HJHS (2:2)
107-127 (2020)

Abstract

Proceedings of the 2nd International Meeting in Clinical Chemistry & Laboratory Medicine & SSCC 6th Annual Conference

December 1-3, 2020 – Riyadh, Saudi Arabia

POSTER PRESENTATION ABSTRACTS

THE ROLE OF OXYSTEROLS AS SELECTIVE OESTROGEN RECEPTOR MODULATORS (SERMS) AT PROMOTING TUMOUR GROWTH IN ADRENOCORTICAL CARCINOMA

Norah Mobarki[1] and Michael Conall Dennedy[2]

[1] Division of Clinical Biochemistry, Department of Central Military Laboratory & Blood Bank, Prince Sultan Military Medical City (PSMMC), Riyadh, KSA,[2] Endocrinology Department, National University of Ireland.

Email: nmobarki@psmmc.med.sa

Background: Adrenocortical carcinoma (ACC) is an aggressive and rare endocrine malignant with very limited treatment options at present. Besides, its recurrence rate is high and can reoccur in a short following period. ACC is a steroidogenisic cancer produces steroid hormones, that all share cholesterol as a key building unit. Thus, cholesterol active metabolites (oxysterols) could potentially interfere these steroids pathways and produce different cellular modifications through different receptors, included Estrogen receptors (ERs). In a previous study on ER+ breast cancer cells, the oxysterols (i.e. 27Hydroxy Cholesterol) promote cell proliferation through oestrogen receptor alpha ERα. Therefore, we hypothesized that oxysterols as selective oestrogen receptor modulators (SERMs), could act similarly via ERs in ACC cells (H295R) and promote cell growth.

Methodology: The aim of the current study was measuring the proliferative effect after using specific drugs. Two cell lines were cultured and treated similarly: MCF7 breast cancer cell (ERα positive control) and H295R adrenocortical cancer cell. The used drugs for both cells treatment were: 27Hydroxy Cholesterol as stimulator (27HC) at various doses (0, 10, 20, 40, 80 uM) either alone or combined with hydroxyl-tamoxifen (OHT) as inhibitor (10uM OHT) and/ or 10nM 17-β estradiol (E2). The incubation period was 24 hours at 8 replicates (n=8). The principle experimental technique was crystal violet staining in which cells growth was measured via the absorbance by spectrophotometer at 550nm.

Results: H295R cells were treated with 27HC (0, 10, 20, 40, 80 uM) alone then incubated for 24-hrs at 37C, stained with the crystal violet dye and measure the light absorbance at 550nm. The high value of absorbance reflects the large number of cells. Findings showed that 27HC plays a role at stimulating cell division as the dose increased. However, this effect is being further enhanced in the presence of: E2 and OHT, which may act collectively to recruit cell receptors and mediate cellular division. E2 used to mimic the biological environment within ACC tissue, OHT is to examine its effect on inhibition tumour growth in ACC case. Likewise, the same treatment scheme was applied on MCF7 cells, the outcomes were correlated to a previous work that 27HC stimulates cell proliferation and OHT inhibits tumour formation.

Conclusion: Overall, 27HC showed an expected effect, whereas, OHT unexpectedly induce cell density not inhibiting the cell division. Therefore, further work should consider the unexpected stimulatory effect of OHT and its mechanistic pathway, prior to suggesting it as an anti-estrogenic drug in ACC setting.

REVIEW ON BIOTIN INTERFERENCE IN CLINICAL CHEMISTRY IMMUNOASSAYS

Zaed A. Asiri, Dr. Zahir H. Alshehry

Biochemistry Laboratory, King Fahad Medical City (KFMC), Riyadh, KSA.

Email: zaiedasiri@hotmail.com

Objectives: This report aims to review the biotin interference with streptavidin/biotin-based

immunoassays mechanisms, identify automated immunoassay systems susceptible to biotin interference, describe how to reduce the risk of biotin interference in vulnerable assays, and review the literature pertaining to biotin interference in endocrine function tests.

Methods: Literatures were reviewed for reports of biotin interference using a systematic search of MEDLINE/PubMed for articles containing terms associated with biotin interference. Together with, abstracts from latest scientific meetings were also identified and reviewed. Also, Information by manufacturer including data in the "Instructions for Use" for each of the methods utilized by seven immunoassay system were assessed. This includes, (21 tests) of the most common immunoassays, in (7) of the major manufacturers (Roche, Ortho Clinical, Siemens, Beckman Coulter, Immuno Diagnostic System, ABBOTT, and DiaSorin Liaison) Immunoassay Instruments that utilizes Streptavirdin biotin interaction. Alongside, the biotin concentration above which erroneous results can happen are indicated for each assay. Finally, the effect of high-biotin concentration on both Competitive, and non-competitive immunoassays.

Results: The recent increase in high-dose biotin as an over-the-counter supplement, have been accompanied by a steady increase in the number of reports of analytical interference by exogenous biotin in the immunoassays especially the tests used to evaluate endocrine function. Since immunoassay methods of similar design are also used for the diagnosis and management of cardiac damage, autoimmune, infectious diseases, etc. Analytical interference attributed to biotin is an issue with an impact on all areas of medicine.

Conclusion: This review serves as a cautionary note for healthcare providers, and laboratory staffs/supervisors to become more aware of immunoassay methods that are susceptible to biotin interference and to consider biotin supplements as potential sources of falsely increased or decreased test results. Moreover, it is highly encouraged to investigate biotin interference in immunoassays known to utilize biotin-streptavidin as part of laboratory method validation studies.

CUT-OFF DETERMINATION IN DRY BLOOD SPOT NEWBORN SCREENING FOR INBORN ERROR OF METABOLISM BY TANDEM MASS SPECTROMETRY AND GENETIC SCREEN PROCESSOR IN SAUDI ARABIA

Abdul Rafiq Khan[1], Souad Al-Enazi[1], Adil-Al Jowed[1], Ahmed Al-Senedy[1], Areej Al-Gahtani[1], Saad Al Ghamdi[1], Lucille Bailey[1], Saleh Zahrani[1], Abeer Al-Anazi[1], Ahmed Al-Faris[1,2], Ali Al-Othaim[1]

[1]King Abdulaziz Medical City, Biochemical Metabolic Lab, Riyadh, KSA, and [2]Qasim University, Qassim, KSA
Email: khanab@ngha.med.sa

Background: Newborn screening (NBS) is a public health program for the screening of infants shortly after birth (48hr-72hr) for a list of conditions that are recommended by national newborn screening committee in Saudi Arabia. An early identification of affected children can help in preventing disabilities and even death

Method: About 103,000 dry blood spot newborn screening samples were collected and transferred to Biochemical Metabolic Laboratory, King Abdul Aziz Medical City, Riyadh from different hospitals during 2013-2020. All samples were analyzed by tandem mass spectrometry (Waters, USA) and genetic screen processor (GSP, Perkin Elmer, USA) by using Chromsystem and Perkin Elmer reagent kits.

Results: Percentile of amino acid, acylcarnitine, 17-hydroxyprogesterone, TSH, GALT and BTD activity have been calculated by statistical analysis of 103,000 results using Microsoft Excel and compared with 122 true positive and 60 proficiency testing samples provided by CDC. Individual cut off, ratios, positive predictive values and false positive rate were calculated. False positive rate was less than 0.04 for all except BTD where it was 0.14 which is due to pre-analytical errors. The analytical PPV were greater than 80% throughout the last eight years calculated from the CDC proficiency samples. These values were compared with the cut-offs determined by Region for Stork Study (R4S) and Centers for Disease Control. In 22 screened disorders, a total of 122 true positive patients were identified. For most of amino acid and acylcarnitine, established cut-off values are greater than R4S and lower than CDC cut-off except Citrulline (< 72µmol/L), Methionine (<

84µmol/l), C4 (<1.35 µmol/L) and C18:1 (3.97µmol/L). For TSH and 17-hydroxyprogesterone, our cut-off was also higher than CDC. Percentiles disorder ranges were calculated from 122 confirmed positive cases for amino acids, amino acid ratios, acylcarnitine's and acylcarnitine's ratios. The high target disorder ranges were obtain from the interval between 99th percentile of normal population and the lowest 5th percentile of all disorder ranges of the same analyte. Most of false positive cases are within this high target ranges. We observed that most of positive proficiency samples are near the lowest 5th percentile of disorder ranges whereas false positive patient samples are near the 99th percentile of the normal population but far away the lowest 5th percentile of disorder ranges. Number of false positive samples were reduced for valine, methionine and C5 after using new cut-off range higher than initial range. The new cut-off of C3 was lower than initial which didn't cause any increase in false positive rate.

Conclusion: Determination and validation of population-based cut-off values and their ratios are extremely important for accurate diagnosis, minimize false positive rate and increase positive predictive values. We have established cut-off levels for each analyte with several ratios which gives excellent screening specificity and sensitivity.

CYTOTOXIC EFFECT OF METFORMIN ON BREAST CANCER CELL LINES

Feryal H. Alharthy[1,2], Aliaa A. Alamoudi[1,2], Amina Alnouri[1]

[1] Clinical biochemistry department, Faculty of medicine and [2]Stem cell unit, King Fahad Medical Research Canter (KFMRC), King Abdulaziz University, Jeddah, KSA.
Email: F.H.al-harthy@hotmail.com

Background: Breast cancer is still one of the most common tumours, and the primary leading cause of cancer deaths in women worldwide. Emerging evidence suggests that metformin, the most widely used antidiabetic drug, shows antitumor effect in various cancer models, however the exact mechanism of action remains to be elusive.

Objectives: In the present study, we aim to investigate the anti-tumour effect of metformin on breast cancer cell lines; MCF-7 and MDA-MB-231, including its cytotoxic effect and effect on apoptosis. We also hypothesise that the drug can target breast cancer stem cells through altering and reprograming their metabolism through inhibiting oxidative phosphorylation which would be required as a main source of energy for cancer stem cells

Methodology and Results: Cell viability was determined using the CCK-8 assay according to the manufacturer's instructions. At 72 hrs, metformin showed cytotoxic effects against MCF-7 and MDA-MB-231 with IC50's of 14.21+1.33 mM and 12+5.8 mM respectively. Effect on apoptosis was detected using Annexin V-FITC coupled with flowcytometry. Both cell lines were treated with the predetermined IC50's of the drug for 48 hrs. Metformin induced 2.1±0.5% and 22.1±2.8% apoptosis in MCF-7 and MDA-MB-231 cells respectively compared to control untreated cell.

Conclusion: In our next step we aim to study the exact effect of metformin on tumour metabolism. We believe that by understanding the mechanism of action on metabolism this will help to establish new strategies of breast cancer treatment by metformin, which is an inexpensive and widely used antidiabetic drug without severe adverse effects.

THE EFFECT OF (LYSULINTM) ON GLYCEMIC CONTROL, SUDOMOTOR FUNCTION AND OTHER COMPONENTS OF METABOLIC SYNDROME IN PATIENTS WITH TYPE 2 DIABETES- PRELIMINARY RESULTS

Hadeel Mofareh[1], Basmah Eldakhakhny[1,2,3], Ghada Agabnoor[1,2,3], Khalid Alshali[3,4], Amani Alhuzali[3,4], Jawaher Alahmadi[3,4], Anwar Borai [3,6], Suhad Bahijri[1,2,3]

[1]Department of Clinical Biochemistry, Faculty of Medicine, [2]Food, Nutrition and Lifestyle Unit, King Fahd Research Center, [3]Saudi Diabetes Research Group (SDRG), Faculty of Medicine, and King Fahd Research Center, [4]Department of Internal Medicine, Faculty of Medicine and [5] Department of Family Medicine, Faculty of Medicine, King Abdulaziz University, Jeddah, KSA and [6] King Abdullah

International Medical Research Center, King Saud bin Abdulaziz University for Health Sciences, King Abdulaziz Medical City, Jeddah, Saudi Arabia
Email: me.nayome@hotmail.com

Background: Type 2 diabetes (T2D) patients are at high risk for developing macrovascular & microvascular complications due to their poor glycemic control (GC). The search continues to find effective and safe measures to improve GC. Lysulin™ is a new dietary supplement for (T2D) and (MS) patients. Its active components are lysine, zinc, and vitamin C, which all have been reported to lower blood glucose, improve insulin resistance, enhance insulin secretion, and lower the glycation of proteins, including that of hemoglobin.

Methods: A double-blind case-control design was employed aiming to recruit 60 T2D patients from endocrinology clinics at King Abdulaziz University Hospital. Anthropometric, blood pressure (BP), and Sudomotor function measurements were taken, and fasting blood samples were obtained to measure glucose, glycated hemoglobin (HbA1c), and lipid profile. Patients were divided randomly into two groups (A & B), given either placebo or Lysulin™, and followed for three months, when all measurements and blood samples were re-taken.

Results: Twenty-three patients completed the study so far. Preliminary results showed that Group-A (GA), unlike Group-B (GB), had a significant decrease in the mean HbA1C (GA Mean/±SD = 9/±1.39, and 8.18/±1.51 before and after respectively, with p=0.01, compared to GB Mean/±SD= 8.26/±1.49, and 7.7/±0.88 before and after respectively with p=0.21), and an increase in mean HDL (GA Mean/±SD = 1.13/±0.22, and 1.20/±0.22 before and after respectively, with p=0.007, compared to GB Mean/±SD= 1.2/±0.26, and 1.32/±0.31 before and after respectively with p=0.35).
Also, Sudomotor function results showed overall improvement in GA where noticeable improvement was mainly in the feet as follows: left feet (GA Mean±SD= 55.33±13.28, and 61.46±12.47 before and after respectively, with p=0.04, compared to GB Mean±SD= 72.62±11.96, and 73.87±11.74 before and after respectively with p=0.6), right feet (GA Mean±SD= 54.6±14.74, and 59.73±12.85 before and after respectively, with p=0.06, compared to GB Mean±SD= 70.87±12.67, and 65.25±13.2 before and after respectively with p=0.2). However, no change in the means of fasting plasma glucose, other lipid variables, or BP were noted in either group.
Conclusion: A definitive conclusion cannot be offered at this time as the study is still in progress, and groups have not been un-blinded yet. Nonetheless, our preliminary results showed a significant difference between the 2 groups.

ETHYL GLUCURONIDE AND ETHYL SULFATE- A REVIEW ON THEIR ROLE IN ALCOHOL POSTMORTEM FORENSIC TOXICOLOGY ANALYSIS

Salma Alsayed[1], Asia Alharbi[2], Asrar Alhejaili[1&3], Reham Aljakhlab[3], Asma Ashankyty[3&4] and Ahmed Al-Asmari[5]

[1]Pathology and Laboratory Medicine Department, Prince Muhammed Bin Abdul-Aziz Hospital, National Guard Health Affairs (NGHA), Medina, [2]Center of Excellence Genomic Medicine Research, and [3] Department of Medical Laboratory Technology, College of Applied Medical Sciences, King Abdulaziz University of Jeddah, [4]Pathology and Laboratory Medicine Department, King Abdulaziz Medical City, NGHA, Jeddah, and 5 King Abdulaziz Hospital, Jeddah Health Affairs, Jeddah, KSA.

Email: SALSAYED0033.stu@uj.edu.sa

Background: Type 2 diabetes (T2D) patients are at high risk for developing macrovascular & microvascular complications due to their poor glycemic control (GC). The search continues to find effective and safe measures to improve GC. Lysulin™ is a new dietary supplement for (T2D) and (MS) patients. Its active components are lysine, zinc, and vitamin C, which all have been reported to lower blood glucose, improve insulin resistance, enhance insulin secretion, and lower the glycation of proteins, including that of hemoglobin.

Methods: A double-blind case-control design was employed aiming to recruit 60 T2D patients from endocrinology clinics at King Abdulaziz University Hospital. Anthropometric, blood pressure (BP), and Sudomotor function measurements were taken, and fasting blood samples were obtained to measure glucose, glycated hemoglobin (HbA1c), and lipid profile. Patients were divided randomly into two groups (A & B), given either placebo or

Lysulin™, and followed for three months, when all measurements and blood samples were re-taken.

Results: Twenty-three patients completed the study so far. Preliminary results showed that Group-A (GA), unlike Group-B (GB), had a significant decrease in the mean HbA1C (GA Mean/±SD = 9/±1.39, and 8.18/±1.51 before and after respectively, with p=0.01, compared to GB Mean/±SD= 8.26/±1.49, and 7.7/±0.88 before and after respectively with p=0.21), and an increase in mean HDL (GA Mean/±SD = 1.13/±0.22, and 1.20/±0.22 before and after respectively, with p=0.007, compared to GB Mean/±SD= 1.2/±0.26, and 1.32/±0.31 before and after respectively with p=0.35).

Also, Sudomotor function results showed overall improvement in GA where noticeable improvement was mainly in the feet as follows: left feet (GA Mean±SD= 55.33±13.28, and 61.46±12.47 before and after respectively, with p=0.04, compared to GB Mean±SD= 72.62±11.96, and 73.87±11.74 before and after respectively with p=0.6), right feet (GA Mean±SD= 54.6±14.74, and 59.73±12.85 before and after respectively, with p=0.06, compared to GB Mean±SD= 70.87±12.67, and 65.25±13.2 before and after respectively with p=0.2). However, no change in the means of fasting plasma glucose, other lipid variables, or BP were noted in either group.

Conclusion: A definitive conclusion cannot be offered at this time as the study is still in progress, and groups have not been un-blinded yet. Nonetheless, our preliminary results showed a significant difference between the 2 groups.

MOLECULAR BASIS OF IGHG4-RELATED LOW SERUM IGG4 SUBCLASSES IN DOWN SYNDROME

Mohammed Jeraiby

Department of Medical Biochemistry, Faculty of Medicine, Jazan University, Jazan, KSA.

Email: mojer2011@hotmail.com

Background: IgG4 deficiency is more frequent among persons with Down syndrome (DS), without identifying explanation. The role of IgG4 deficiency is not fully established for many affected persons in the general population are asymptomatic. Nevertheless, in the context of DS it may be an important factor in repeated infections and even stroke. The aim of the present study was to investigate the molecular mechanism of IgG4 deficiency at the level of the heavy chain gene (IGHG4) gene.

Method: Quantitative real-time polymerase chain reaction (Q-PCR) was carried out to measure IGHG4 copies number with SYBR Green detection and comparison to a reference gene (36B4). A IGHG4/36B4 ratio was considered normal (2 copies of IGHG4) when between 0.8 and 1.2. We studied 44 DS persons: 21 males and 23 females from 7 years to 57 years, composed of 23 DS persons (11 males and 12 females) carrying severe IgG4 deficiency (<0.02 g /L), 5 having an IgG4 level not detectable and 21 DS subjects (10 males and 11 females) with no IgG4 deficiency (level >0.1 g /L). The patient group was compared with 38 healthy donners (controls) without DS.

Results: IGHG4 heterozygous deletion was found in 16 (69.6%) DS patients with IgG4 deficiency versus in 2 (9.5%) DS subjects without IgG4 deficiency (p =0.0001 with Yates correction). in the control group, no deletion was seen.

Conclusion: IGHG4 haploinsufficiency is highly correlated to IgG4 deficiency is our population with DS, but other factors exist that need to be identified.

BIOCHEMICAL ALTERATION IN BLOOD STRESS MARKER AND OTHER VITALS OF SAUDI MEDICOS IN PRE AND POST REAL TIME CARDIAC CATHETERIZATION PROCEDURE

Maher Alobaysi[1], Turki Albacker[2], Waleed Alharbi[2], Fahad A Al Abbasi[3], Osama Almogbel[2],SadikMohammed[4], Vikas Kumar[5] and Firoz Anwar[3]

[1]Department of Basic Medical Sciences, Faculty of Medicine, King Fahad Medical City, Riyadh, [2]Department of Cardiac Sciences, College of Medicine. King Saud University Medical City, Riyadh, [3]Department of Biochemistry, Faculty of Science, and King Abdulaziz University, Jeddah, KSA, and [4]Department of Anesthesiology, All India Institute of Medical Sciences, Jodhpur, Rajasthan, [5]Department of Pharmaceutical Sciences, Shalom Institute of Health and Allied Sciences (SIHAS), Sam Higginbottom University of Agriculture, Technology & Sciences (SHUATS), Allahabad, India

Email: maherm0m@gmail.com

Background: A prospective cohort study that deciphers the alteration in stress marker and blood profile among trainee medicos during Pre and Post Cardiac Catherization procedure during clinical training on them.

Methods: Total 25 medicos were enrolled, only 10 were able to complete the criteria for the whole set of study, free from anxiety and were not on any medication before enrollment of study. Standard Kits were used for blood profile analysis. Pre and Post (Mean±SD), P– value, and Conf. Interval (95%) with respect to cortisol, White blood corpuscles, Glucose etc. along with other vitals (Heart rate, BP) as per Resuscitation assessment tool were made.

Result: Normality was tested was performed using Kolmogorov Smirnov test. Cortisol ($P<0.05$) and white blood cells (WBC) count ($P<0.05$) showed a significant different in pre and post catherization procedure. Significant ($P<0.05$) linear correlation was found between pre and post values for heart rate (HR), WBC, Electrolytes, blood urea nitrogen (BUN), Cortisol (COR), tri-iodothyronine (FT3), thyroxine (FT4), thyrotropin (TSH) and Vit D in paired sample correlation. WBC counts measured before and after intervention were 5.81±1.12 and5.19±0.98 respectively, a significant fall in the WBC count and increase in cortisol after intervention by paired 't' test between the means (0.6171 confidence interval 0.2198 to 1.014) (p-value 0.009) & 261.57±110.94 and342.98±122.29 (-81.4 confidence interval -145.58 to -17.25) (p-value 0.02) respectively.

Conclusion: Drastic variation in WBC count and cortisol level in both cardiac catherization procedure medicos and need to be accounted before designing the curriculum or assigning any duty to them.

IDENTIFICATION OF ABNORMAL PROTEINS IN THE BLOOD OF PATIENTS WITH TYPE2 DIABETES AND DRY EYE SYNDROME

Rawan Baqar[1], Rawan Aljadaani[1], Hala Bamalem[1], Rwzan Alamoudi[1], Shatha Jambi[1], Rouzana Khayat[1], Urszula Deneka[2], Amani Alhalwan[1]

[1] College of Applied Medical Sciences, King Saud bin Abdulaziz University for Health Sciences, Jeddah, KSA and [2] Department of medical informatics and statistics with E-learning, Medical University of Lublin, Lublin, Poland.

Email: rawanbaqar@gmail.com

Background: Diabetes mellitus (DM) is highly prevalent and an increasingly significant public health problem in the Saudi population and worldwide. Diabetes creates a high-risk of blindness and other ocular disorders. According to previous studies it found that there is relation between diabetes type 2 and dry eye disease. Moreover, Lactoferrin is a protein decrease in both diseases, diabetes type2 and Dry eye syndrome, and consider as biomarker. In addition, lactoferrin protein is mainly produce by neutrophils, so studying neutrophils in the blood can lead us to understand more about clinical investigation of diabetes type 2 and dry eye disease. This study is about determine the clinical characteristics of patients type 2 diabetic with dry eye disease (DED) and to identify the associated biomarker that related to it.

Method: A total of 500 patients with type 2 diabetic with dry eye disease in NGHA hospital community were randomly selected. All results were retrospectively extracted from the hospital's database. The study was designed based on cross-sectional and the statistical data had been analyzed by the SPSS version 20. The patient data was collected for four groups; two positive control diabetes type 2 and dry eye disease, negative control- healthy patients, and study group diabetes type 2 with dry eye disease. Furthermore, the records of patients CBC blood test and biochemical screening test were collected from the hospital laboratory records, then use biostatical t-test for results validation.

Results: Of the 500 subjects, (20%) were diagnosed with DED and type 2 diabetes with ophthalmic complication (52 %). There was a significant association between type 2 diabetes with DED and type 2 diabetes based on the reduction of neutrophil count 1.69 ± 0.8 and 3.4 ± 1.7, respectively comparing by healthy subjects 5.1 ($P < 0.07$) as well as less levels of albumin 41.3 ±. 1.52.

Conclusion: The significant association has been identified between type 2 diabetes with dry eye

disease and type 2 diabetes decreased neutrophil count is correlated with the disease's biomarker lactoferrin protein. The examination of neutrophil count should be considered as routine screening of type 2 diabetes with eye complication to prevent future eye disease and help treatment strategies.

AL BORG MEDICAL LABORATORIES'S IN-HOUSE NOVEL MULTIPLEX RT-QPCR FOR DETECTING SARS-COV-2

Bilal Alkhizzi[1], Y. AlMihmad[1], M. AlMujtaba[1], Z. Awan[1], S. AlAmoudi[2], F. Hakami[3], A. Khitamy[3], R. Sutaih[4]

[1]Al Borg Medical Laboratories, R&D department, [2]Al Borg Medical Laboratories, clinical pathology department, [3]King Abdulaziz Medical City in Jeddah, [4]East Jeddah Hospital, laboratory and blood bank department, Jeddah, KSA.

Email:b.alkhizzi@alborglaboratories.com

Background: Limited supply of SARS-Cov-2 detection kits constitutes one of the major challenges facing testing centers worldwide. A few groups have even suggested sample pooling as a backup plan. We were able to develop and validate a robust one-step RT-qPCR triplex assay for detecting the virus using novel primers and probes, which can accurately diagnose up to 94 RNA samples in a 96-well format per qPCR machine in less than 2 hours. To the best of our knowledge, this test is the first locally developed test to be approved for clinical use in the history of Saudi Arabia in the genomics field.

Methods: All SARS-CoV-2 full genomic sequences published as of April 14th, 2020 were retrieved and aligned by the MUSCLE software. Primers and probes were designed to target conserved areas in all viral strains, as well as the ubiquitously expressed GAPDH to serve as the internal control for the assay. Oligo specificity was determined in silico for other coronaviruses, as well as other respiratory pathogens, by the primer BLAST tool from NCBI. RNA was extracted at Al Borg's molecular diagnostics unit. Assay sensitivity was determined by preparing serial RNA dilutions of confirmed positive samples by RT-qPCR. All RT-qPCR reactions were performed using the TaqPath™ 1-Step RT-qPCR Master Mix (A15299, Applied Biosystems™). Finally, two rounds of clinical validation at the National Guard Hospital and Al Borg's molecular diagnostics unit were performed on 165 samples.

Results: Our proprietary oligos encompass a wider range of viral strains than those recommended by the World Health Organization, for which a few mismatches have been reported. In silico analysis revealed no unspecific targeting for other related viruses, and the two viral targets in the triplex had qPCR efficiencies of 101% and 104%. Final clinical validation shows 98.2% concordance between our in-house triplex and the international commercial IVD-approved kits used at the NGH's molecular diagnostics unit.

Conclusion: We have successfully developed a novel triplex RT-qPCR assay to detect the SARSCoV-2 which was consequently approved by the Saudi FDA for Al Borg's internal use. This assay will enable Al Borg to expand its testing capacity and help the country in fighting and containing this lethal virus.

LEAN SIX SIGMA METHODOLOGIES REDUCE TURNAROUND TIMES FOR EXPEDITE CHEMISTRY TESTS

Salam Saadeddin, Noha Al-Humidan, Ali Al-Johi, Waleed Al-Madani, Najla Besharah, Fadwa Al-Harthi, Khaled Al Sowayigh and Mohammed Al-Seini.

Division of Clinical Biochemistry, Department of Central Military Laboratory &Blood Bank, Prince Sultan Military Medical City Riyadh, KSA.

Email: saadeddin@psmmc.med.sa

Background: Workflow organization is a major task of laboratory management. Recently, methodologies such as Lean Six Sigma started to be adopted by clinical laboratories and some successful implementations have been reported. We studied the use of Lean Six Sigma in decreasing the turnaround time (TAT) of chemistry expedite tests.

Methods: This study was a longitudinal, before–after analysis of process improvements in the central laboratory of our hospital. We used the five-stage Six Sigma system, known as define, measure, analyze, improve, and control (DMAIC), to identify and solve problems related to TAT in

the hospital. The laboratory TAT for chemistry expedite tests including, total delay time (from test request to verification) and times of steps involved in the overall process (including factors that might affect the time from leaving the wards until arriving to central specimen reception (CSR), test requesting, arriving to lab, analysis and verification) were measured over a period of two weeks. Factors critical to quality (CTQs) and to process (CTPs) were identified and analysis of the process was made. After that, an action plan was constructed and implemented over a period of 7 months, followed by repeat of total and different steps in TAT measurements.

Results: The pre-analytical process in the reception area was improved by eliminating 2 hours and 2 minutes of non-value-adding work and the analysis to verification time was reduced by 32 minutes. Turnaround time (TAT) also improved for expedite chemistry tests from 108 to 84 min after applying Lean.

Conclusion: Successful implementation of Lean Six Sigma significantly improved all the selected performance metrics. This quality-improvement methodology has the potential to significantly improve clinical laboratories.

EVALUATION OF ?-HYDROXYBUTYRATE ASSAY IN SERUM OR PLASMA USING KINETIC ENZYMATIC METHOD (RANDOX KITS) ON ROCHE COBAS C702 ANALYZER

Mohammad Sulaiman, Salam Saadeddin, Khalil Softa, Sami Al-Suneed & Michellie Sarmiento

Clinical Chemistry division, Central Military Laboratories & Blood Bank, Prince Sultan Military Medical City, Riyadh, KSA

Email:MSULAIMAN@psmmc.med.sa

Background: The β-hydroxybutyrate (βOHB) is the major ketone body produced in the liver as a result of oxidation of fatty acids and is emerging as the biomarker of ketoacidosis and ketogenic state in diabetic, alcoholic and severely injured patients, because it is more sensitive and stable biomarker of ketosis when compared to acetone and acetoacetate and its levels are more elevated compared to both. The aim of this study is to evaluate the clinical validation and implementation of βOHB assay in peripheral blood using kinetic enzymatic method (Randox kits) on Roche Cobas c702 analyzer.

Methods**:** Serum or plasma samples were collected from 30 diabetic patients and 40 healthy individuals. The samples from diabetic patients and RIQAS samples were used for method comparison, samples of healthy individuals were used for reference interval and commercial control material was used for precision. The precision, linearity, comparison, limit of detection and reference interval was measured as per the CLSI standards (EP05-A3, EP06-A, EP09-A3, EP17-A2 & EP28-A3C respectively). The βOHB was analyzed on automated COBAS c702 platform using Randox kits.

Results: 50 samples were analyzed for precision. Percent CV (% CV) for low and high concentrations were 3.2 and 3.1, respectively. The linearity of the assay ranged between 0.03 to 4.5 mmol/L on c702 automated cobas analyzer. The test comparison between Prince Sultan Military Medical City (PSMMC) and another accredited laboratory showed good correlation throughout the whole measuring range with correlation coefficient (R= 0.9988). Other comparison between PSMMC Lab and RIQAS samples showed good correlation throughout the whole measuring range with correlation coefficient (R= 0.9995). The limit of detection of the βOHB analyte using serum/plasma was 0.03 mmol/L. The reference range, based on serum/plasma samples from 40 healthy individuals was 0.03 - 0.30 mmol/L.

Conclusion: Overall performance of βOHB using Randox kits on automated COBAS c702 platform was acceptable. It provides reliable results for patients' samples testing.

ANALYTICAL PERFORMANCE OF POINT OF CARE BLOOD GAS ANALYZER GEM PREMIER 4000

Nuha AL Humaidan, Wafa Natif, Kathelyn Mendoza

Clinical Chemistry division, Central Military Laboratories & Blood Bank, Prince Sultan Military Medical City, Riyadh, KSA

Email: nalhumaidan@psmmc.med.sa

Background: The analytical performance of the portable critical care system blood gas analyzer GEM Premier 4000 was evaluated to the currently in use benchtop Cobas b221 in measuring blood gases , electrolytes , metabolites , hemoglobin and its derivatives to determine whether GEM Premier 4000 measurements at the bedside of patients in the Intensive Care Units (ICU)and Operating Theaters of PSMMC would be as reliable as those performed by the current Cobas b221.

Methods: Total Precision was studied based on CLSI EP05-A3 at two levels of Calibration Verification solutions for each test, the solutions were run in 5 replicates over 5 days and coefficients of variation(%CVs) were calculated. Linearity was done according to CLSI EP06-A using different concentrations spanning the analytical measuring range for each test. Accuracy was performed by evaluating 25 heparinized arterial, venous and capillary blood samples collected from adult and pediatric ICU patients, the samples were analyzed immediately upon collection. Correlation were calculated using Scatter and Error Index Plots and total allowable error for pH, blood gases [Partial Pressure of Carbon Dioxide($pC0_{2)}$, Partial Pressure of Oxygen (pO_2)], Electrolytes [Sodium(Na^+), Potassium(K^+) ,Chloride (Cl^-), and Ionized Calcium(Ca^{2+})] ,Metabolites [Glucose(Glu), Lactate(Lac) and Total Bilirubin(TBil)] ,and the CO-Oximetry [Total Hemoglobin (tHb), Methemoglobin (MetHb), Carboxyhemoglobin (COHb), Oxyhemoglobin (O_2Hb) and Deoxyhemoglobin (HHB)].

Results: The coefficients of variation (CVs) were less than 3% for all parameters and the standard deviation (SD) were consistent with those claimed by the manufacturer for all tests. GEM Premier 4000 showed satisfactory correlation with Cobas b221 with (R) values equal to or greater than 0.975, slope values were within 0.90 - 1.10,and the intercepts were 0 or close enough to zero for all tests, the results were within the recommended total allowable error values.

Conclusion: Overall performance of GEM Premier 4000 system was acceptable, it provided reliable results with respect to precision and linearity, and it demonstrated good correlation with the current in use Cobas b221 for all tests.

BETA-2 MICROGLUBULIN AND RENAL FAILURE IN MULTIPLE MYELOMA

Najla Besharah, Ahmad Al Saffar, Nada Al Zahrani, Saad Al-Awwad

Clinical Chemistry division, Central Military Laboratories & Blood Bank, Prince Sultan Military Medical City, Riyadh, KSA

Email: nalbesharah@psmmc.med.sa

Background: Multiple Myeloma (MM) is a cancer of plasma cells in bone marrow. Abnormal proteins from the myeloma cells can cause kidney damage through a variety of mechanisms. B2 Macroglobulin (B2M) is a protein secreted by B-cells that correlates to myeloma cell mass may also indicate kidney damage. B2M level is elevated in plasma of 75% of patients with MM at the time of diagnosis. Although serum B2M is a known prognostic marker for tumor burden, its correlation with markers of renal function is not clear. This study was aimed to determine the serum levels of B2M, albumin, globulins, urea and creatinine in MM patients and study the correlations between B2M and markers of renal function.

Methods: A retrospective study of 40 MM patients attended clinics from 2017 – 2020: 16 females (age, 65 ± 25 years) and 24 males (66 ± 30 years). B2M was measured by Nephelometry using Bekman Coulter Immage 800 Immunochemistry System. Globulin was assessed by Capillary 2 Flex Piercing Sebia. The remaining tests were conducted on Roche Cobas System.

Results: Mean B2M levels were higher in MM patient mean ± SD (12.88 ± 14.96 mg/L) as compared to normal upper limit (2.52 mg/L). Urea (10.87 ± 7.82 mmol/L) and creatinine (170.88 ±

162.82 umol/L) levels were also higher in MM patients as compared to their respective normal limits. Mean albumin level (32.77 ± 7.18 g/L) was lower than normal whereas globulin level (24.89 ± 20.85 g/L) was higher than normal reference. A significant correlation was observed between B2M and urea (R^2=0.368, P<0.05) but not between B2M and creatinine (R^2=0.078, P=0.568). Patients' age was significantly correlated with B2M (R^2=0.367, P<0.05) but not with urea (R^2=0.131, P=0.419).

Conclusion: Our findings suggest that B2M could be used as a prognostic marker for prediction of renal function in MM patients. More importantly, the direct correlation between B2M and urea was found to be independent of patients' age.

ORAL PRESENTATION ABSTRACTS

The Future of Laboratory Medicine in a Changing World

Graham Beastall
IFCC Past President, Glasgow, UK
Email: gbeastall@googlemail.com

The results of laboratory medicine investigations influence a high percentage of all clinical decisions and so have an important impact on clinical outcomes and patient safety. This places a responsibility on laboratory medicine specialists to ensure the quality of the services that they provide and their appropriateness in a rapidly evolving global healthcare environment.

It is informative to look at what the world of business sees as the megatrends in healthcare:

- An ageing population with an increase in chronic disease
- Wellness screening and the prevention of disease
- Technological advance supporting personalised medicine
- Innovation and increased demand, especially in emerging countries
- Evidence-based medicine and the implementation of clinical practice guidelines
- Environmental challenges to health: water, air, food, congestion
- Global pandemics
- Delivery by non-medical healthcare professionals
- Philanthropy, especially in developing countries#
- Patients influencing decisions on their healthcare
- Medical tourism; travelling to other countries for healthcare
- Rising costs and inadequate budgets

Laboratory medicine is an important contributor to these megatrends. Therefore, specialists should seek to shape the future of laboratory medicine rather than react to change.

The opportunity to 'shape the future' comes through active engagement with current drivers for change in laboratory medicine:

- Globalisation
- Technological and informatic development
- Integrated diagnostics
- Patient-centred care
- Adding value to improve clinical outcomes
- Smarter ways of working

'Shaping the future' requires leadership at international, national, and local levels. It is an opportunity for all laboratory medicine specialists.

Human Capital Development Cornerstone is Everyday Assignments

Majdah Abdulhadi Shugdar
Director General –General Administration of Training, Education & Training Evaluation Commission
Email: Mshugdar@etec.gov.sa

Laboratory stakeholders recognize not only the importance of their people but also the need to provide the right skills to enable their employees. Investing in skills development can lead to greater satisfaction and employee retention which helps all stakeholders win. As

the economy develops, the needed skilled manpower is supplied by human capital endowed with training, education, and improved health.

We will discuss how Human Capital Development can improve the performance of the education and training of laboratory sector at all stages from early education to continuing education, and how they should invest in training on an international levels in accordance with modern realities, growth requirements and the local and global labor market, in cooperation with all the related parties.

What Laboratory Manager Needs in the Era of Corona and Artificial Intelligence

Aaron Han
Adjunct Professor of Pathology College of Medicine, Mohammad Bin Rashid University, Dubai, UAE
Email: aaron.han@mbru.ac.ae

The novel pandemic of 2020 has brought the laboratory to the forefront of public health and medicine. With the severity and extensiveness of the illness, the demands on the laboratory for timely and accurate testing has been of utmost importance. The rapid dissemination of scientific information such as sequencing data from China has allowed the healthcare community to respond with appropriate genetic tests and other test platforms. The ability to scale testing is supported by transparency of results, the framework for quality lab testing, and many labs who are certified and accredited.

The tools for evaluation, verification and validation of testing is examined within the College of American Pathologist checklist framework. The provision of proficiency testing, and EQA validation kits has given labs the cross checks to confirm test quality.

We explore some of the tests used for COVID detection and disease stratification. In addition we examine the role of antibody testing, and newer antigen tests. Recommendations for strategies in the overlapping influenza season are discussed.

Logistic Issues to Consider to Improve Laboratory Quality Services

Hisham Shams
Medical Director, Life Diagnostics Laboratories, UAE
Email:h.shams@lifedx.net

Physicians depend on laboratory data in their daily medical decisions. The lab results can have significant impact on patient care and outcomes. This is why the importance of quality laboratory services is indisputable.

In the laboratory, everything starts with proper management of samples. It is crucial to the accuracy and reliability of testing, and, hence, to the trust in laboratory services. When the test is ordered, it starts a complicated process that requires proper specimen collection and transport; and effective logistics and communication.

The wide geographic footprint of Saudi Arabia, and the new regulations of the ministry of health giving independent labs the green light to widen their range of operation, by allowing them to open collection sites, makes the need for new sample management approaches has become critically important. The labs in Saudi are also striving to meet the regulatory and National/International accreditation requirements, and when it comes to the complexity of lab specimen management , this requires a highly sophisticated system of controls, monitors, and useful reports. These systems would also prevent errors that can lead to quality failures, and reduce the chance of unnecessary costs.

This presentation will address quality issues related to specimen management and logistics. It will provide a framework for evaluating specimen processes, overview examples of improved operations related to logistics and supply, and present examples of how laboratories can make the necessary changes.

HCG Between Myth and Reality

Heba Kary
Consultant, Chemical Pathology, King Fahad Armed Forces Hospital-Jeddah, KSA
Email:hebaKary@yahoo.com

Human chorionic gonadotropin (hCG) is a routinely ordered clinical test used to assess pregnancy status, and less commonly ordered

as a tumor marker. While the interpretation of hCG for pregnancy or oncology applications is usually straightforward, the complexity of the molecule and its isoforms and the variety of matrices and testing platforms for hCG create multiple layers of complexity that can lead to challenges in accurate ordering and interpretation. Therefore, it is important for both clinicians and laboratorians to understand the basics of hCG physiology, pathophysiology, and testing to ensure appropriate hCG test utilization and interpretation.

CA19.9 as Tumor Marker is it Reliable

Manal Al KIndi
Senior Consultant, Pathology & Laboratory Medicine Division, The Royal Hospital, Oman
Email:dralkindimanal@gmail.com

Carbohydrate antigen (CA 19.9) is the most extensively studied and validated serum biomarker for the diagnosis of pancreatic cancer . CA 19-9 serum levels can provide important information regarding the prognosis, survival, response to chemotherapy and predict post-operative recurrence. However, there are some limitation for the use of ca19.9 for example non-specific expression in several benign and malignant diseases, false negative results in Lewis negative genotype and an increased false positive results in the presence of obstructive jaundice .In addition there are some analytical consideration that should always consider such as the specificity and sensitivity of the assay , analytical methods, standardization and other source of errors.

Recent Advances in the Molecular Diagnosis of Breast Cancer

Laila Abdel-Wareth
Chair of Clinical Pathology, National Reference Laboratory, Cleveland Clinic Abu Dhabi-UAE)
Email: Warethl@Clevelandclinicabudhabi.ae

Breast cancer is the second most frequently diagnosed malignancy just behind lung cancer, accounting for over two million cases each year globally. It is also the leading cause of cancer death in women worldwide. The genetic predisposition is emerging as one of the key risk factors in the development of breast as well as ovarian cancer.

BRCA1 and BRCA2 are the best-known genes associated with hereditary breast and ovarian cancer. However, recent advances in molecular techniques, Next-Generation Sequencing in particular, have led to the identification of many new genes involved in the predisposition to breast and/or ovarian cancer.

In addition to germline mutations, identification of somatic gene mutations has also contributed a great deal to molecular profiling and individualized treatment of patients diagnosed with breast cancer.

This presentation will discuss recent advances in both fronts and highlight their role in breast cancer risk prediction and treatment.

Overview of Covid-19 Infection

Nisreen AlSherbini
Head of Infectious Diseases Division, Prince Sultan Military Medical City, Riyadh
Email:nalsherbini@psmmc.med.sa

COVID-19 infection, caused by the SARS-CoV-2 virus, which initially emerged in Wuhan, China in December 2019 was declared a Public Health Emergency of International Concern one month later, then reached pandemic status by mid-March 2020. No country has remained untouched and as of today there have been more than 40 million affected cases worldwide. Populations most at risk of infection with serious morbidity or mortality include smokers or those with hypertension, diabetes, chronic cardiac and lung diseases and other chronic illnesses, elderly people and immunocompromised patients. Most infected people will develop mild to moderate illness and recover without hospitalization. Many symptoms are nonspecific fever, fatigue so that the differential diagnosis encompasses a wide range of infections, respiratory and other diseases. The most common symptom are involving the respiratory system: cough, sputum, shortness of breath. Extra pulmonary manifestation can occur at presentation or as a complication in severe infection. Diagnosis is made by using clinical, laboratory and radiological features as all of these can be nonspecific Specific laboratory

diagnosis is based on the detection of viral ribonucleic acid (RNA) by real-time polymerase chain reaction (RT-PCR) of nasal and oro-pharyngeal swab samples. Management involves early detection of the positive cases, prompt and timely isolation, treatment of symptoms, supportive care. Many different specific treatments are being used in clinical trials and via compassionate use protocols and guidelines.

The Evidence of SARS-CoV-2 Infectivity Based on RT-PCR Results and Virus Culture

Hosam Zowawi
Clinical Microbiologist and Infectious Diseases Scientist, King Saud bin Abdualziz University for Health Sciences-KSA
Email:zowawih@ksau-hs.edu.sa

The best strategy to control COVID-19 epidemic is to Test, Trace and Isolate. Diagnosis of COVID-19 is carried out routinely using real-time PCR for SARS-COV-2. Although most of the available tests are qualitative, cycle threshold (Ct) may reflect viral load. Also, prolonged positive rt-PCR results with COVID-19 patients have been reported even after several weeks of symptom onset and after full recovery. It is ideal to use virus culture to confirm if those patients are shedding transmissible viruses. However, SARS-CoV-2 culture is not a routinely used method and requires certain capabilities that are not widely available. Instead of virus culture, and in order to role-out the non-infectious cases, it was suggested to leverage the Ct values as an indicative to determine the infectiousness. This talk will summarize some of the key findings that have established the evidences to rely on Ct value and days after diagnosis to role-out SARS-CoV-2 transmissibility.

COVID-19 and Biochemical Markers

Nafila Al Riyami
Senior Consultant, Medical Biochemist, Sultan Qaboos University Hospital, SQU - Oman
Email: nafilariyami@gmail.com

As we continue to experience the COVID-19 pandemic as a global community, with no real cure or vaccine available in the very near future in sight, the need to understand, manage and live with this disease with the least amount of casualties is absolutely essential. Hence , the amount of literature published in these last few months has been overwhelming , to say the least. In this talk, I will attempt to review the main biochemical and immunological markers that have been effective in the risk stratification and management of COVID-19 patients across the globe. The preliminary results of a local study at Sultan Qaboos University Hospital (SQUH) , Oman , in which various biochemical and immunological markers were measured in COVID-19 patients are briefly discussed.

Emerging Business Continuity Challenges: Lessons Learned From the COVID-19 Pandemic

Faisal Ibrahim
Director of Quality Assurance, *National Reference Laboratory – Abu Dhabi*
Email: faisali40@hotmail.com

Business Continuity (BC) is the strategic and tactical capability of the organization to plan for and respond to incidents and business disruptions in order to continue business operations at an acceptable level and minimal disruption. COVID-19 pandemic represents a real threat to the continuation of laboratory operation services as it can negatively impact caregivers health and wellbeing, supply chain, finance, and most importantly, delivery of results for patient care.

Today, Business Continuity Management is being recognized as a critical element in the emergency and crisis management. Building this capability requires support from the top management to ensure the availability of the needed resources.

The National Reference Laboratory (NRL) in the UAE formed a team late February 2020 to manage all BC related activities. The previously prepared BC program served as a foundation for Covid-19 BC response. The main objectives of the BC program are:

- Ensure continuity of business and minimize business disruption
- Align NRL BC activities with local and national regulations and guidelines

- Caregiver's health and safety
- Compliance with all new regulations related to Covid-19
- Continually improve NRL resilience to internal and external challenges

The BC team was in a continuous communication with various shareholders such as Department of Health, Dubai Health Authority, Police, and National Emergency Crisis and disaster Management (NCEMA) to ensure all guidance and updates are followed as the situation and developments were rapidly changing.

Several meetings were held internally and externally to timely respond and address the changes and developments. Frequent and concise communication to NRL staff played a major role in the success of the BC program.

The BC team worked in a number of activities including:

- Working with the Facility Management team to scale up the cleaning and sterilization activities, conduct frequent decontamination of common areas, and fumigate the workplace after hours and on weekends
- Remodel the office space and pantries to observe for physical distancing and placing signage's throughout the facilities
- Completed a comprehensive risk assessment for the remodeled areas of the laboratory
- Collaborate with suppliers to ensure that critical supplies are available and global supply chain shortage do not lead to cessation of work
- Restructure of work schedule by forming separate teams for each department to avoid cross-contamination of the various team members
- Frequent testing of staff to ensure timely identification of COVID19 cases and taking precautionary measures
- Securing accommodation and monitoring of Covid-19 positive caregivers
- Hotel accommodation was offered and arranged for laboratory caregivers working directly with COVID 19 testing to isolate them from their families and the community
- Obtain approval from the authorities to allow staff to travel to and from work during the curfew hours

Despite all challenges, NRL continued its operation throughout the pandemic without any disruption of its services. This is a testament of the organization's resilience and readiness to operate in challenging times. NRL team spirit during the pandemic, played a major role in the success of the organization to conduct thousands of tests on a daily basis which contributed to place the United Arab Emirates on the top of the World Chart for the number of tests performed per capita

Update on CAP: Clinical Chemistry Standards

Suzanne Kamel-Mohamed
Laboratory Director. *WYOMED Lab, Laramie, Wyoming Labtech Diagnostic LLC (USA)*
Email: Skamel131@hotmail.com

We are living in an unprecedented era in the file of clinical laboratory that we have not experienced in our lifetime.

With the covid-19 pandemic, clinical laboratories found themselves facing the need of validating testing in very short time, and move from one testing platform to another, in order to keep the continuity of testing without interruption and providing clinicians with results in timely manner to be able to treat critically ill patients. Such an extreme shortage of supplies and steady high demand is a worldwide crisis, that Medical laboratories had never faced before.

International and national organizations are approving Instrumentation and reagents to be used for Covid-19 testing with an emergency use authorization. Laboratorians still to validate those testing methods effectively and safely, including IgG, IgM, and IgA testing by chemistry analyzers.

New CAP Clinical Chemistry Standards that were published in the Chemistry and All Common check lists of 2019, and 2020 will be discussed in this presentation. Those Standards include, but not limited, to the followings:

Manufacturer's Instructions, Verification of Test Performance for FDA-cleared/approved Tests, Verification of Test Performance for tests approved by an Internationally Recognized Regulatory Authority, and Validation of Test Performance for modified FDA-cleared/approved tests and LDTs

Instruments Comparison:
Comparability of Instruments and Methods, in general and especially for those that are different platforms but producing results of same analytes as for Covid-19 antibodies.

Method Validation.
Manufacturer's Instructions, Verification of Test Performance for FDA-cleared/approved Tests, Verification of Test Performance for tests approved by an Internationally Recognized Regulatory Authority, and Validation of Test Performance for modified FDA-cleared/approved tests and Laboratory developed tests (LDT)

Calibration:
Calibration procedure, verification materials, recalibration verification criteria, AMR materials,
Cutoff values

Quality Control:
Qualitative (Fluorescent Antibody Stain), QC range establishment for unassuaged control materials or verification for assayed

Test reporting:
Specially for both Anti-Nuclear Antibody

HIV testing:
The laboratory follows public health recommendations or guidelines for HIV primary diagnostic testing, including primary screening and additional (supplemental and/or confirmatory) testing.

CBAHI 2020

Nouf Al Saleem
Manager of Clinical Laboratories and Blood Banks Accreditations Sections/ Laboratories Surveyor, Saudi Council Board Accreditation-Riyadh-KSA)
Email: nbinsaleem@cbahi.gov.sa

As a result of the complex healthcare system, preventable medical errors can occur and lead to adverse events that affect patient safety and quality as well as leading to wasted resources. Medical errors were found to be responsible for around 250,000 deaths per year in US. In laboratories, errors can occur at any stage of sample processing; pre-analytical, analytical, and post analytical stages.

To overcome this challenge, it was mandatory to understand the nature of the complex system and human nature and to apply a quality management system that ensures reliable organizations that provide high quality error free services. Quality Assurance (QA) as one of the main quality management system's components, ensures comply with certain standards to prevent mistakes from happening. Accreditation as a form of external quality assurance process reflects the commitment and the comply of healthcare facilities in meeting standards that enhance to optimize the quality of services and patient care.

This lecture will highlight the role of CBAHI as the Saudi healthcare accreditation body in supporting healthcare institutes to implement quality and patient safety standards. Focusing on laboratories standards in all its active programs, and the approaches adapted in reaction with COVID-19 pandemic in 2020.

Point-of-Care Testing and the Covid-19 Pandemic

Adil Khan
Associate Prof. of Pathology/Director of POCT & Clinical Chemistry, Temple University Health System, Lewis Katz School of Medicine, Temple University-Philadelphia, USA
Email: adil.khan@temple.edu

Adil I. Khan PhD is an Associate Professor of Pathology at the Lewis Katz School of Medicine, Temple University, in Philadelphia and the Director for Point-of-Care Testing and Clinical Chemistry for the Temple University Health System. He completed his MSc from the United Kingdom in Immunology of Infectious Diseases from at the London School of Hygiene & Tropical Medicine (1992) and his PhD in Immunology from the Hammersmith Hospital Campus of the National Heart & Lung Institute, Imperial College

London (2000). Dr. Khan then pursued a postdoctoral research fellowship at the University of Calgary, Canada studying the role of L-selectin and CD44 in models of acute inflammation, followed by a Postdoctoral Clinical Chemistry Training Fellowship at the University of Texas Southwestern Medical Center at Dallas. Since 2006 he has been teaching at Temple University, lecturing to pathology residents, medical students, and students of podiatric medicine. Dr. Khan's research interests include understanding the role of adhesion molecules and extracellular vesicles in inflammation, and identifying novel markers of inflammation. On the clinical side, as well as providing expert consultation to his colleagues, he his interest is in clinical trials of point-of-care testing devices /laboratory instruments, and assay development. He is a national and international speaker, has numerous publications, co-authored various laboratory guidelines for the Clinical Laboratory Standards Institute, organized workshops and symposia. He has also been the treasurer and past chair of the Philadelphia section of the American Association of Clinical Chemistry and is currently the Chair of the International Federation of Clinical Chemistry and Laboratory Medicine Executive Board Committee on Point-of-Care Testing.

Point-of-Care Testing and the Covid-19 Pandemic

Najwa Adlan
Core Lab & Blood Bank Supervisor, Al Dara Hospital & Medical Center, Riyadh, KSA
Email: najwa_kka@hotmail.com

Point-of-care testing (POCT) is the analysis of patient specimens outside the clinical laboratory, near or at the site of patient care, usually performed by clinical staff who are not laboratorian, as ordered from the treating physician. It can provide a rapid result near the patient and which can be acted upon immediately. Fast turnaround time is crucial in many cases to save lives; it is also believed to aid in better patient outcomes and disease management. Point of care testing can cost more than a conventional laboratory test that mandates cost analysis before implementing proper resource management. This is a review for different accreditation bodies, specifically the Central Board of Saudi Healthcare Accreditation, College of American pathologist and ISO 15189. In addition to discussion of comparison and ways to apply standards. In a survey performed, it was noticed that the level of knowledge of test specification and interferences is remarkably higher in organizations that have applied more accreditations standards.

Evolution of a POCT Training and Competency Renewal Program

Jonathan Harris
Senior Manager, POCT & Quality, National Reference Laboratory / Cleveland Clinic, UAE
Email: jnmharris2000@yahoo.com

The point-of-care testing (POCT) department at Cleveland Clinic Abu Dhabi set out to transform the organization and management of its training and competency renewal program. Managing competencies in any large hospital is challenging for all POCT coordinators. Initially, a paper-based system was created, which was cumbersome and error prone, which led to many clerical and logistical challenges. As the scope of the program grew, this approach became more difficult to govern.

In an effort to streamline the process, the department embarked on several continuous improvement projects to address this pressing issue. In collaboration with the laboratory information technology and hospital learning specialist teams, the POCT department has successfully streamlined and standardized its competency approach, migrating to Learning Management System (LMS) platform. Although limitations in devices and middleware systems for POCT remain challenging, using the resources and expertise available has led to significant improvements and efficiencies. The transition has been educational and hugely beneficial to the laboratory and the hospital.

In collaboration with our nursing education colleagues, the POCT team plan more enhancements and innovations in the year ahead. This includes simulation, game-based learning, and the concept of gamification (which is an available functionality on LMS). Discussions are taking place with other Middleware providers with a view to integrate with LMS also. The POCT team will also look at different methods of assessing competency,

which will add value to experienced staff as well as new ones to promote deeper learning. Error detection reports will be pulled annually from middlewares and analyzed before recertification. Key learning points will be derived from this analysis. Any caregiver identified with multiple errors will be retrained.

The evolution of the POCT training and recertification program has been one of discovery and deep learning. This has only been made possible through collaboration with IT service, nursing education, and superusers on the floors. The training program that exists now is more sophisticated and superior than what existed at the outset. This is a credit to the tenacity and passion of the POCT team (manager and coordinators), IT team, nursing colleagues, and nursing leadership.

Automation in Clinical Laboratory, Establishment and Considerations

Zahir Alshehry
Consultant Clinical Scientist & Head of Clinical Chemistry, King Fahad Medical City-Riyadh
Email: zalshehry@kfmc.med.sa

Laboratory services are one of the highly demanded services in the healthcare system, more than 80% of clinical decisions depend on laboratory services. However, with the advancement in the healthcare system, it is facing many challenges including increased demand, incremented cost of these services and the need to utilize the resources to meet the governmental and community expectations.

These challenges drive the need to “do more with less” logistics and manpower. “Automation in clinical laboratories” concept emerged to improve the laboratory performance with minimal involvement of medical technologists. The automation concept evolved over decades from analytical automation (or tests’ procedure automation) to full automation which includes pre-analytical, analytical and post-analytical processes. However, this progression was not that easy to address, due to a lot of challenges that were faced during this development.

Each laboratory has its own nature of the scope of services, demands, design and resources which drive the decision-makers to go for automating the lab process or not. Therefore, the establishment of the automation system should take into consideration many challenges that are dependent on the laboratory sittings, goals, scope of services and resources.

In this presentation we will discuss the feature of automation systems, the process of establishment and the challenges that need to be taken into consideration from planning the automation project, selection, establishment, until launch.

Aldosterone & Renin: A Key Workup of Hypertension

Gruson Damien
Head of Department of Clinical Biochemistry, Cliniques Universitaires Saint Luc, Brussels
Email: damien.gruson@uclouvain.be

Hypertensive condition is more and more common in the general population, and the identification of its origin is important and allows the initiation of the appropriate treatment and the prevention of adverse cardiovascular events. Primary aldosteronism (PA), first described by J. Conn in 1955, represents around 8–10% of refractory hypertension. PA results from an abnormal secretion of aldosterone, mainly adenoma of the adrenals. Screening for PA should be initiated in patients with severe hypertension, refractory hypertension, hypertension in young patient, hypertension associated with hypokalemia, a familial hypertension, a familial history of primary hyperaldosteronism and an adrenal incidentaloma. An efficient screening for PA and rapid initiation of treatment will improve the quality of life and prognosis of patients.

Biomarkers, and more specifically the measurement of aldosterone and renin, are key contributors to identify the hypertensive patients with PA. Indeed, the aldosterone to renin ratio (ARR) is currently the most reliable marker used in the screening for PA. The use of the ARR has led to

a marked increase in the detection rate of PA. However, ARR is dependent on the reliability and sensitivity of the aldosterone and renin measurements. Automated assays have been developed for renin and therefore an automated aldosterone assay may facilitate both assays on the same blood sample.

Testing for aldosterone and renin might also participate to the sub-phenotyping and risk estimation of cardiovascular diseases such as heart failure.

Freelite® in the Management of Multiple Myeloma

James Iain Keith Last
Medical Science Liaison Manager for International Sales, The Binding Site Group Ltd. - UK
Email: james.last@bindingsite.co.uk

Monoclonal free light chains (FLC) are valuable disease biomarkers in patients with plasma cell proliferative disorders. Increasing evidence highlights the importance of laboratory algorithms that measure monoclonal FLC, both at diagnosis and when monitoring response to treatment, in multiple myeloma (MM) patients. Freelite® is a latex-enhanced immunoassay that provides an independent measurement of serum κ and λ FLC. The calculation of a κ/λ serum FLC ratio provides a sensitive numerical indicator of clonality. Freelite was developed using polyclonal antibodies to detect the diverse variety of pathological monoclonal FLC produced by patients with multiple myeloma and other monoclonal gammopathies.

The introduction of serum FLC immunoassays has impacted on laboratory practice for the management of multiple myeloma. In 2014, an involved/uninvolved sFLC ratio □ 100 (iFLC □ 100 mg/L) has been included as part of the IMWG diagnostic criteria for MM patients without evidence of end organ damage. The clinical utility of these immunoassays at diagnosis, for patient monitoring and for prognosis has been acknowledged in guidelines published by the International Myeloma Working Group (IMWG). These consensus guidelines recommend serum FLC assessment in combination with serum protein electrophoresis (SPE) at diagnosis of clonal plasma cell disorders. This simple serum-based algorithm at diagnosis negates the need for 24-hour urine studies for diagnoses other than light chain amyloidosis. Serum FLC measurement should be routinely performed during the monitoring of AL amyloidosis, oligosecretory multiple myeloma and light chain deposition disease with periodic measurement for the detection of light chain escape. Furthermore, the IMWG uniform response criteria also define a stringent complete response (sCR) as requiring a normal serum FLC ratio. More recently, evidence has been provided for using sFLC measurement instead of uBJP measurement as the target of response assessment in LCMM in addition to a growing volume of evidence indicating the clinical benefit of including sFLC measurement in the serial monitoring of patients with MGUS, the precursor disease stage to MM.

The incorporation of serum FLC immunoassays into diagnostic, prognostic and monitoring algorithms for multiple myeloma and other plasma cell disorders has led to a paradigm shift in the understanding of these diseases and revolutionised how they are managed.

The Value of Preeclampsia Assays (sFlt-1/PlGF) in Clinical Management , The Earlier is the Better

Manu Vatish
Senior Clinical Fellow & Consultant in Obstetrics, Nuffield Department of Women's & Reproductive Health, University of Oxford, UK
Email: manu.vatish@wrh.ox.ac.uk

Preeclampsia is a pregnancy disorder causing substantial maternal and fetal morbidity and mortality. Its diagnosis currently depends upon identification of new onset hypertension and proteinuria or evidence of end organ damage. There is a clinical need for enhanced screening to prevent unnecessary resource use and improve outcomes. Although the combination of new onset hypertension and proteinuria define and hence diagnose the disorder, they are poorly predictive of adverse outcomes. Preeclampsia is ultimately a placental disease caused by

syncytiotrophoblast dysfunction. The angiogenic factors soluble fms-like tyrosine kinase 1 and placental growth factor, both originating at least in part from the syncytiotrophoblast, are biomarkers with predictive potential for preeclampsia and related adverse outcomes. Recent work with the soluble fms-like tyrosine kinase 1/placental growth factor ratio has identified key measurement cutoffs, with one having a high negative predictive value for preeclampsia. The soluble fms-like tyrosine kinase 1/placental growth factor ratio seems particularly promising as a screening measure, able to accurately predict the short-term absence of preeclampsia and suggest the likelihood of adverse events within 4 weeks. The ratio can be used to allocate specific management plans to patients according to risk. We will discuss the science behind sFlt1/PlGF and how clinical studies have led to its implementation as routine testing in Oxford and the UK.

Challenges in Medical Education During COvid-19 Pandemic

Altaf AbdulKhaliq
Assistant Professor of Clinical Biochemistry, College of Medicine & Consultant of Investigative Endocrinology, Metabolism & Bone Metabolism, College of Medicine, Umm Al-Qura University, Makkah, Jeddah-KSA
Email: dr.altaf@gmail.com

Following the declaration of COVID-19 as a pandemic status by WHO on March 2020 [1], tremendous risks have emerged in medical education especially for the newly medical graduates and junior doctors. The need for adaptation in medical education was inevitable and crucial during this situation globally. In Saudi Arabia, the quarantine status began earlier than the declaration, so almost all medical students and other health specialties students' clinical, practical, or laboratory training stopped in the hospitals, because the health-care sectors concerned on taking care of patients with COVID-19 and avoiding the spread of the infection. Furthermore, much pressure has increased the necessity to ensure the appropriate training of the students to strengthen the nearly graduating workforce reserve. Hence, all medical colleges had the urgency for constructing strategic plans to continue the learning process and formulate the appropriate assessment methods. The ramification of COVID-19 pandemic is challenging the medical educational expertise to deal and adapt with these exceptional circumstances. Huge dependent on technology for online, simulated, and virtual learning have been taken place globally during this period. Heterogenous assessment approaches were adopted by medical colleges either nationally or internationally. Currently, with persistence of COVID-19 pandemic, medical colleges and hospitals are adapting the "new normal" status, however, would the students gain the education and clinical experience they need to qualify to next level?

Therefore, the related presentation to this abstract will consider the following objectives:

- Determine the impact of COVID-19 pandemic on ME process.
- Identify the challenges that Medical Colleges have encountered during physical distancing.
- Explain the strategic plan to overcome the pointed issues and step forward.
- Highlight on the fundamental roles of technology in teaching and assessment.
- Discuss the Placement-Based Learning vs Bedside Teaching in adapting to the "new normal".

Developing Research Ideas

Suhad Bahijri
Department of Clinical Biochemistry, Head of Saudi Diabetes Research Group (SDRG), Faculty of Medicine & King Fahad Medical Research Centre, King Abdulaziz University, Jeddah-KSA
Email: sb@kau.edu.sa

Coming up with ideas for research is not an easy task, but it becomes easier with time and experience. Research is a form of problem solving, so the problem has to be first identified. Reading is the first step. Once a point of interest is found, search engines and various sites will provide enough information to help in deciding whether the chosen topic is worth researching, and feasible to do or not. Following the initial reading, the second step is to start narrowing

down the areas of interest. This is achieved by picking the topic of most interest then reading in depth about it. The third step is making a list of all limitations and points left unanswered in earlier published studies about the topic of choice. This is followed by more serious reading and searching the scientific journals for updates on various points on the list, using appropriate tools and key word. Writing notes of how references intersect and formulating final question to be researched is the last step.

Finally, it is most important to always keep an inquisitive mind, choose an enjoyable topic without prior expectations of results to avoid bias and disappointments. Remember that

Alcohol Toxicity

Sumayah Aljenedil
Consultant Chemical Pathologist, Clinical Lipidologist, Department of Pathology and Laboratory Medicine, King Faisal Specialist Hospital Research Center, Riyadh, KSA)
Email: dr.sumaia@hotmail.com

Objective of the presentation:

1. Outline the common toxic alcohols
2. Discuss the pharmacology, kinetics and pathophysiology of the toxic alcohols
3. Discuss the diagnosis, clinical manifestations,
4. Review the management of patients poisoned by these agents

The Use of Portable Raman Spectroscopy for Detection of Drugs in and Outside of the Laboratory

Sulaf Assi
Senior Lecturer in Analytical Forensic Chemistry, *Liverpool John Moores University, UK*
Email: s.assi@ljmu.ac.uk

Over the last few years, handheld Raman spectroscopy has emerged as a powerful tool for the instant identification of wide variety of analyse including drug substances. Particularly in cases of drugs and metabolites, Raman spectroscopy provides a fingerprint signature that is characteristic to the specific analogue. Handheld Raman offers a further advantage in being rapid, of light-weight, long battery life time and thus in can carry the laboratory to the sample saving the time and cost involved in analysis. Yet, there are challenges associated with the use of handheld Raman spectroscopy for identification of drugs in different matrices. Therefore, this presentation aims at evaluating the use of handheld Raman spectroscopy for chemical analysis of drugs in products and biological fluids. In this respect, conventional and surface enhanced Raman spectroscopic methods will be assessed for identification of drugs at different sites including: street drugs, counterfeit medicines, drugs and metabolites in biological fluids and tissues. The assessment criteria will consider the International Conference on Harmonisation and pharmacopeial guidelines in reference to classical analytical techniques such as gas chromatography-mass spectrometry and immunoassays. Subsequently, the outcomes will be beneficial for scientists, practitioners, regulatory officers and law enforcement officers dealing with medicinal and drug products

Hair Analysis in Clinical & Forensic Toxicology

Alberto Salomone
Associate Professor, University of Turin, Italy
Email: alberto.salomone@antidoping.piemonte.it

Serious challenges to detect the presence of psychoactive substances in biological matrices, especially urine, are posed by the extensive metabolic transformation that these substances undergo once introduced into the body. Furthermore, most drugs are eliminated from blood and urine within a few hours or days. Thus, only very recent use can be detected, preventing clear knowledge of the real consumption of these new drugs in the population.

To circumvent these limits, the detection of the parent drugs in hair samples has been proposed. Unlike in urine, the parent drug usually represents the target analyte in the keratin matrix, that incorporates it from the sweat and/or the bloodstream, the sebum, and from external contamination. The drug-fixing into the hair structure resists hair growth for several months and leads to a potential chronological trace of exposure, with further periods corresponding to hair segments more distant from the root.

Because of its long diagnostic window, hair analysis represents a fundamental approach to obtain useful information about past use, which can be of help in clinical (such as intoxication cases) or forensic situations (such as sexual assaults or children sedation). More in general, hair analysis is important to understand new phenomena of drug abuse, drug diffusion among selected populations on geographical or sociological basis, and drug use patterns and prevalence. In this presentation, hair analysis will be introduced and discussed. Different examples from clinical and forensic cases will be also presented.

50 Years of Laboratory Medicine

Roger Bertholf
University of Florida Health Science Center, ASCP-USA
Email: roger.bertholf@jax.ufl.edu

This session will look back at 50 years of the ASCP journal Laboratory Medicine. Important events in the history of the journal will be highlighted, and the evolution of clinical laboratory practice since 1970 will be discussed. Several influential papers will be selected from the archives of Laboratory Medicine and presented, with a discussion of their impact on the profession. Historic anecdotes will be included, and the session will also involve trivia questions to challenge attendees' recollection of various aspects of the journal's history. The session is intended to be fun and informative.

Learning Objectives:

- Describe how and why the journal *Laboratory Medicine* was created and the professional group it was intended to serve.
- Trace the evolution of *Laboratory Medicine* in the context of clinical laboratory practice over the past 50 years.
- Cite several influential scientific papers that appeared in *Laboratory Medicine*

www.hjhs.org.sa

HJHS | Hail Journal of Health Sciences

Date of Submission: November 24, 2020
Date of Publishing: November 30, 2020

All abstracts were reviewed by the Saudi Society for Clinical Chemistry-Scientific Committee