectively percentile 50, 90 and 95 of the results for each analyte at different levels of concentration.

Results and discussion
For each analyte, day-to-day precision is reported according to the concentration level compared to state-of-the-art as defined in 1999 by SFBC (Ann Biol Clin 1999; 57(6): 685) and analytical goals based on biological variation. For some analytes (eg: Na), no difference was observed whatever the concentration level within the pathophysiologic range, for other analytes (eg: ALT) precision depends on the concentration level. Precision differs according to the method used as well, as it is clearly demonstrated for creatinin using enzymatic assay as compared to Jaffe reaction method.

Conclusion
Definition of the state-of-the-art is proposed according to analytes, concentration level and for some of them, to the method used. These data may be used by medical laboratories for setting analytical performance specifications.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W038

EVALUATION OF INTERNAL & EXTERNAL QUALITY CONTROL PROGRAMS OF THYROID HORMONES CENTRAL LABORATORY EXPERIENCE

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Background: In clinical labortaories, Internal quality control (IQC) procedures and External quality control programs (EQCP) are important for the analytical performance and goals. The objective of the study was to compare the the internal third party daily quality control program (IQCP) & monthly External Quality Control (EQCP)program data to evaluate the clinical analytical performance of the thryoid hormones.
Methods: In our laboratory, we were implemented a common third party daily internal quality control Program (IQCP) (Bio-Rad Interlaboratory Program Unity) and monthly External Quality Control Program (EQCP) (Bio-Rad). By ongoing monitoring with daily and montly reports interlaboratory IQCP provides comparable results by SDI %Bias For IQC Thyroid hormones test performance results; (FT4, FT3 and TSH) (Bias% SDI) were colleceted for December 2015 & one year form the software for each control level. Also EQCP results of the peer group (Bias %-SDI) of Dec & one year (SDI) levels were obtained from the performance reports. Thyroid hormones (FT4, FT3 and TSH) test performed with Abbott Diagnostic İ2000 immunassay instrument.
Results:
IQCP and EQCP's Bias%, SDI, peer group participant number(N) and number of the points, were given in Figure1. All SDI levels were < 1 except for FT4 ; in Dec2015 FT4 IQC Level 2 and Level 3 SDI values were 1.02 &1,27.The number of IQCP points were much higher than the EQCP points while the participant number was visa versa for both periods. Since the number of the points were greater in IQCP it led to increase Bias%&SDI levels.

Conclusion: Use a thirty party control program with a software provides daily comparable results so you don't need to wait for your EQCP report to monitor performance of your laboratory.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W040

USING ICTERUS INDEX TO RULE OUT HYPERBILIRUBINAEMIA

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Introduction: Serum index measurements, including icterus index (IC) measurement, are routinely performed on all clinical specimens in many laboratories. This studies examines whether IC values can predict hyperbilirubinaemia and can potentially be used to avoid unnecessary bilirubin (TBil) measurements.

Methods: In our laboratory, serum index measurements are automatically performed on all samples analysed on the 3 Beckman Coulter DxC-800 clinical chemistry analysers. Anonymised details of all simultaneous IC and TBil (diazo, manufacturer supplied reagent) measurements for 6 months (Jan to June 2016) were extracted from the laboratory database. The locally derived TBil reference interval is 7-31 umol/L. Excel 2003 and Analyse-it were used to prepare a ROC curve to assess the ability of IC to predict TBil > 31 umol/L.

Results: There were 51111 paired IC and TBil results. In 5562 (10.9%) cases, TBil > 31 umol/L. The sensitivity and specificity, with 95% CIs, for IC to predict TBil > 31 umol/L were: IC >0 Sensitivity 1.000 (0.999-1.000), Specificity 0.004 (0.003-0.005); IC >1: Sensitivity 0.992 (0.989-0.994), Specificity 0.753 (0.749-0.757). Using an IC>0, 183 tests are avoided (2 false negatives) and IC>1, 34345 tests are avoided (47 false negatives).

Conclusion: Withholding bilirubin measurement on specimens with IC of 0 or 1 would reduce bilirubin test volumes by 67% with only a 0.08% false negative rate. The false negative rate could potentially be reduced further on analytical systems reporting smaller IC increments. The logistics of performing IC measurement prior to initiating bilirubin measurement would require close collaboration with diagnostic manufacturers and IT vendors.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W041

ADAPTATION OF PROCALCITONIN PETITION FROM EMERGENCY ROOM SERVICE

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BACKGROUND
Procalcitonin (PCT) is an immune modulator, differentiating it from other groups of inflammatorily active molecules (cytokines, leukocytary surface markers, acute phase proteins). Furthermore, PCT is very early (increases its concentration at 2-3 hours, with a plasma half-life of 25 hours).
Procalcitonin has been introduced in routine diagnostics: In the emergency room, the questions about sepsis diagnosis, differential diagnostic questions, or the necessity of antibiotic treatment are in the foreground.
International Sepsis Definition Conference (ISDC) redefined Signs of Systemic Inflammatory Response Syndrome (SIRS): tachypnea (over 20 breaths/minute) or hyperventilation (arterial pCO2 less than 32 mmHg), tachycardia (over 30 beats/minute), fever or hypothermia (over 38 or less than 36 degrees Celsius), leukocytosis o leucopoenia (over 12000 or less than 4000 leukocytes/mm3). A medical request is accepted to do a PCT if the patient has 2 or more sings.
The diagnostic performance can improve when the patients are selected on there clinical criteria. The aim of this study is check the compliance of the ISCD criteria on the demand of PCT in our Emergency Room Service.
METHODS
Procalcitonines petitions of May 2016 of patients adults from Emergency Room Service was reviewed. The PCT was analyzed by fluoroimmunoassay (B•R•A•H•M•S PCT sensitive KRYPTOR). The search was conducted with the Onmium program. The presence/absence of the ISDC criteria was inspected.
RESULTS
690 PCT were studied:
• 566(82,03 %) PCT negative: 377(66,61 %) did not pass the criteria(39,26 % with 0 criteria); 189(33,39 %) passed the criteria(74,07 %, 22,22 % and 3,7 % with 2, 3 and 4 criteria respectively).
• 124(17,97 %) PCT positive: 28(22,58 %) did not pass the criteria(82,14 % with 1 criterion); 96(77,42%) passed the criteria(66,67 %, 28,12 % and 5,21 % with 2, 3 and 4 criteria respectively).
Clinicians do not document all criteria. The less documented is breaths/min or pCO2 (65,94 %): 175 medical requests with 1 criterion.
CONCLUSIONS
It is necessary:
• Control of PCT demand from the laboratory following the ISDC criteria.
• Remember clinicians to analyze and record the tachypnea or hyperventilation in the diagnosis of sepsis

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Laboratory Management, Accreditation, Quality Assurance

Cod: W042

MONITORING THE TEMPERATURES OF RED BLOOD CELLS USING TEMPERATURE-SENSITIVE INDICATORS

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Background: The 30-min rule is currently used to maintain a core temperature of red blood cells (RBCs) below 10°C during transportation. To validate the 30-min rule, we monitored the temperatures of RBCs using temperature-sensitive indicators (TIs).
Methods: Two US FDA-approved TIs, Safe-T-Vue 10 (STV10) (Temptime Corporation, Morris Plains, NJ, USA) and Timestrip Blood Temp 10 (BT10) (Timestrip UK Ltd, Cambridge, UK), were attached to 30 units of RBCs. During transportation and transfusion of RBCs, the time to show color changes of two TIs was monitored. In additional 12 units of blood, both core and surface temperatures were measured together.
Results: In 30 units of RBCs, the median time of color change was 20.0 min in STV10 and 5.3 min in BT10 ($P < 0.0001$); 90% ($n = 27$) of STV10 and 100% ($n = 30$) of BT10 displayed color changes within 30 min. Among the 12 units of blood, 83.3% ($n = 10$) reached a core temperature of 10°C within 30 min. In these units, the median time of color change was 25.5 min in STV10 and 15 min in BT 10 ($P = 0.0152$); 75% ($n = 9$) of STV10 and 100% ($n = 12$) of BT10 displayed color changes within 30 min.
Conclusions: The time for color change in two TIs varied considerably, and most of them showed color change within 30 min. The 30-min rule for RBCs should be reconsidered for patient blood management.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W043

AN EQA SCHEME FOR QUALITATIVE FOB AND FIT – A 2 YEAR EXPERIENCE

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Worldwide, colorectal cancer is the third most common form of cancer after lung and breast cancer and the fourth most common cause of cancer death. In developed countries the incidence is higher and accounts for an even higher proportion of cancer deaths. Many countries have implemented population-based screening programmes; the design often influenced by cost, available resources and acceptability of the test.
Weqas has developed an EQA Scheme for the qualitative detection of faecal haemoglobin suitable for both guaiac based tests (FOB) and Faecal Immunochemical tests (FIT) often used in these screening programmes.
The base material is organic material which closely mirrors the basic constituents of human faeces. This material is then spiked with human whole blood to cover the pathological range and analytical range for both FOB and FIT (0 – 3.5 mg Hb/g matrix).
Material is dispensed aseptically into 0.3g aliquots and stored at 4°C until dispatch. Samples are dispatched every 10 weeks and participants are asked to analyse 2 samples every 2 weeks.
For long term storage, the material is stored at -20°C. Stability of the material at participant site storage was assessed by reviewing % positive results for a batch of material over a 6 month period. Results plotted against concentration and time of assay showed that there was no significant difference in % positivity for a given concentration between week 1 and week 10 of storage.
Samples targeted to just above the FOB cut-off for 3 batches were also tested at 6 and 11 month intervals at Weqas. All samples gave the expected results on re-testing.
Batch to Batch variability was assessed by reviewing the % positive results for 4 batches of material made over a 6 month period. Data suggests no significant difference between % positive rates at similar concentrations across different batches.
The spiked haemoglobin concentration is used to determine the correct interpretative comments and the scoring system broadly reflects clinical importance. A correct result (in agreement with interpretive comment) is given a score of 0. A score of 4 is assigned for a gross misclassification of the result. The sensitivities of the methods and the intended purpose of the kits are also taken into account in the scoring.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W044

MODERN APPROACH TO REFORMING OF THE LABORATORY MEDICINE OF UKRAINE

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Background
Analysis of laboratory medicine state in Ukraine shows that the partially preserved Soviet regulatory framework in this area and the absence of any concept of the quality assurance of clinical laboratory tests at the governmental level cannot ensure the quality of medical laboratory services for their consumers - patients and doctors.
The priority is the harmonization of national regulatory frameworks of the medical laboratory services with the best European and international practices, which will make it possible to build systems of quality assurance in all medical laboratories in Ukraine.

Results & Discussion
For this purpose, ACCLMU was created in 2007. To increase credibility, the decision was made recently that Ukrainian Society of Clinical Laboratory Diagnostics which is a full member of IFCC and EFLM will join ACCLMU.
ACCLMU developed several concepts for the reforming the laboratory services system in Ukraine on the basis of building system of quality assurance of laboratory tests in accordance with modern requirements.
Also, ACCLMU participated actively in the development and implementation in the Ukrainian legislation of documents identical to the European directives, in particular 98/79/EC.
In 2009, TC 166 was created by ACCLMU as a mirror to ISO/TC 212. For today, more than 30 national standards were developed by TC 166 in the field of laboratory medicine, including DSTU EN ISO 15189:2015.
The most important ACCLMU activities are the modernization and harmonization of specialists training programs with European requirements as well as creation of system of medical laboratories specialists certification and of an effective system of accreditation of medical laboratories. To this end ACCLMU constantly conducts conferences and seminars, publishes guidelines etc.
The implementation of all these tasks is impossible without defining the requirements for the accuracy and traceability of clinical laboratory tests, of reference ranges etc. which is not done yet.
ACCLMU exerts a lot of efforts to modernize the national laboratory service structure, in particular through the centralization of laboratory tests.

Conclusion
ACCLMU is committed to achieve the global goal of ensuring the availability of laboratory services and their compliance with the requirements of evidence-based medicine.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W045

LOCAL COMPARISON OF UNIVAC AND VACUETTE SERUM VACUUM TUBES FOR ROUTINE CLINICAL INVESTIGATIONS IN CONDITION OF MEDICAL LABORATORY

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Backround. Preanalytical phase of modern Laboratory process demands special technology such as blood collection devices that are used in phlebotomy. Vacuum blood tubes are one of the most crucial parts of integrated system for preanalytical devises that could bring variability to the laboratory results. Local comparison of vacuum blood tubes in medical laboratories by available methods is recommended by international standardization and helps to validate the quality of the testes tubes for healthcare needs.
Methods. Results of laboratory investigations received from serum vacuum tubes for routine clinical investigations of different manufacturers Univac (Unimed, Russia) and Vacuette (Greiner, Austria) were compared in medical laboratory according CLSI EP-9A (Method comparison and Bias Estimation using Patient Samples). Bias calculated assuming that results from Vacuette tubes were referent. Comparisons included 18 analytes in 40 patients. Sample collections were made in two tubes of Univac and Vacuette for each patient using CLSI H3-A6. Concentrations were measured using RX Imola Randox (Ireland) in duplicates from each sample. Differences in results were assessed for statistical significance with the Student paired t-test. Coefficient of variation (CV%) from duplicates compared between tubes with estimating of significant difference by F-test. Allowable Total Error (ATE) was estimated for the acceptability for clinical interpretation.
Results: Results of comparisons of tubes showed statistical significant difference on concentration between samples from Univac and Vacuette tubes ($p<0,05$) for creatinine (Cre), total protein (TP), high-density lipoprotein (HDL), urate (UA) and chlorides (CL). The precision of repeatability in tubes were higher for Univac ($p<0,05$) for alkaline phosphatase (ALP), amylase (Amy), creatinkinase (CK) and alaninaminotransferase (ALT). It was higher for Vacuette tubes ($p<0,05$) for potassium (K) and total calcium (TC). All results were in limits of ATE. Variability of imprecision exceeded quality goals based on biological variation for TC for results received from Vacuette tubes ($p<0,05$) but it had no influence to TE %. Conclusion: Comparison of Univac and Vacuette serum vacuum tubes for routine clinical investigations showed similar results. Variabilities of TE% from both types of tubes were within quality goals and did not influence to test interpretation.

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Laboratory Management, Accreditation, Quality Assurance

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LESSON LEARNED FROM FINANCING LABORATORY DIAGNOSTICS IN SLOVAKIA

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Background
Before 1989 no informations on system of financing laboratory diagnostics in Slovakia was available. After 1989 the interest for transparent financing system increased dramatically. We describe methods used, results achieved and further development in the last 20 years in the field of financing laboratory diagnostics in Slovakia.

Method
A task force of 150 specialists in laboratory diagnostics from 29 hospitals run a pilot study during the 1993-1997 in 109 clinical laboratories in 6 laboratory disciplines: the spectrum and number of laboratory tests, costs of material, personnel, investments, overheads and other cost categories were mmonitored and analyzed, aggregate average cost per 1 test in EUR for each discipline were calculated. Eventually individual cost for each laboratory test in each laboratory discipline for "Fee for Tests Catalogue" were calculated.

Results
Agregate average costs per 1 Test: Clinical Chemistry 0,6 EUR, Hematology 0,8 EUR, Microbiology 0,7 EUR, Genetics 19 EUR, Immunology 3 EUR, Clinical Pharmacology 5 EUR. Fee for Tests Catalogue was presented at the end of 1997 to the Department of Health. Since 1998 system of financing laboratory diagnostics based on the above mentioned "Fee for Tests Catalogue" was introduced by the Slovak Government and is used up to this time.

Conclusions
The task force for financing laboratory diagnostics finished it´s activity at the end of 1997: that was a big mistake, because: no further study actualizing the costs has been made. In addition mismanagement, hidden agenda and activities of lobbying groups distorted the calculated costs in the favour of lobbyists. And it only got worse: the balance between commerce and medicine was shifted in favour of commerce: economists, not laboratory medicine specialist make managerial decision and govern laboratory diagnostics. The lesson learned is: splitting medical and financial accountability is bad. Specialist in laboratory medicine must be accountable for both: medicine and financing.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W047

EUROPEAN HPV DNA TEST EXTERNAL QUALITY ASSURANCE SCHEME (EHEQAS)

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Background / Objective
To improve the quality of laboratories in HPV detection and typing we run the program of external quality control - EHEQAS.

Methods
EHEQAS was founded in 2006 and by 2016 already 25 laboratories from 8 European countries are participating. Batches of 5-7 samples are sent from the coordinator to participants 1-2 times per year. Samples are either real patient samples (including cervical cell pellets) or prepared from international standards as standalone dilutions or mixtures with real patient samples. Samples that are not international standards are pre-tested by reference laboratories and only samples for which there is a high level of agreement between reference laboratories are used. To test for reproducibility, samples are used in duplicate in the same and in different rounds. Linearity is evaluated by different dilutions of the same sample in the same and in different rounds. Results are evaluated and consensus results are issued and announced to participants in a confidential way. Marks are awarded to participants based on defined rules that reflect the clinical value of the result (e.g. higher penalty for errors regarding types 16 and 18). Certificates of competence that reflect the performance of a laboratory during the past 4 years are issued.

Results
Until now 219 samples have been tested in 22 rounds: 60 negative, 62 single infections, 97 co-infections. 31 different types (6, 11, 16, 18, 31, 33, 34, 35, 39, 40, 42, 43, 45, 51, 52, 53, 54, 55, 56, 58, 59, 61, 62, 66, 68, 70, 73, 81, 82, 83, 84) were detected during the period 2006-10 and the same 31 types were also fully represented during the period 2011-15. Laboratories using IVD tests made significant errors in HPV detection and typing, depending on the skills of laboratory personnel and on whether they correctly followed manufacturer's instructions.

Conclusions
There is a gradual increase in the number of participants and in the quality of their performance. EHEQAS improves quality with the coordinating team providing feedback to participants on how to improve their methodology. EHEQAS assesses the quality of laboratories in: (a) detecting a shift in sensitivity and specificity in time. (b) HPV typing (high- or low-resolution). Successful participation in EHEQAS is extremely helpful to high-quality HPV labs that also verify or validate their methods: success in an EQA is a prerequisite for granting ISO15189 accreditation.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W048

ARCHITECT TESTOSTERONE ASSAY – PRECISION STUDY TO CHECK FOR ASSAY ROBUSTNESS.

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Testosterone is an important androgen hormone in the health and well-being of men and women, it plays an important role in the diagnosis of many conditions and can guide treatment decisions. Assay imprecision expressed as percent coefficient of variation (%CV) reflects the robustness of the test method variation and reagent lot/calibrator lot variation. To check the robustness of the ARCHITECT Testosterone assay a precision study based on CLSI EP05-A3 was performed, using analysis of variance (ANOVA) In a second step the study results were compared to the results of the manufacturer's 5-day Precision Study which uses a similar set-up.
The ARCHITECT Testosterone Controls Low (0.34 nmol/L) , Medium (2.62 nmol/L) and High (8.07 nmol/L) as well as the Biorad Multiconstituent Lyphocheck Contols (MCC) Level 1 (6.79 nmol/L) , Level 2 (21.56 nmol/L) and Level 3 (30.56 nmol/L) were included in the study. Testing was performed on 5 days during the month of June 2016. Each day one run was performed in the morning and in the afternoon (calibration was performed per run)including all calibrators, the ARCHITECT Testosterone and the Biorad MCC controls using three instruments with three 3 different reagent and 2 calibrator lot combinations. For the estimation of the variance components (%CV and Standard Deviation (SD)) the SAS PROC MIXED procedure with the METHOD=REML was used.
For the ARCHITECT Testosterone Low, Medium and High Control total %CV were found at 7.2%, 6.5% and 5.5% .Total %CV values during the Abbott internal validation study were 7.2%, 5.4% and 3.8% respectively. Values for the total %CV were found at 4.0% for Biorad MCC Level 1, 4.2% for both Level 2 and 3. Respective results seen during internal validation study were 5.4%, 3.3% and 3.3%. Total %CV was found less or equal than the upper 95% CI of the Abbott internal validation study with the exception of High Level Control having slightly higher total %CV.
In conclusion precision study results showed comparable performance to the manufacturer's 5-day Precision Study performed as part of the internal assay validation studies before launch of the assay. These results confirm the robustness of the assay in a routine laboratory with reliable, constant performance.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W049

ROBUST QUALITY CONTROL LIMITS FOR TESTOSTERONE BASED ON PRECISION STUDY RESULTS

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Accurate testosterone measurement is required across a wide range of concentrations for diagnosis and treatment of several disorders involving the male sex hormones. This includes primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, hirsutism in females and virilization (masculinization) due to tumors as well as polycystic ovaries and adrenogenital syndromes. Effective quality control (QC) management with appropriate control limits for the analytical process is essential to ensure correct and valid measurement at the different clinical decision levels. The objective of the evaluation was to characterize the analytical process including both, process variation and test method error and to set realistic QC limits including all the Precision Study estimated variation components.
A precision study protocol according to CLSI EP05-A3 was performed on three ARCHITECT instruments using three lots of reagents and two calibrator lot combinations. ARCHITECT Testosterone controls Low, Medium and High as well as the Biorad Multiconstituent Lyphocheck Contols Level 1, Level 2 and Level 3 were included in the study. Overall coefficient of variation (% CV) for the different controls ranged between 4.0% to 7.2%. Analysis of Variance (ANOVA) was used to determine the variance components. The main drivers for variation were run to run, day to day and calibration to calibration variance. Less influence was seen by instruments , reagents and calibrator lots. Variation caused by lot to lot was included in the overall variation.
Upper and lower QC limits were set at process mean ± 3 Standard Deviations (SD) of the overall results, and in a more robust approach the mean ± 3 upper 95% confidence interval (CI) of the overall SD was used. Using statistical process control capability analysis, an estimate of the sigma level quality for the QC limits was determined using individual results from the study. CPK levels were ranging between 0.96 and 1.35 with corresponding long term sigma levels of 4.3 to 5.4, for the robust alternative values were 1.6 to 1.8 with long term sigma levels of 6.3 to 6.8, respectively.
In conclusion the precision study set-up allowed the characterization of the process and test method variance components. The estimate of long term sigma level at which the process operates is well above 4, and above 6 for the robust alternative. This approach will result in effective and efficient QC management in the laboratory.

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Cod: W050

IMPLEMENTING KLEIHAUER-BETKE TEST EXTERNAL QUALITY CONTROL PROGRAM; A FRENCH EXPERIENCE

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Background
The Kleihauer-Betke test (KBT) is a laboratory test used to quantify foetomaternal hemorrhage. Although this method has proved to be useful clinically, this test is often criticized. It is a manual test with a high level of variability, difficult to standardize and requiring technical expertise. Even if the flow cytometry is used to replace the KBT, it is not widely used and display limitations such as F-cells interferences. With the legal obligation for French laboratories to be accredited, came the need for an external quality control program.
Methods
The CNRHP and ASQUALAB has set up an EQC consisting in sending a stained smear, a whole blood sample (a calibrated mix of fetal and maternal cells with a target value) and the clinical case study.
Results
Two assessments were conducted with 57 and 45 laboratories. The interlaboratory variability ranges from 25% to 30%. The average of the laboratories is superior to the target value, most probably resulting from overestimation of adult erythrocytes.
Conclusions
This evaluation demonstrates the difficulties to standardize the KBT and the need for an EQC.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W051

CP/CPM CORRELATION ALLOWS TO KNOW THE NATURE OF THE ANALYTICAL ERROR

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Background

Process capability, a tool to measure the performance of quality control, indicates the degree of adjustment of the process to target. Under the Analysis Process Capability, process capacity index (Cps) is presented as a useful tool to know the extent of the value of the control material used compared to the fixed error (Upper Limit (ULE) and Limit lower (LLE)). So this analysis meets the clinical needs, unlike the classic concept of quality control mean±3 standard deviations (SD) for SD extensive testing. The minimum limit for these indexes capacity is 1, although it is sometimes seen as at least 1.3.

Methods

Data quality control was studied, for a period of 3 months, in 53 magnitudes: 41 in serum (biochemistry 28 and 13 inmunuchemistry) and 12 in urine. For all magnitudes, we calculated Cp index (Potential Capability)=(ULE–LLE)/6*SDobserved, and Taguchi index Cpm (Real Capability)=((ULE–LLE)/6*SDobserved)/RAIZ(1+((μobserved-μreference)/SDobserved)2). Finally, the correlation Cp/Cpm was calculated. SD: Standart Deviation, μ: mean.

Results

7 serum magnitudes (4 biochemistry and 3 immunochemistry) and none urine, had Cp value below 1; this value also correlated with a value less than 1 for Cpm. Cp/Cpm ratio for all analytes was higher than 1, with a value above 1.4 to 13 magnitudes (12 in serum and 1 in urine). Of these 13 magnitudes, 3 had a value greater than 1 Cp with Cpm value less than 1.

Conclusions

The study of the indices separately, Cp and Cpm, it is useful to estimate the methods capabilities both potential and real. So, methods with value below 1 are not adequately conforming to the specifications set. On the other hand, it is interesting to know the Cp/Cpm ratio value since it was found that ratios above 1.4 were related to the presence of a systematic error in the method, while below this value prevailing imprecision. Thus these indices not only allow us to know the degree of adjustment methods to our specifications, but also allows us to know the predominant type of mistake considering a baseline study with ES=0. Thus they provide more information than the sigma metric, in the sense categorize the nature of the error based on ES=0.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W052

DETERMINATION OF THE MINIMUM VALUE OF SIGMA METRIC BASED ON PROCESS CAPABILITY INDICES

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Background

The process ability to assess the performance of quality control, can be determined using different tools. One of them, Six Sigma metric (SM) measures performance based on the variability of the same expressed as defects per million opportunities (DPMO). In clinical laboratory, a value of SM 3 is considered the minimum quality. Alternatively, it is the process capability indices (Cps) which provide insight into the extent of the value of the control material used compared to the fixed error (Upper Limit (ULE) and Lower Limit (LLE)). It is established as acceptable minimum value 1 for these Cps indices.

Methods

Data quality control was studied, for a period of 3 months, in 53 magnitudes: 41 in serum (biochemistry 28 and 13 inmunuchemistry) and 12 in urine. For all magnitudes, the value of SM was calculated by using the Z-Score statistical method for calculating DPMOs, and the other hand also was calculated Taguchi index: Cpm (Real Capability)=((ULE–LLE)/6*SDobserved)/RAIZ(1+((μobserved-μreference)/SDobserved)2). Numerical comparison between the two rates was performed. SD: Standart Deviation, μ: mean.

Results

Based acceptance cutoff SM 3, only 6 of the 53 magnitudes breaching this level (all serum). Moreover, 12 of 53 magnitudes had a value less than 1 Cpm (all serum). In the correlation Cpm versus SM, 12 of these magnitudes was found that 6 had a SM value below 3 and the other 6 above 3.

Conclusions

The SM value knowledge allows us to objectively compare processes in the clinical laboratory, and design quality control schemes. This information can be supplemented with the calculation of Cps. Analyzing our data, we note that reference to the minimum 1 for Cpm would be necessary to increase the minimum value of SM to 3.5 for optimal process performance measured by these methods. If we will rise 1.3 (optimal level) Cpm value would need to raise the threshold of SM to 4. It is necessary to increase the value SM with respect to the minimum accepted, 3, to ensure adequate process capability for all methods use in the clinical laboratory.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W053

ROLE OF PROFFESIONAL ASSOCIATIONS AND LABORATORY SPECIALISTS IN POCT GOVERNANCE

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Background: Laboratory medicine in Slovenia is regulated by the Bylaw of Laboratory Medicine. It covers six fields of laboratory medicine including POCT. The basic requirements for POCT, whether operating in hospitals with laboratory support or in doctors‘ offices without one is that it must be supervised by licenced laboratory or specialist of laboratory medicine.
Methods: Slovenian Association for Clinical Chemistry and Laboratory Medicine has the initiative and main role in quality management improvement processes. A POCT working group (WG – POCT) was appointed to help users with appropriate implementation of POCT system. The national guidelines for POCT were prepared and published. The WG – POCT conducted several organised trainings through different professional societies for different POCT users (nurses, medical doctors, biochemists and clinical chemistry technicians) The programme covers the preanalytical issues including sample collection, patient identification, IQC protocols, EQA requirements, as well as postanalytical factors documentation and traceability of results. EQAS for POCT glucose, Hb, qualitative urine test and CBC are organised on national level.
Results: in the period 2008 – 2016 180 applicants (doctors‘ offices) applied for working licence at Ministry of Health. 73 obtained a working licence, 40 out of 73 had to implement certain corrective actions for non-compliance and 10 were found not complying. Other applicants withdrawn their application at Ministry of Health. POCT working licence imply to fulfilment of requests of the Bylaw.
Conclusion: A significant improvement in quality of POCT has been achieved. POCT users are trained in majority, IQC protocols are set in place to certain extent, participation in EQAS is accepted as mandatory. Nevertheless, several issues should still be set in place; Internal quality control to be implemented on risk management platform, staff competence reviewed and collaboration with licenced laboratories acknowledged by all involved parties.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W054

ERROR RATE IN BLOOD SMEAR MICROSCOPY RESULT TRANSCRIPTION: CONSERVATIVE ESTIMATOR OF DATA TRANSCRIPTION ERRORS ON INTRA-ANALYTICAL LEVEL IN LABORATORY MEDICINE

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As an integral part of evaluation of laboratory compliance with ISO 15189:2012 IFCC Working Group: Laboratory Errors and Patient Safety proposed mandatory calculation of transcription errors during intra-analytical phase. It was advised to perform a manual calculation of error prevalence covering all manually entered results with daily data collection and monthly data analysis.
The author discusses selection of alternative estimator for the same parameter, algorithm of automated calculation, indicator output based on East Viru Central Hospital (EVCH) data and work process gain from switching to the alternative.
The estimator must be derived from the data with known constraint(s) on its value and be not sensitive i.e. it will remain unnoticed and uncorrected in hospital information system. It is beneficial if this estimator is based on a value which in being entered by majority of laboratory personnel.
The estimator satisfying those criteria in EVCH laboratory is "error rate in blood smear microscopy result transcription". The author takes advantage of two mathematical constraints on smear results: the cell type percentages must sum to 100% and the number of accounted cell types is easily counted.
The new indicator estimates transcription error rate in EVCH laboratory at 0:60±0.24%
(95% CI) with ca 800 smears per month. The width of the confidence intervals i.e. the precision of estimation described above depends on the sample size so this new estimator is particularly beneficial for the labs with a large number of blood smears.
Implementation of the new calculation procedure requires ca 10 min per month (data query time included) compared to perhaps several hours a day when done according to IFCC WEPS recommendation.
The procedure of selection and calculation of an estimator yields an unbiased, low variance
estimator of transcription error rate during intra-analytical phase.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W055

EVALUATION OF SIGMA SCALE PERFORMACE FOR 13 TESTS RUN WITH ABBOTT ARCHITECT CI8200

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Background: Six sigma is a universally accepted tool for measuring production performance on a scale from 0 to 6. It has lately been successfully implemented in the laboratory field along with method validation, to make decisions on the suitability of a method but also to improve and customize the internal quality control plan. The aim of this study was to evaluate the performance on a sigma scale of 13 clinical chemistry and immunology assays run with Abbott Architect ci8200, and implement the results in our QC planning.
Method: We determined sigma using measurement of variability approach and sigma-metrics equation. The first step was to determine performance specifications: we used total allowable error from CLIA guidelines for glucose, AST, ALT, ALP, urea, creatinine, cholesterol, triglycerides, uric acid, HDL and Iron. For GGT, TSH and PSA there were no specifications from CLIA, so we used Riqos data on biological variation. The second step was Bias determination: we used external quality control data from a complete 6 month RIQAS cycle. The third step was to calculate Imprecision (CV%). For that we computed the mean, SD, and CV% from our internal quality controls of the last 8 months. Sigma scale was calculated for every test using sigma-metrics equation: Sigma = (TEa – Bias)/CV.
Results: We obtained a sigma value > 6 for 10 parameters: AST, ALT, creatinine, cholesterol, triglycerides, uric acid, HDL, GGT, Iron, and PSA. The other three parameters, glucose, ALP and TSH, had sigma scale between 3 and 6.
Conclusions: We obtained world class performance (> 6 sigma) for 10 of our assays and therefore concluded that the methods in use for this assays were appropriate and we need not be very strict with our internal quality control rules. This way we would minimize false rejections and reduce costs. We achieved acceptable results (3 – 6 sigma) for glucose ALP and TSH, implying that for these tests there is need of improvement and more strict QC rules.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W056

ESTIMATION OF MEASUREMENT UNCERTAINTY FOR CREATININE, CHOLESTEROL AND URIC ACID, MEASURED WITH ABBOTT ARCHITECT CI8200

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Background: Measurement Uncertainty (MU) is defined in the International Vocabulary of Metrology (VIM) as "a non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand". The aim of this study was to describe our experience in calculating MU for three clinical chemistry assays in order to fulfill an important technical requirement of ISO 15189.
Method: We used the "Top Down" approach to calculate MU for Uric Acid, Creatinine and Cholesterol, run with Abbott Architect ci8200. After précising the measurand and the sources of uncertainty in a fish diagram, we estimated type A uncertainty as Imprecision, calculating SD and CV% from Internal QC data from the previous 8 months. We also estimated type B uncertainty, which included calibrator uncertainty provided by the manufacturer and Bias from external quality control reports (RIQAS). SDI for the three assays was < 2. According to GUM guidelines, if SDI is less than 2, the bias is considered irrelevant, hence is not included in the calculations. The combined uncertainty was calculated as SQRT (A2 + B2).The expanded uncertainty was calculated by multiplying the result with a coverage factor of 1.96, for a 95 % confidence interval.
Results: We decided to use Riqos' 2014 desirable and optimal specifications on total allowable error as performance criteria, respectively: for uric acid < 11.97 % and < 6%; for creatinine: 8.87% and <7.7 %; and for cholesterol < 9.01 % and < 4.5 %. Our MU results for the three assays were as follows: uric acid MU = 5.3 %; creatinine MU = 5.8% and cholesterol MU = 3.8%. The results were lower than both desirable and optimal performance criteria.
Conclusions: Both assays meet desirable and optimal performance specifications according to Riqos data on biological variation. By calculating MU we have increased further the reliability of the results, since we now have a quantitative estimate of where the true value of these analytes lies, with a 95 % confidence interval.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W057

LABORATORY IMPLEMENTATION OF A CONTROL SYSTEM VALIDITY OF RESULTS

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Background
The high number of tests measured in Clinical Laboratory involve a high use of resources, so their rational use is essential for a good performance of laboratory. Too many times a physician request the same test that another physician has been done from another department within a few days.
The aim of this work is to implement an electronic control system that avoids to repeat a lab test, which result is already known and valid for that date.

Methods
We programed in the laboratory information system (LIS) the days of valid results for each test and depending on the origin of the request, the LIS, at the moment of request registration, writes automatically a note with the known result, avoiding a new processing of the sample. The physician receives in his report the valid result for his request obtained from the result already known and the date of sample collection. Laboratory keeps the specimen properly preserved for 7 days if necessary repeat some sample.
We have defined a validity results control system for 66 assays from different areas of the laboratory, which studies 1076 different analytes, and started in 2016.

Results
In 9 months, from January to September, in the laboratory has been made 4 228 622 test, and the LIS has avoid 7695 tests. 1044 tests belongs to emergency requests and 6651 tests were from routine analysis. The origin of the request where more tests were repeated was primary care. The 10 test that more frequently has been avoid are: Alanine Aminotransferase, Carcinoembryonic antigen, Creatinine, Cholesterol, Triglycerides, Rubella IgG, Aspartate Aminotransferase, Gamma-Glutamyltransferase, Alkaline Phosphatase and Carbohydrate antigen 19.9. These 10 tests together reach 68 percent and only Alanine Aminotransferase reaches 15 percent. 4173 tests belongs to requests for male patients and 3522 for female patients. The age range of patients goes from 1 to 101 years.

Conclusions
Due to the high number of test that are measured in the daily practice in a clinical laboratory, the appropriate management of request is very important for an efficient economic management.
We used the lab scientific organizations advice and the published data in order to narrow the days that applies the control system for each test.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W058

A PROPOSAL FOR ESTIMATING MEASUREMENT UNCERTAINTY USING QUALITY CONTROL DATA AND EXTERNAL QUALITY ASSESSMENT SCHEMES

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Background:
In order to comply with the accreditation process, ISO 15189:2012 requires that medical laboratories estimate the measurement uncertainty (MU) of their measurement procedure (MP). However, ISO 15189 does not specify a method for deriving the estimation of MU. Aim of this study is to describe the strategy used for MU estimation of tests of different areas of our laboratory, including clinical biochemistry, haematology and coagulation, clinical molecular biology and diagnostic immunology.

Methods:
To define the model for MU estimation, several MPs were evaluated for: a) classifying test in relation to the clinical purpose, b) identifying criteria for calculating the MU component. The imprecision and the bias and bias uncertainty were calculated by using the long-term internal quality control (IQC) results and external quality assessment schemes (EQAs) results, respectively. Several guidelines and manuscripts were studied before selecting MU models.

Results:
For a total of 263 MPs, two MU models estimation were identified: a) the first model including only the imprecision component, which has been calculated for the test results principally used in monitoring patient's results, (e.g. tumour markers) (51 MPs); b) second model, MU was calculated by combining imprecision, bias and bias uncertainty (190 MPs). For a total of 28 MPs, those in which a significant trend was observed between imprecision and/or bias and analyte concentrations, MU was calculated on different levels of analytes concentration. For 22 MPs, EQAs statistics were not feasible for MU calculation.

Conclusions:
The models proposed appeared to be suitable for MU estimation in medical laboratories, thanks to the availability of IQC and EQA data. Further, these models were developed accounting the different test purpose and the clinical needs to produce effective information in order to improve patients' outcome.

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Cod: W059

PERFORMANCE OF EXTERNAL QUALITY ASSESSMENT AND AUDIT IN PRE-EXAMINATION PHASE

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Ensuring performance of pre-examination phase removes large proportion of errors and increases confidence level of customers. As no commercial EQAS is yet available in India a few laboratories created an ILC program and assessing the monthly score. The structure of such ILC involves:
• Selection of quality indicators at pre- examination phase.
• Scoring on each quality indicators.
• Scoring of performance of participating laboratories on every month.
• Quarterly audit.
• Group discussion to remove observed non compliances.
• Suggestion for continual improvements.
The quality indicators are:
1. Interaction with customers.
2. Transparency regarding tests being performed and outsourced by the laboratory.
3. Traceability of the patient entry to transport.
4. Ensuring proper sample storage before being transported to the laboratories and transport condition.
5. Safe transport to the laboratory.
6. Safe disposal of collection materials.
7. Attitude of workers involved in the pre examination phase.
8. Ensuring quality of primary sample containers.
9. Special transport arrangement for labile parameters.
10. Assessment of time frame of the pre-examination phase.
11. Immunization of the phlebotomists.
12. Risk management in the pre-examination phase.
13. Confidentiality of patient information.
14. Ethical conduct.
15. Action against emergency situation.

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Cod: W060

HOW EFFECTIVE IS ELECTRONIC GATE-KEEPING IN INFLUENCING TEST REQUESTING BEHAVIOUR AND COST SAVING: A RE-EVALUATION

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Introduction: Helath care budgets are under increasing pressure and clinical laboratories have therefore developed strategies to adapt to the increase in laboratory workload. Unnecessary repeat testing can contribute up to 25% of a laboratory's total workload. Electronic gatekeeping (EGK) has been implemented at selected laboratories in South Africa, as a demand management strategy to limit unnecessary repeat testing. Here, we performed an audit of chemistry tests subjected to EGK to determine its merit and effectiveness as a sustainable demand management tool.

Method: A retrospective observational audit of all chemistry test requests at the Pretoria NHLS academic laboratory over a period of 27 months was performed. EGK rules were programmed into the laboratory information system. Tests violating the programmed EGK rules are rejected upon registration, prior to analysis. Cost savings were computed from the number of tests subjected to EGK. The impact of EGK on the test requesting pattern of clinicians was deduced from the percentage trend of EGK-held tests following the implementation of the demand management strategy. Trend analysis for the urea and electrolytes test profile, liver function test profile and thyroid function test profile was also executed.

Results: The total savings generated from EGK test rejections amounted to (currency ZAR) R2 222 966 (2.4% of billed tests – R92 417 278). Greatest savings were generated from high cost tests: glycated haemoglobin (R 279 379), urea (R276 739) and thyroid stimulating hormone (R225 394). The average number of EGK-held tests as a percentage of their total requested number over the 27 month period was 2.80% (Becomes 3.10% if I exclude December 2013 – April 2014). Test profile trends mirrored the pattern of the total number of EGK-held tests.

Discussion: The total savings from EGK-held tests were not as effective as anticipated and were only moderate. This may have some impact on in a cost-constrained setting. The monthly percentage of EGK-held tests and test profiles were largely unchanged therefore EGK was concluded not to have a substantial effect on the clinician test requesting pattern. On its own, EGK does not appear to as effective a strategy as anticipated or demonstrated in other studies.

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BENEFITS OF AUTOVERIFICATION IMPLEMENTATION AT THE LARGEST UNIVERSITY HOSPITAL IN THAILAND

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Background: Autoverification (AV) is the process in clinical laboratories to report results that are automated actions performed by a computer system using criteria, logic established and tested by the medical staff of the laboratories. The number of test orders is increasing every year; therefore, AV was considered to implement in the laboratory in order to increase productivity. The purposes of this study are to study the accuracy and efficiency of the implementation of AV system. **Methods:** AV rules we set in the laboratory information system (LIS) consist of validation ranges, critical values, delta check, and complex rules which established by brainstorming among clinical pathologists and medical technologists. We used 500 retrospective data to determine the accuracy of AV rules by comparing with manual verification by five experienced medical technologists. We studied the efficiency of the implementation of AV system by using data from one month of error reporting, calculating the decline of full time employee per day by using AV passing rate, using five-question questionnaire from 43 staff for their satisfaction and collecting data before and after implementation of AV from 20 official working days for turnaround time (TAT). **Results:** The accuracy of AV rules was 80.2%; no difference in billable test per hour during 24 h of 20 official working days while TAT was slightly reduced from 45 to 41 minutes (P = 0.166). The passing rates of chemistry, coagulation, hematology and microscopy were 95.0, 85.0, 39.0 and 43.0% respectively. The error report detected decreased from 0.0008 % to 0.0007%. Staff were reduced 0.12, 0.33, 0.05 FTEs for all days, peak hour, and non-peak hour, respectively. Staff satisfaction were increased from 65% to 89%. **Conclusion:** Our AV rules provide the high accuracy and the passing rate was quite similar to previous studies in chemistry, coagulation and urinalysis. Overall staff satisfaction was increased, while error rate and FTEs were to some extent reduced after the implementation of AV.

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Cod: W062

TEN YEARS´ EVALUATION OF PERFORMANCE FOR THYROID-STIMULATING HORMONE AND PROSTATE SPECIFIC ANTIGEN IN EQAS "BUENOS AIRES"

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EQAS "Buenos Aires" has provided external quality assessment schemes since 1979. At present it is accredited under ISO/IEC 17043:2010, and is active in Argentina and other Latin American countries. Briefly, human sera based samples are lyophilized and sent once a year together with instructions and calendar, for monthly process. Target values TV are assigned as consensus mean for each peer group, and acceptance limits are stated as TV±3SD. End of round reports are prepared from cumulative data, and labs are ranked in performance bands for mean CV% and mean Bias% calculated from repeated samples along each yearly cycle.

We present data from the last ten years´ period for two important analytes, tested with different immunoassay techniques. Range concentration for TSH samples was 0,5 to 20 mUI/L, and for PSA samples, 0.05 to 20 ng/ml. Labs included were those with continuous participation along ten years.

Major platforms used in 2005 were EQLIA 18%, CMIA 1%, CLIA 45%, IRMA 12%, and MEIA 21%.

This distribution is at present EQLIA 44%, CMIA 17%, CLIA 34% and other minor methods are ELFA 2% and ELISA 3%.

For TSH, 103 labs could be evaluated. 75% labs showed performance improvement, and 15.5% remained without changes. Median CV was 8.3% in 2005 and 4.6% in 2015.

For PSA, 69 labs could be evaluated. 80% labs showed performance improvement, and 7% remained without changes. Median CV was 8.6% in 2005 and 4.5 % in 2015.

Performance improvement can be attributed to changes in technology, better implementation of internal QC practices in labs, and harmonization efforts between methods. These data show the importance of EQAS in IVD surveillance and in the quality improvement of clinical labs in order to achieve better patient safety and care.

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Cod: W063

ARCHIPIELAB: WHY WE DON`T WANT A TOTAL LABORATORY AUTOMATION (TLA)

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BACKGROUND: The old structure of the laboratory building was initially upsetting: it was impossible to implement a big TLA. Now we have a different vision. TLA is not the best option for us considering our workload. Our Laboratory serves a Health Area of 547300 people (73 extraction points) and 4 hospitals (1.500 beds). It consists of 5 specialities: Biochemistry, Immunology, Microbiology, Haematology, Genetics
METHODS: Statistics and indicators from LIS Servolab (Siemens)
RESULTS: TLAs can manage around 3500 specimens per hour. Even connecting high speed instruments the limiting factor is that a single patient is multiplied by 2, 3 or 4 depending on the different fluids and requisitions. These are our figures and workflow solutions: a-2500 Patients per day; b-Unique Preanalytic Area and Administrative Area for the 5 specialized laboratories; c-Islands of automation for different fluids or biological samples:
Serum automation: transport track for Biochemistry and Immunochemistry analyzers: 2500 samples plus 300 serology containers
Citrated plasma: Haemostasis: 3 connected analyzers: 435 samples per day
Blood sample: Haematology: 4 analyzers: 2000 samples/day plus 400 HbA1c containers
Urine automation: 4 analyzers: 1000 samples/day
These 6635 samples mean 85% of our day workload. A TLA manages samples without control of patient time. So the turnaround time for a single patient is not controlled. Our workflow: samples of a patient are simultaneously being processed in five analytical islands being finished in a fifth of the time a TLA would need. Even the General Practitioners patient results are available at the end of the shift for the 85% of our processes
TLA is supposed to reduce the operators and personnel costs, but one person per area is still mandatory. To handle our number of samples several work shifts would be needed. Only one of our five automated islands needs two work shifts
CONCLUSIONS: The functionality of a TLA is not suitable for laboratories with large amount of samples and a limited turnaround time. Independent Islands of work allow better control of laboratory workflows, reduction of costs, and improve the outcomes of equipments and results. It is an expensive workflow solution for vendors, but very suitable for laboratory professionals and patients

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Laboratory Management, Accreditation, Quality Assurance

Cod: W064

NATIONAL AND INTERNATIONAL STANDARD AND POSITION PAPER OF THE CLINICAL PATHOLOGY AND LABORATORY MEDICINE ITALIAN SOCIETY (SIPMEL). NEW OPERATIVE PROCEDURE'S APPLICATION IN THE SUPERVISION AND REMOTE CONTROL OF NEAR PATIENT TESTING

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Background
PoCT is a Laboratory Medicine's analytical/organizational modality, aimed to improve treatments near to the patient. It needs to be activated if the traditional activity is not accessible or not well-timed to the clinical condition, and if it is efficient to implement. AOUP presents a high number of PoCT (43 BGA Werfen I.L.; 115 glucose monitors Roche; etc.). Up to today, these PoCT have carried out non-monitored activity, with difficulties unknown for the Laboratory. It arises the need to activate an Operative Procedure (OP), according to ISO and Italian legislation, to regulate this process.
Methods
CLSI, ISO 22879, and Position Paper Study Group PoCT SIPMel helped to define the OP. The application is attributed to the Laboratory Director (LD), to the Hospital Unit Medical Direction (HUMD), to the Operative Group (OG: laboratory/departments personnel that supervises daily activities, including the responsibility for the instrument QC), and to the Multidisciplinary Directional Group (MDG: Laboratory, HUMD, Nursing Direction, HTA, Clinical Area). The aim to MDG is to evaluate the introduction of any PoCT product/device/system, independently from the purchasing modality, and to establish the responsibilities/authorities defined in the PoCT healthcare organization.
Results
PoCT management with supervision/instrument remote control (hospital intranet). Without remote interfacing, control guarantee through OG's periodic check, in accordance with LD, on MDG's direction. The OG controls (administrative software) the on-the-net instrumentation's functionality, verifies QC automatically performed (in case of BGA) or manually performed by the department (in case of glucose monitors and/or other instrumentation), collaborates to solve ordinary/extraordinary instrumentation problems. Periodically, it carries out alignment checks among analyzers positioned in different departments.
Conclusions
With this OP, all PoCT are included, before the implementation, in a risk management and quality assurance program, following the path MDG-HUMD-LD-OG. The interface with the Laboratory IS will guarantee all results' recovery and the complete management of the "Near the Patient Care", within the informatics folder of the Pleiade platform.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W065

FROM PREPARATION TO ADMINISTRATION OF ANTINEOPLASTIC DRUGS. DEFINITION AND SHARING OF COMMON GUIDELINES CONCERNING THE MANAGEMENT AND THE PREVENTION OF EXPOSURE RISK IN CAREGIVERS THROUGHOUT ITALY

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Background
In 2004, the National Institute for Safety and Health on Workplaces (Istituto Nazionale Salute e Sicurezza sul Lavoro, NIOSH) shared the document Preventing Occupational Exposure Antineoplastic and Other Hazarous Drugs in Health Care Settings in order to sensitize caregivers about the accidental exposure to harmful drugs. Furthermore, additional clear information concerning the risk from antineoplastic drug exposure and the strategies to prevent it have been included within the Consensus Document (1995) prepared by the ISPESL Working Group, and the Guidelines for safety and health workers' exposed to antitumor drugs.
Methods
Many Local Health Services have Pharmaceutical Services responsible for the preparation of antineoplastic drugs. Several categories of workers/caregivers are exposed to those agents from reconsitution up to administration. Exposed workers should receive adequate information about a) the risks, b) the safest and correct way of drug handling, c) the use of individual and collective protection devices, d) the monitoring of environment pollution and workers' health. Furthermore, highest attention should be addressed to environment cleaning, waste disposal and safety procedures in case of individual or environmental contamination.
Results
A procedure to safely manage all of the steps, from drug preparation up to administratiom has been planned, including strategies to prevent or to minimize workers' exposure to antineoplastic drugs.
All of the caregivers, including physicians, nurse staff (who may administer pharmacological treatments) and other personnel (i.e., pharmacists, technicians) have specific responsibilities according to their roles.
Conclusions
In Italy, the definition and sharing of common guidelines concerning the risk coming from antitumoral drug handling is still incomplete. The elaboration of activities widely accepted should be developed at the regional and national level, in order to guarantee safety, quality efficiency and economical sustainability of centers for handling cancer chemotherapies.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W066

INCREASE IN JOB SATISFACTION OF HOSPITAL LABORATORY EMPLOYEES THROUGH QUALITY MANAGEMENT PROCESSES

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Introduction
Many studies have proven that employees' satisfaction is a major factor in their engagement, and therefore it is very important to measure and improve it. The Laboratory Division of the Hillel Yaffe Medical Center applied several quality management methodologies over the last 6 years such as EFQM (European Foundation of Quality Management), ISO-9001 (international quality standard) and JCI (Joint Commission International), during which employees' satisfaction was measured.
Methods
Employees' satisfaction was measured in 2010, 2013 and 2016, using the Gallup Q12 survey. The survey results were analyzed according to 4 main categories: professional perception, personal development, superior's attitude and organizational support. The changes in scores were compared using the unpaired t-test.
Results
The average satisfaction score in 2016 was 4.39±0.55 (out of 5) and significantly higher than in 2010, (4.02±0.58; $p>0.01$). The highest score in the survey was in the professional perception category; employees understand the importance of their work, know its goals and have the right conditions to achieve them. This category was scored 4.53 in 2010 and rose slightly to 4.61 in 2016. In questions regarding the fulfillment of potential at work there was significant improvement over the years (4.02±0.8 in 2010 vs. 4.35±0.6 in 2016 ($p<0.05$)).During this period several changes were made: assignment to special projects, professional education and quality management. Superiors' attitude got a low score in 2010 (3.41±0.4). Following the survey, special training was given to managers to improve interpersonal relationships. Moreover, a committee was established for improving the workers welfare. In 2016, the employees' satisfaction with their superiors was 4.35±0.3, significantly higher than in 2010 ($p<0.05$).
Discussion
This study demonstrates an increase in job satisfaction of laboratory personnel over a period of quality management implementation. Over the last 6 years the quality management in the laboratory division improved, resulting in ISO-9001 certification and JCI accreditation. It should be noted that during this period of time the lab work burden was significantly increased. The results suggest that placing employees in the center, promoting quality infrastructure and raising the value of the laboratory, increases employees' satisfaction and engagement.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W067

EXPERIENCE &INTELLIANGE ARE MORE IMPORTANT THAN TECHNOLOGY

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Background: In clinical laboratories innovation provides fast and efficient solutions with moduler systems. Our aim is to observe the effect of changing the configuration of modular systems test panel, on the workflow and turnaround time (TAT)
Methods: Our laboratory began to serve since January 2015. 23 hospital outsourcing testing and 3 hospital routine clinical laboratory testing were performing in our laboratory. For clinical chemistry(CC) and immunassay(IA) testing we have two modular system with a capacity 4000 enzymatic test/hr for CC,400test/hr for immunassay. In these instruments we were performing 34 CC, 28 IA tests. The capacity of our laboratory was 7000 tubes/day and 450000 test/month. First we investigate the workflow of our laboratory & testing capacity in April 2015 (one week) than we changed the configuration of the modular systems test panels and also reorganize the carrier service. In January2016 we again obtained our workflow analysis and compare the periods.
Results:
Each period (April 2015-January 2016) total number of the test/hour and TAT (from acceptation to the result (mean minimum-Maximum)) for CC were 12262test/hr, 126 min (30-245 min) and 13624 test/hr, 113 min(55-196min) while for IA4272 test/hr, 250 (55-488min) and 4467test/hr, 211min(55-386min) respectively. For CC, testing capacity increased 11% while the TAT was decreased 11%. In addition for IA,testing capacity increased 4.5%, TAT decreased 17 % while the test distribution didn't changed. When we compare the number of test/ tube between the weeks for CC 8.6 test/tube for 2015, 9.5 test/tube for 2016 while that was 2. test/tube and 2.3 test/tube for IA. The number of the tubes per hour of the periods were given in Figure 1.

Conclusion:
However consolidation of the instrument in central laboratories offers efficiency and reduce costs experience of the laboratory directors and a team work with the supplier company had a critical role for improving the management of the laboratory.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W068

PREPARATION AND AUDIT STAGES TO TS EN ISO 15189 ACCREDITATION IN CLINICAL LABORATORIES ANKARA CENTRAL LABORATORY EXPERIENCE

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Background: The primary goal of today's laboratories is to establish a system that will ensure quality and reliability in and target continuous improvement of laboratory results that have 70% effectiveness in clinical decision making process. For this purpose, we aimed to share our experience about the objective of TS-EN ISO- 15189 Accreditation rules in Clinical Laboratories and assure all process steps of test results produced.
Material & Methods: Our laboratory started accreditation studies on May04, 2015 and applied at the Turkish Accreditation Agency(TURKAK) on December25, 2015. Our Laboratory offers services to 23 healthcare facilities from one single center, and accepting 7000 samples per day. In line with the accreditation and quality goal in the preparation and planning stage, all data were regularly monitored in order to follow laboratory performance criteria and the process was revised based on the continuous improvement policy and the goals set were tried to attain. Our documentation was prepared in about 1200 pages in total as 25General Procedures, 40Instructions, 15 Descriptions of Job, 20Lists, 23Standard Operating Procedures (SOP), 11Plans and 66Forms together with the Quality Manual in line with the accreditation standards. Our Quality Control procedures and analytical process are followed with internal quality controls and external quality control memberships and our Laboratory obtained successfully outcomes by participating comparison and qualification tests relating to the scope we are accredited to. Our Laboratory applies the quality service with no compromise in line with the client requests with periodical surveys conducted every year. Under the title of training, regular trainings are implemented and employee satisfaction questionnaires are done.
Results: Our Laboratory was audited by TURKAK audit team on May25-27, 2016 with respect to both administrative and technical conditions. Our Laboratory completed the 3-day audit with total 7 minor faults; 5 in administrative conditions and 2in technical conditions.
Conclusion:The quality model being implemented by our Laboratory was found conforming to TS-EN ISO-15189 and entitled to receive the TURKAK brand over 4parameters. Our Laboratory achieved the goal of being the first Clinical Laboratory of healthcare facilities subordinated to the Ministry of Health and 19th Laboratory holding Medical Laboratory Accreditation certificate in Turkey.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W069

BIOSAFETY CHALLENGES IN THE TUBERCULOSIS LABORATORY AT SAMFYA ZONAL HEALTH CENTER – NEED FOR INTERVENTION.

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Background
Mycobacterium tuberculosis infections are a proven hazard to laboratory personnel as well as others who may be exposed to infectious aerosols in the laboratory. The risk of infection can be minimized through the application of the appropriate biosafety and containment principles and practices. Clinical specimens from suspected or known cases of tuberculosis are considered potentially infectious and must be handled with appropriate precautions. The objective of this study was to assess the biosafety levels in the Tuberculosis Laboratory at Samfya Zonal Health Center in Luapula, Zambia.

Methods
Mycobacterium Tuberculosis: Assessing Your Laboratory 2009 Edition was a tool used for the assessment. This tool consists of a series of 94 questions in total but only questions on safety from 18 A and B to 37 were sincerely answered in the presence of all Laboratory personnel performing TB testing at Samfya Zonal health center.

Results
Of the 20 questions in the Safety section of the TB Laboratory tool, only 2 were freely and sincerely answered YES while 18 were NO or maybe (somehow), giving a very low 10% safety in the TB Laboratory.

Conclusion
The biosafety challenge in the TB laboratory at Samfya Zonal Health Center Laboratory is very severe, serious and requires immediate intervention to protect Laboratory personnel and other health staff. A second sincere assessment will be carried out after corrective measures identified have been implemented.

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Laboratory Management, Accreditation, Quality Assurance

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ANALYTICAL PROCESS AUTOMATION: KEY TO LABORATORY EFFECTIVENESS

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Background
To succeed in competitive environment modern laboratory must program all internal and external processes in a way to perform its' activities with a capacity driven by laboratory users' demands and demonstrated ability to recustomize its' activities due to changes in users' requests in a critical short time. Laboratory process' mobility with required degree of stability and integrity can be achieved only by laboratory automatization using proper IT-solutions and their total validated integration.
The effectiveness of laboratory management characterizes in ability to process all specimens of different type and amount for wide range of tests ordered in the time period defined by users with minimum resources and expanses needed.
Method
Stated objectives: increase in effectiveness, decrease in laboratory turnaround time
Processes to be re-engineered: sample labelling, sample aliquoting, sample proceeding, handling and storage, test results validation
Chosen IT-solution: Middleware "LabOnLine" ("Omnilab", Italy)
"LabOnLine" creates a balanced sample tracking system programmed in accordance with specimen type and preanalytical requirements for analytes assessed, as well as synchronize all laboratory software solutions managing different internal and external laboratory processes from sample collection and test ordering to reporting of results.
Results
Middleware installed gave an opportunity to process 4 times more test per day than in 2009 (2000 vs 8000) by the same number of employees.
The results were achieved by more than 3 times increase in number of tests in tube, 10 times reduction of aliquots amount, and time expanses for manual sample tracking, test management (automated dilution and re-testing), and validation as well as reduction of equipment downtime.
"LabOnLine" keeps all laboratory process under control on a real-time base and allows laboratory management to make operational decisions based on direct cumulative data at any place with access to the Internet.
Conclusion
Summing up the implementation of middleware "LabOnLine" highly increase the effectiveness of laboratory operations resulting in productivity increase and decrease of expanses, reduction of errors due to misidentification of samples and delays in test reports caused by many manual operations at each process stage that finally results in increase of patient safety.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W071

SIGMA METRICS: PERFORMANCE OF 4 ANALYTES IN EQAS "BUENOS AIRES" PROGBA - CEMIC

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EQAS "Buenos Aires" ProgBA – CEMIC was established in 1979 and got ISO/IEC 17043:2010 accreditation in 2011. We analyzed results from 2015-2016 to evaluate method differences for 4 components tested by cell counting, immunoassays or chemistry: erythrocytes, thyrotropin TSH, glucose and uric acid. Human based, home-made materials were sent to >100 laboratories: stabilized whole blood (cell counting) and lyophilized sera (immunoassays; chemistry). Target values were assigned as consensus mean, BLCV% was calculated as between-laboratory CV% and acceptance limits were stated as + 3SD. Peer groups with at least 10 results were included. Quality specifications for σ metrics were based on biological variation BV or CLIA.
For erythrocytes σ was calculated from BV (n=163 labs, TV= 4.16+ 0.01 1012/L, BLCV%= 2.69); major peer groups were Cell-Dyn Ruby (n=16, σ=2.4), and Sysmex XS 1000i (n=30, σ= 4.8).
For TSH (n=190 labs, TV= 1,52+0,01 mUI/L, BLCV%=13,5), σ was calculated from BV. Major platforms were Cobas 6000 (n = 31, σ = 5.6), Cobas 411 (n= 55, σ 3,5), Roche Modular (n = 7, σ 9.1), Abbott Architect (n = 30, σ 2.9), Beckman Coulter Unicel (n = 5, σ =2.3), ADVIA Centaur (n = 16, σ =0.9), Immulite 2000 (n=18, σ 2.7 and Immulite 1000 (n=20, σ 2.2).
For glucose (n=310, TV=393,86+0,71 mg/dl, BLCV%=4,95), σ calculated from CLIA, major platforms were ADVIA1800 (n=5, σ=4.1), BiosystemsA25 (n=13, σ =2.0), Wiener CB350i (n=10, σ=3.1), Wiener CM250 (n=20, σ=1.7), Abbott Architect (n=22, σ=2.8), Cobas 6000 (n=31, σ=2.8), Cobas C111 (n=8, σ=2.8), Cobas C311 (n=40, σ=3.2), Siemens Dimension (n=19, σ=2,6), Ortho Vitros (n=14, σ=2.6)
For uric acid (n=292, TV=4.71 + 0.02 mg/dl , BLCV%=8.5), σ calculated from CLIA, major platforms were ADVIA 1800 (n=5, σ=4.7), BiosystemsA25 (n=13, σ=0.9), Wiener CB350i (n=10, σ=2.7), Wiener CM250 (n=20, σ=1.7), Abbott Architect (n=22, σ=5.2), Cobas6000 (n=31, σ 3.2), Cobas C111 (n=8, σ 1.8), Cobas C311 (n=40, σ 3.0), Siemens Dimension (n=19, σ=2,0), Ortho Vitros (n=14, σ=2.5).
Methods that exceeded acceptable performance (4 σ) were found for all analytes, reflecting also different laboratory implementation. Adjustment of reference intervals per method and urgent harmonization in immunoassays is needed, as differences have not been overcome yet.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W072

ACCREDITATION OF MEDICAL LABORATORIES IN REPUBLIC OF MACEDONIA

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BACKGROUND: 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. ISO/IEC 15189:2012 is a globally recognized standard that specifies requirements for quality and competence particular to medical laboratories. It is for use by medical laboratories in developing their quality management systems and assessing their competence.
METHOD/RESULTS: In a non-discriminatory manner, accreditation is accessible to every client submitting an accreditation application to the national Institute for accreditation. Quality systems in and accreditation of laboratories in our country are in varying phases of development. Some laboratories have established accreditation systems; others are still in the planning phase. Obtaining accreditation is still voluntary and there is poor participation of public sector laboratories. Till October 2016, four medical laboratories have been accredited according to MKS EN ISO/IEC 17025:2006 and five medical laboratories have been accredited according to MKC EN ISO 15189:2013. All accredited laboratories participate in EQAS concerning the analytical phase. A large proportion of errors occur in the pre-analytical phase and the problem is that the most EQA organizations do not offer pre-analytical EQA schemes. The first step in improving the quality of the preanalytical phase is to describe potential errors and to try to estimate which errors are most dangerous for the outcome of the patient. Existing pre-analytical procedures should be compared to existing recommendations and thereafter improved to minimize the risk of errors.
CONCLUSIONS: Development of a national standard as a starting standard for any country is one of the logical ways of implementing and initiating an accreditation programme. The standard may differ from one country to another depending on the state of development of the quality system in health laboratories. The national standard must be aligned with the international standard. In the case of medical laboratories, the aim of accreditation to ISO 15189 shall be the final target.

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Laboratory Management, Accreditation, Quality Assurance

Cod: W073

SWEAT TEST: RESULTS OF A TWELVE YEARS EXTERNAL QUALITY ASSESSMENT SCHEMES (EQAS)

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BACKGROUND: Sweat test is a very useful tool for diagnosis of Cystic Fibrosis. An EQAS was implemented since 2003. The results of the participant laboratories show discrepancies between the methods used. The aim of this survey is to evaluate the reliability of the results and to define the differences between the methods. This exercise is intended to improve the interpretation of sweat test.
METHODS: Material used is prepared adding NaCl to an artificial matrix similar to the sweat. 3 times/year, 2 samples were analysed by the participants.
RESULTS: 112 laboratories participate . 43% used Sweat Chek ®or Nanoduct® (ELITech–WescorTM) and measure the sweat conductivity,30% used Exsudose® (TEM SEGATM) (Chloride selective electrode), 15% used titrimetry and 12% coulometry to measure Chloride ion. The interlaboratory mean observed was calculated according to ISO 13528. Means and CVs of conductimetry measurement (mmol/L NaCl Eq.) differed from those expressed as Cl^- (mmol/L Cl^-). Interlaboratory variations (CVs) are lying between 4% and 7%, lower are obtained by conductimetry and coulometry methods, higher by Exsudose® and titrimetric method. Reference range value used differs according to the system, respectively <40 or 30 mmol/L Cl^- (dependent on age) and <60 mmol/l NaCl Eq. for the sweat ions; a value <50 mmol/L NaCl Eq excluding diagnosis. The limits used for diagnosis are 60mmol/L Cl^- and 90 mmol/l NaCl Eq. For control samples with mean level 30 mmol/L Cl^- and 44.5 mmol/L NaCl Eq.,no laboratory using a Cl^- measurement found a result >40 mmol/L and all the conductimetric results are less than 50 mmol/L NaCl Eq. For control samples with pathologic value (mean 71 mmol/L Cl^-), using Cl^- measurement, all the results showed a pathological result >60 mmol/l except one laboratory showing a value in the grey zone (40-60). Using conductimetry, all the results were >68 mmol/L NaCl Eq. For patient samples such a value have to be confirmed using chloride measurement.
CONCLUSION:The sweat test EQAS data is intended to evaluate the analytical performance of the method used. No direct relationship could be demonstrated between analytical performance of the methods used and the exclusion or confirmation of diagnosis. Learning from those results, it is necessary to stress about the fact that EQAS do not evaluate the first part of the test, which is the sweat stimulation and collection

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Laboratory Management, Accreditation, Quality Assurance

Cod: W074

SIX SIGMA TOOL AS GUIDE FOR INTERNAL QUALITY MANAGEMENT IN ROUTINE CHEMISTRY, DIVISION OF LABORATORY MEDICINE, UMMC.

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Introduction
The Division of Laboratory Medicine in University Malaya Medical Centre is one of the main diagnostic laboratories in this hospital. Most of the laboratory results produced in our laboratory contributed significantly in patient care and patient management. Internal Quality controls played an important role for laboratory to ensure that results that produced meet the required quality in terms of accuracy and precision. The aim of this study was to see how implementation of Six Sigma can improve our internal quality control (IQC) management.
Method
Two levels of IQC for routine assays were performed using Advia 2400 Clinical Chemistry System (Siemens Healthcare Diagnostic). These data were used to calculate of Sigma metrics using Biorad Unity software. Most of the selected quality goals were choose based on biological variation (BV) quality specifications follow by CLIA and CAP regulations.
Results
With highly good performance of Advia 2400 Clinical Chemistry System, almost 63% of tests on –board able achieved higher quality goals (at least the desirable BV quality goal). About 96% of the tests in this study achieved Sigma metrics greater than 4. Tests such as ALB, ALT, Amy, TBIL, DHDL, CK, CO2, GGT, Iron, LDH, Mg, P, Lactic, TG, Urea, Uric acid and Transferrin were some of the assays that performed very well with sigma greater than 6. Other assays such ALP, AST, DBIL, Cl, Creatinine, Glu, K, Total Protein and Na had acceptable performance with sigma metrics greater than 4 but less than 6. Calcium and total cholesterol were the tests with sigma metrics less than 4.
Conclusion
Six Sigma is a useful tool served as quality indicator helped us to focus on problematic assays, reduced false rejection and increase error detections. Patient care and management can be beneficial from improved IQC management with higher quality analysis.