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O-01

MANAGING REAGENT LOT-TO-LOT VARIATION: A PRAGMATIC APPROACH

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Reagent lot changes have been known to cause significant shift in quality control (QC) and/ or patient results. Verification studies prior to a new reagent lot change are vital to maintain consistency of analytical performance over time. The objective of this study is to propose a pragmatic approach for lot-to-lot verification (LTLV) to meet the requirements in ISO 15189:2022. We reviewed LTLV data for the period of March 2020 through May 2022 for 30 routine chemistry and 15 immunoassays reagents used on Siemens Atellica Solution. Analyses of retained patient samples and QC wereused to compare the lot change. In general, LTLV studies identified no significant change of patient and QC results for most of the routine chemistry reagents while some immunoassay reagents did showed significant shift in patient results. Based on these findings and through literature review, we proposed a pragmatic approach for LTLV. The tests are divided into 3 groups, (1) tests which the analysis of QC samples is sufficient, (2) tests that rarely show lot-to-lot variationfor either patient or QC results and (3) tests with significant lot-to-lot variations in patient results. In addition, commutability studies performed have provided evidence that QC samples alone can be used for LTLV for selectedtests. Finally, using this procedure we are able to detect cumulative bias between multiple reagent lots over time. As medical laboratories are challenged with marked differences in size and competence, it is criticalto develop a procedure which is practical and timesaving. By using this procedure, the LTLV findings can be shared among laboratories using similar measuring systems in order to reduce the burden of each individual laboratory. Therefore, we suggest users of other measuring systems come out with their own LTLV procedure for similar purposes.

O–02

EMBRACING TECHNOLOGY: DIGITAL TRANSFORMATION OF QUALITY MONITORING PROGRAM BY PUBLIC HEALTH LABORATORY

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Quality of laboratory test results produced by primary health clinic laboratories are crucial in disease risk assessments towards improving patient's health status. In ensuring its accuracy and reliability, these laboratories are required to enrol in External Quality Assurance (EQA) Programs. Since 2005, Public Health Laboratories (PHL) have been appointed by Bahagian Pembangunan Kesihatan Keluarga (BPKK) as coordinators to monitor EQA performances subscribed by primary health clinics laboratories as well as to provide EQA performance reports which reflect quality of the results to stakeholders. Coordinating EQA performance's tasks involve many manual processes, hence, it provides room for issues such as data discrepancies, late reports, insufficient information and etc. To overcome these issues, National Public Health Laboratory has developed a digital online system; Aplikasi Pemantauan External Quality Assurance (APEQ) that has shifted the paradigm of EQA monitoring program adhering to new Guideline on Monitoring of EQA Performances for Health Clinics Laboratories published in 2022. An effective project management tools such as Need-Approach-Benefit-Challenges (NABC) analysis and blue ocean strategy tool; Eliminate-Reduce-Raise-Create (ERRC) grid has been used to evaluate existing monitoring practice. A chargeless no-code low-code platform was adopted to develop APEQ which serves as data hub accessible to primary health clinic laboratories, coordinators and stakeholders. A trial phase was conducted in central zone states followed by a survey amongst users to evaluate its application. A total of 81% (N=26) respondents agreed on the easy accessibility of APEQ, 62% agreed that APEQ application was timesaving, 69% agreed that APEQ improved EQA monitoring management and would prefer to continue this system in future. EQA monitoring program coordinated by PHL in Malaysia has successfully underwent digital transformation in adherence to new workflow. Its use has now been expanded in all primary health clinic laboratories in Malaysia attributed by strong supports from stakeholders and end- users.

O–03

EVALUATION OF RISK-BASED QUALITY CONTROL SOFTWARE FOR RISK MANAGEMENT INDEX (RMI) CALCULATION IN ROUTINE BIOCHEMISTRY TESTING AT HOSPITAL SELAYANG

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Risk-based quality control (QC) is integration of risk management elements in medical laboratory quality management, especially in statistical QC (SQC) plans. This concept has been outlined in Clinical and Laboratory Standards Institute (CLSI) EP23-A (2011) and CLSI C24- Ed4 (2016) where laboratory QC should be used to mitigate patient risk by designing risk-based SQC strategies that could prevent / minimize the patient's harm. In this study, we evaluate the risk management parameter called "Risk Management Index" (RMI) in serum and urine routine biochemistry testing (n=35) at Hospital Selayang using a web-based software of Bio-Rad Mission:Control 2.0™ (https://mc.qcnet.com). On the basis of RMI, the test was categorized as a "managed-risk" (RMI ≤ 1) or an "unmanaged-risk" (RMI > 1) to assess whether the risk of patient harm in our routine testing is adequately managed or not. For RMI computation, we determined the long-term QC performance, analytical performance specifications, current QC rules and its frequency, severity of harm category, mean time between failures (MTBF), probability of harm given unreliable result (Ph|u) and number of patients for each analyte before performing the analysis on the designated software. Our results showed the majority of routine biochemistry testing in our laboratory exhibited RMI ≤ 1 (managed-risk) with current SQC plans. For those tests that are at higher risk (RMI > 1), there are recommendations from software to improve the RMI such as selection of suitable QC rules and its frequency. In addition, we could review other SQC strategies including the frequency of calibration, number of patient samples between QC events and utilization of EQA samples to monitor analytical stability. In summary, we found this software is practical and easy to be implemented in clinical laboratories in order to easily control and manage the risk which is also in line with the latest MS ISO15189:2022 requirement.

O–04

STUDY OF VITAMIN-D RECEPTOR GENE AND ANGIOTENSIN II RECEPTOR GENE POLYMORPHISMS IN PATIENTS WITH ESSENTIAL HYPERTENSION

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Essential hypertension is form of a complex, multifactorial, and polygenic trait. It is also called as primary hypertension or idiopathic hypertension (Gold black hypertension) to investigate the Vitamin-D Receptor gene polymorphism and angiotensin II Receptor gene polymorphism in Essential hypertension subjects. Age and gender matched 200 control subjects were obtained from the general population. Both male and female hypertensive patients aged between 25-60 years with systolic blood pressure (SBP) ≥140mmHg and/ or diastolic blood pressure (DBP) ≥ 90mmHg were included in this study. DNA extracted from peripheral blood samples of patients and controls were used for SNP genotyping of VDR gene and Angiotensin gene receptor polymorphism using PCR-RFLP method. In our study recessive model ff genotype shown statistical significance compared to the combination of FF+Ff genotype. The present data represents codominant, recessive and over dominant models showed statistical significance in EHTN when compared to controls. The dominant model showed no statistical significance in EHTN subjects in comparison to controls. Genotyping of AT1 receptor gene was detected by restriction endonuclease (Dde I) A1166C polymorphism using RFLP-RTPCR. The codominant model showed statistical significance in EHTN when compared to controls. The dominant and recessive model showed statistical significance in EHTN subjects in comparison to controls. Over dominant models showed not statistically significance in EHTN when compared to controls. In our present study the genotypic distribution of AT1 receptor gene polymorphism and allelic frequency of A and C alleles in cases and controls are as follows, The CC genotype was found to be associated with folds increased risk for Essential hypertensives compared to AA genotype. Based on the recessive model CC genotype shown statistical significance compared to the combination of AA+CA genotype. Our data suggest that VDR gene Fok I polymorphism is associated with the risk of developing EHTN.

O–05

THE DIAGNOSTIC PERFORMANCE OF SERUM ELECSYS PIVKA-II ALONE OR IN COMBINATION WITH AFP IN HEPATOCELLULAR CARCINOMA PATIENTS AT HOSPITAL UNIVERSITI SAINS MALAYSIA (USM): A PRELIMINARY STUDY

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Hepatocellular carcinoma (HCC) is known to have a poor prognosis. Serum alpha-fetoprotein (AFP) is the most widely used biomarker for HCC despite its limitation. Protein Induced by Vitamin-K Absence-II (PIVKAII), has been proposed as an emerging biomarker for HCC. It remains controversial whether PIVKA-II has a better diagnostic performance than AFP for HCC patients. This study aimed to determine the diagnostic performance of Serum Elecsys PIVKA-II alone or combination with AFP in HCC patients at Hospital Universiti Sains Malaysia (USM). A one-year cross-sectional study was conducted in Hospital USM, Kelantan, from January to December 2022. A total of 62 subjects were recruited for this study and divided into two groups: HCC (n=30), and healthy subjects (n=32). The subjects' demographic data were documented, and a venous blood sample was obtained. Serum Elecsys PIVKA-II was analysed by the chemiluminescent immunoassay method using Cobas e immunoassay analyser. The receiver operator curve (ROC) analysis was conducted to evaluate the diagnostic value of AFP and PIVKA-II for diagnosing HCC. The Elecsys PIVKA test was shown to have 85.2% sensitivity and 97.5% specificity at a cut-off of 26.02 ng/ml. AFP had a sensitivity of 73.1% and a specificity of 90 % at a cut-off of 3.20 ng/ml. The AUC of PIVKA-II and AFP was 0.90 (95% CI: 0.92-0.97) and 0.79 (95% CI 0.77-0.82), respectively. The combination of AFP and PIVKA-II yielded a high sensitivity of 92.3% and a specificity of 97.06 with the AUC of 0.96 (95% CI 0.94-0.98). Elecsys PIVKA-II is superior to AFP in HCC screening, and AFP, in combination with PIVKA-II, significantly improves the diagnostic performance of HCC. Future studies with a multi-centre design and a larger sample size are needed to explore the role of PIVKA -II in the management of HCC patients.