

المؤتمر السنوي السادس
للجمعية السعودية
للكيمياء السريرية

6th ANNUAL
CONFERENCE

Saudi Society for
Clinical Chemistry

DECEMBER 1-3, 2020



ABSTRACT BOOK

الجمعية تحت إشراف



الهيئة السعودية للتخصصات الصحية
Saudi Commission for Health Specialties



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Introduction and Welcome

Dear Colleagues,


We are pleased to host the 2nd International Meeting in Clinical Chemistry & Laboratory Medicine & 6th Annual Meeting Saudi Society for Clinical Chemistry with an education and scientific programs paired with industry workshops from 1-3 December 2020.

The virtual meeting is designed to meet the needs of laboratory Physicians, Supervisors, Directors, and Managers, as well as pathologists and other laboratory professionals overseeing or carrying out Clinical Chemistry, Toxicology, Clinical Pathology and Point-of-Care Testing.

The scientific program features experts from International Federation of Clinical Chemistry and Laboratory Medicine, USA, Europe, the Middle East and Saudi Arabia, sharing recent advances and innovations. Scientific conference attendees will listen and network with experts in the field and engage with their peers for a unique learning experience. Furthermore, the scientific program will feature the latest updates of clinical testing including, laboratory management, tumor biomarkers, accreditation and quality management, COVID-19 disease, automation, point-of-care testing, education and research, and toxicology.

The meeting is a learning and sharing platform for all laboratory workers to advance professionally and develop solution for daily practice in the laboratory. We would like to take this opportunity to extend our gratitude to the Saudi Commission for Health Specialties, our speakers for their support to Saudi Society for Clinical Chemistry. We also like to offer special thanks to our sponsors for their participation and support for the conference.

On behalf of Saudi Society for Clinical Chemistry, we wish you a successful meeting and look forward seeing you again in 2021.

 **Dr. Samia Sobki**
SSCC President



1-3 December 2020

Management Board for Saudi Society for Clinical Chemistry

2018 – 2022

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1-3 December 2020

Speakers Day (1)

- ❖ Dr. Graham Beastall, *IFCC Representative, UK*
- ❖ Dr. Majdah Abdulhadi Shugdar, *General Administration of Training Education and Training Evaluation and Commission*
- ❖ Dr. Aaron Han, *Mohammad Bin Rashid University, Dubai, UAE*
- ❖ Dr. Hisham Shams, *Life Diagnostics Laboratories, UAE*
- ❖ Dr. Heba Kary, *King Fahad Armed Forces Hospital, Jeddah, KSA*
- ❖ Dr. Manal Al Kindi, *Royal Hospital, Oman*
- ❖ Dr. Laila Abdel-Wareth, *National Reference Lab/Cleveland Clinic Abu Dhabi, UAE*
- ❖ Dr. Nisreen Alsherbini, *Prince Sultan Military Medical City, Riyadh, KSA*
- ❖ Dr. Hosam Zowawi, *King Saud Bin Abdulaziz University for Health Sciences, KSA*
- ❖ Dr. Nafila Riyami, *Sultan Qaboos University Hospital, Oman*

Speakers Day (2)

- ❖ Mr. Faisal Ibrahim, *National Reference Laboratory, UAE*
- ❖ Dr. Suzanne Kamel-Mohamed, *WYOMED Lab, Laramie, Wyoming Labtech Diagnostic LLC (USA)USA*
- ❖ Ms. Nouf Al Saleem, *Saudi Council Board Accreditation, Riyadh, KSA*
- ❖ Dr. Adil Khan, *Lewis Katz School of Medicine, Temple University-Philadelphia, USA*
- ❖ Ms. Najwa Adlan, *Al Dara Hospital Medical Center, Riyadh, KSA*
- ❖ Mr. Jonathan Harris, *National Reference Laboratory/Cleveland Clinic, Abu Dhabi, UAE*
- ❖ Dr. Zahir Alshehry, *King Fahad Medical City, Riyadh, KSA*
- ❖ Prof. Gruson Damien, *Cliniques Universitaires Saint Luc, Brussels*
- ❖ Dr. James Lain Keith Last, *The Binding Site Group Ltd., UK*
- ❖ Prof. Manu Vatish, *Nuffield Department of Women's & Productive Health, University of Oxford, (UK)*

Speakers Day (3)

- ❖ Dr. Altaf Abdulkhaliq, *Umm Al-Qura University, Makkah, Jeddah, KSA*
- ❖ Dr. Kamran Mirza, *Loyola University Chicago, Health Sciences Campus (ASCP-USA)*
- ❖ Prof. Sohad Bahijri, *King Abdulaziz University, Jeddah-KSA*
- ❖ Dr. Sumayah Aljenedil, *King Faisal Specialist Hospital Research Center, Riyadh, KSA*
- ❖ Dr. Sulaf Assi, *Liverpool John Moores University, UK*
- ❖ Prof. Alberto Salomone, *University of Turin, Italy*
- ❖ Dr. Roger Bertholf, *University of Florida Health Science Center, ASCP-USA*

Moderators

- ❖ Dr. Nashaat Nafouri, *NGHA, Jeddah, KSA*
- ❖ Prof. Khalid Al Harbi, *King Saud University Hospital, KSA, Riyadh*
- ❖ Dr. Zuheir Awan, *KAU/Al Borg, Jeddah, KSA*
- ❖ Dr. Ali Al Johi, *PSMMC, Riyadh, KSA*
- ❖ Dr. Malak Al Mashali, *PSMMC, Riyadh, KSA*
- ❖ Dr. Anwar Borai, *NGH, Jeddah, KSA*
- ❖ Dr. Sultan Mohammed Alouffi, *University of Hail, KSA*
- ❖ Dr. Waleed Al Omaim, *KFSHRC, Riyadh, KSA*
- ❖ Dr. Salam Saadeddin, *PSMMC, Riyadh*

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Workshop 1 Speakers

- ❖ Mr. Jean-Charles Clouet, *Siemens*
- ❖ Mr. James Freeman, *Siemens*
- ❖ Dr. Wim van der Helm, *Roche Diagnostic*
- ❖ Mr. Nico Vandepoele, *Bio-Rad/Al Jeel*

Workshop 2 Speakers

- ❖ Dr. Moner Ragas, *Beckman, UAE*
- ❖ Dr. Marvin Berman, *Abbott*
- ❖ MS. Stephanie Penaud, *Becton Dickinson*

Workshops 1 & 2 Moderators

- ❖ DR. Ali Al Shanguity, *MOH, Riyadh, KSA*
- ❖ Dr. Fahad Al Harbi, *PSMMC, Riyadh*



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1-3 December 2020

Scientific Program

DAY 1 SCHEDULE: Tuesday, December 1, 2020

4:00 pm – 4:15 pm	Opening Remarks	Dr. Ali Al Othaim (SSCC Vice-President,)
Time		Speakers
PLENARY LECTURE Keynote IFCC Lecture		
4:15 pm – 5:00 pm	The Future of Laboratory Medicine in a Changing World	Dr. Graham Beastall (IFCC Representative- UK)
SESSION 1 Laboratory Management Moderator: Dr. Nashaat Nafouri		
5:00 pm – 5:25 pm	Human Capital Development Cornerstone is Everyday Assignments	Dr. Majdah Abdulhadi Shugdar (Director General - ESTEC)
5:25 pm – 5:50 pm	What Laboratory Manager Needs in the Era of Corona and Artificial Intelligence	Dr. Aaron Han (American Hospital Dubai Lab - UAE)
5:50 pm – 6:15 pm	Logistic Issues to Consider to Improve Laboratory Quality Services	Dr. Hisham Shams (Life Diagnostics Laboratories, UAE)
6:15 pm – 6:25 pm	Question and Answer	
6:25 pm – 6:40 pm	Break	
SESSION 2 Tumor Biomarkers Moderator: Prof. Khalid K. Al Harbi		
6:40 pm - 7:05 pm	HCG Between Myth and Reality	Dr. Heba Kary (KFACFH – KSA)
7:05 pm – 7:30 pm	CA19.9 as Tumor Marker is it Reliable	Dr. Manal Al Kindi (Royal Hospital - Oman)
7:30 pm – 7:55 pm	Recent Advances in the Molecular Diagnosis of Breast Cancer	Dr. Laila Abdel-Wareth (National Reference Laboratory, Cleveland Clinic Abu Dhabi-UAE)
7:55 pm – 8:05 pm	Question & Answer	
8:05 pm – 8:20 pm	Break	
SESSION 3 COVID-19 Moderator: Dr. Zuheir Awan		
8:20 pm – 8:45 pm	Overview of Covid-19 Infection	Dr. Nisreen AlSherbini (PSMMC-KSA)
8:45 pm – 9:10 pm	The Evidence of SARS-CoV-2 Infectivity Based on RT-PCR Results and Virus Culture	Dr. Hosam Zowawi (King Saud bin Abdulaziz University -KSA)
9:10 pm – 9:35 pm	COVID-19 and Biochemical Markers	Dr. Nafila Al Riyami (SQU - Oman)
9:35 pm – 9:45 pm	Question and Answer	



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Scientific Program

DAY 2 SCHEDULE: Wednesday, December 2, 2020

Time		Speakers
Virtual Booth/Industry Workshop 1 Moderator: Dr. Ali Al Shangity		
3:30 pm – 3:40 pm	Siemens Healthineers Multiple Testing Solution Related to COVID19	Mr. Jean-Charles Clouet <i>Head of Clinical Marketing, Siemens Healthineers</i>
3:40 pm – 4:00 pm	Latest Collaboration Study with CDC	Mr. James Freeman <i>Vice President Global Immunoassay Dev., Siemens Healthineers</i>
4:00 pm - 4:20 pm	SARS-CoV-2 Serology Testing	Dr. Wim van der Helm <i>Head of Healthcare Development –Roche Diagnostic</i>
4:20 pm – 4:40 pm	Evaluation Mean/SD and How to Perform QC Cross-cover Studies According to CLSI C24	Mr. Nico Vandepoele <i>(Scientific and Professional Affairs Manager – Bio-Rad)</i>
4:40pm – 4:55pm	Questions and Answers	
SESSION 4 Accreditation & Quality Management Moderator: Dr. Ali Al Johi		
5:00 pm – 5:25 pm	Emerging Business Continuity Challenges: Lessons Learned From the COVID-19 Pandemic	Mr. Faisal Ibrahim <i>(National Reference Laboratory-UAE)</i>
5:25 pm – 5:50 pm	Update on CAP: Clinical Chemistry Standards	Dr. Suzanne Kamel-Mohamed <i>(WYOMED Lab, Laramie, Wyoming Labtech Diagnostic LLC -USA)</i>
5:50 pm – 6:15 pm	CBAHI 2020	Ms. Nouf Al Saleem <i>(Saudi Council Board Accreditation-KSA)</i>
6:15 pm – 6:25 pm	Question and Answer	
6:25 pm – 6:40 pm	Break	
SESSION 5 Point-of-Care Testing Moderator: Dr. Malak Al Mashaali		
6:40 pm - 7:05 pm	Point-of-Care Testing and the Covid-19 Pandemic	Dr. Adil Khan <i>(Lewis Katz School of Medicine, Temple University- USA)</i>
7:05 pm – 7:30 pm	POCT: Meeting Accreditation Standards	Ms. Najwa Adlan <i>(Al Dara Hospital & Medical Center - KSA)</i>
7:30 pm – 7:55 pm	Evolution of a POCT Training and Competency Renewal Program	Mr. Jonathan Harris <i>(National Reference Laboratory, Cleveland Clinic Abu Dhabi-UAE)</i>
7:55 pm – 8:05 pm	Question & Answer	
8:05 pm – 8:20 pm	Break	
SESSION 6 General Clinical Chemistry Moderator: Dr. Anwar Borai		
8:20 pm – 8:40 pm	Automation in Clinical Laboratory, Establishment and Considerations	Dr. Zahir Alshehry <i>(King Fahad Medical City-Riyadh)</i>
8:40 pm – 9:00 pm	Aldosterone & Renin: A Key Workup of Hypertension	Prof. Gruson Damien <i>(Cliniques Universitaires Saint Luc, Brussels)</i>
9:00 pm – 9:20 pm	Freelite in the Management of Multiple Myeloma	Dr. James Iain Keith Last <i>(The Binding Site Group Ltd. -UK)</i>
9:20 pm – 9:40 pm	The Value of Preeclampsia Assays (sFlt-1/PIGF) in Clinical Management, the Earlier is the Better	Prof. Manu Vatish <i>(University of Oxford -UK)</i>
9:40 pm – 9:50 pm	Question and Answer	

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Scientific Program

DAY 3 SCHEDULE: Thursday, December 3, 2020

Time		Speakers
Virtual Booth/Industry Workshop 2 Moderator: Dr. Fahad Al Harbi		
4:00 pm - 4:20 pm	Beckman Coulter Total Solutions to Fight Against COVID-19 Pandemic	Dr. Moner Ragas (Beckman- UAE)
4:20 pm - 4:40 pm	Metabolic Syndrome, Diabetes Care and Improved Healthcare using HbA1c	Dr. Marvin Berman (Abbott)
4:40 pm - 4:55 pm	Extending the COVID-19 Testing Capacity with POC Solutions	Ms. Stéphanie Penaud (BD EMA Product Manager BD)
SESSION 7 Education & Research Moderator: Dr. Sultan Alouffi		
5:00 pm - 5:25 pm	Challenges in Medical Education During COVID-19 Pandemic	Dr. Altaf AbdulKhalig (Umm Al-Qura University - KSA)
5:25 pm - 5:50 pm	Using Social Media for Pathology Education	Dr. Kamran Mirza (ASCP-USA)
5:50 pm - 6:15 pm	Developing Research Ideas	Prof. Suhad Bahijri (KAU-KSA)
6:15 pm - 6:25 pm	Question & Answer	
6:25 pm - 6:40 pm	Break	
SESSION 8 Toxicology Moderator: Dr. Waleed Al Omair		
6:40 pm - 7:05 pm	Alcohol Toxicity	Dr. Sumayah Aljenedil (KFSHRC-KSA)
7:05 pm - 7:30 pm	The Use of Portable Raman Spectroscopy for Detection of Drugs In and Outside of the Laboratory	Dr. Sulaf Assi (Liverpool John Moores University, UK)
7:30 pm - 7:55 pm	Hair Analysis in Clinical & Forensic Toxicology	Prof. Alberto Salomone (University of Turin - Italy)
7:55 pm - 8:05 pm	Question & Answer	
8:05 pm - 8:20 pm	Break	
SESSION 9 Moderator: Dr. Salam Saadeddin		
8:20 pm - 8:45 pm	50 Years of Laboratory Medicine	Dr. Roger Bertholf (ASCP-USA)
8:45 pm - 9:10 pm	Poster Session Awards Announcement	Dr. Salam Saadeddin (SSCC-Chairman of the Scientific Committee)
9:10 pm - 9:20 pm	General Assembly	Dr. Samia Sobki/Dr. Ali Al Othaim (SSCC President & vice president)
9:30 pm - 9:40 pm	Closing Remarks	Dr. Salam Saadeddin (SSCC-Chairman of the Scientific Committee)

1-3 December 2020

Oral Presentation Abstracts

The Future of Laboratory Medicine in a Changing World

Dr. Graham Beastall

IFCC Past President

Glasgow, UK

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 personalized 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:

- Globalization
- Technological and informatic development
- Integrated diagnostics
- Patient-centered 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.

Oral Presentation Abstracts

Human Capital Development Cornerstone is Everyday Assignments

Dr. Majdah Abdulhadi Shugdar

*Director General – General Administration of Training
Education & Training Evaluation Commission*

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.

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Oral Presentation Abstracts

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

Dr. Aaron Han

*Adjunct Professor of Pathology College of Medicine
Mohammad Bin Rashid University, Dubai, UAE*

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.

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Oral Presentation Abstracts

Logistic Issues to Consider in Improving Laboratory Quality Services

Dr. Hisham Shams

Medical Director

Life Diagnostics Laboratories, UAE

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.



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Oral Presentation Abstracts

HCG Between Myth and Reality

Dr. Heba Kary

Consultant, Chemical Pathology

King Fahad Armed Forces Hospital-Jeddah, KSA

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.

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Oral Presentation Abstracts

CA19.9 as Tumor Marker: is it Reliable?

Dr. Manal Al Kindi

Senior Consultant, Pathology & Laboratory Medicine Division
The Royal Hospital, Oman

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.

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Oral Presentation Abstracts

Recent Advances in the Molecular Diagnosis of Breast Cancer

Dr. Laila Abdel-Wareth

Chair of Clinical Pathology

National Reference Laboratory, Cleveland Clinic Abu Dhabi-UAE)

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.

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Oral Presentation Abstracts

Overview of Covid-19 Infection

Dr. Nisreen AlSherbini

*Head of Infectious Diseases Division
Prince Sultan Military Medical City, Riyadh*

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.



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Oral Presentation Abstracts

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

Dr. Hosam Zowawi

*Clinical Microbiologist and Infectious Diseases Scientist
King Saud bin Abdulaziz University for Health Sciences-KSA*

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.

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Oral Presentation Abstracts

COVID-19 and Biochemical Markers

Dr. Nafila Al Riyami
Senior Consultant, Medical Biochemist
Sultan Qaboos University Hospital, SQU - Oman

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.

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Oral Presentation Abstracts

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

Mr. Faisal Ibrahim

Director of Quality Assurance

National Reference Laboratory – Abu Dhabi

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

Oral Presentation Abstracts

Update on CAP: Clinical Chemistry Standards

Dr. Suzanne Kamel-Mohamed

Laboratory Director

WYOMED Lab, Laramie, Wyoming Labtech Diagnostic LLC (USA)

We are living in an unprecedented era in the field 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 unassayed 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.

Oral Presentation Abstracts

CBAHI 2020

Ms. Nouf Al Saleem

*Manager of Clinical Laboratories and Blood Banks Accreditations Sections/ Laboratories Surveyor
Saudi Council Board Accreditation-Riyadh-KSA)*

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.



1-3 December 2020

Oral Presentation Abstracts

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

Dr. Adil Khan

*Associate Prof. of Pathology/Director of POCT & Clinical Chemistry, Temple University Health System
Lewis Katz School of Medicine, Temple University-Philadelphia, USA*

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.

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Oral Presentation Abstracts

POCT: Meeting Accreditation Standards

Ms. Najwa Adlan

Core Lab & Blood Bank Supervisor

Al Dara Hospital & Medical Center, Riyadh, KSA

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.

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Oral Presentation Abstracts

Evolution of a POCT Training and Competency Renewal Program

Mr. Jonathan Harris

*Senior Manager, POCT & Quality
National Reference Laboratory / Cleveland Clinic, UAE*

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.

Oral Presentation Abstracts

Automation in Clinical Laboratory: establishment and considerations

Dr. Zahir Alshehry

*Consultant Clinical Scientist & Head of Clinical Chemistry
King Fahad Medical City-Riyadh*

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.



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Oral Presentation Abstracts

Aldosterone & Renin: A Key Workup of Hypertension

Prof. Gruson Damien

*Head of Department of Clinical Biochemistry
Cliniques Universitaires Saint Luc, Brussels*

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.



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Oral Presentation Abstracts

The Utility of Freelite® in the Management of Multiple Myeloma

Dr. James Iain Keith Last

*Medical Science Liaison Manager for International Sales
The Binding Site Group Ltd. - 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.

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Oral Presentation Abstracts

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

Prof. Manu Vatish

*Senior Clinical Fellow & Consultant in Obstetrics
Nuffield Department of Women's & Reproductive Health
University of Oxford, 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.

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Oral Presentation Abstracts

Challenges in Medical Education During COVID-19 Pandemic

Dr. Altaf AbdulKhalig

*Assistant Professor of Clinical Biochemistry, College of Medicine & Consultant of Investigative Endocrinology,
Metabolism & Bone Metabolism
College of Medicine, Umm Al-Qura University, Makkah, KSA*

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".

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Oral Presentation Abstracts

Developing Research Ideas

Prof. 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*

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

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Oral Presentation Abstracts

Alcohol Toxicity

Dr. Sumayah Aljenedil

*Consultant Chemical Pathologist, Clinical Lipidologist
Department of Pathology and Laboratory Medicine
King Faisal Specialist Hospital Research Center, Riyadh, KSA)*

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

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Oral Presentation Abstracts

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

Dr. Sulaf Assi

*Senior Lecturer in Analytical Forensic Chemistry
Liverpool John Moores University, UK*

Over the last few years, handheld Raman spectroscopy has emerged as a powerful tool for the instant identification of wide variety of analysis 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 lightweight, long battery lifetime 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 Harmonization 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

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Oral Presentation Abstracts

Hair Analysis in Clinical & Forensic Toxicology

Prof. Alberto Salomone

Associate Professor

University of Turin, Italy

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.



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Oral Presentation Abstracts

50 Years of Laboratory Medicine

Dr. Roger Bertholf

Professor (with Tenur)

University of Florida Health Science Center, ASCP-USA

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*

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Workshops Oral Presentation Abstracts

SARS-CoV-2 Serology Testing

Dr. Wim van der Helm

Head of Healthcare Development –Roche Diagnostic

Diagnostic tests are an essential service in the delivery of healthcare. In vitro diagnostic testing has become an indispensable tool in clinical practice. It can provide critical information at every step of the patient pathway. Results of in vitro testing influence as many as 70% of clinical decisions. Never has this been more true as the COVID-19 pandemic has opened a whole new window into the world of diagnostic testing. The COVID-19 pandemic has disrupted the lives of billions of people, nearly overwhelming healthcare systems and pushing the global economy to the brink of collapse. The quest for effective treatments and a preventive vaccine starts with – and depends on – the broad availability of fast, accurate and reliable testing.

Testing for SARS-CoV-2 involves either Nucleic acid tests (NATs) to detect viral RNA directly, or antigen testing, to detect viral proteins directly, determining if someone is currently infected with the virus. Detection of the immune response (antibodies), determining whether someone has been infected and developed antibodies in response to viral infection. NATs and antigen tests are generally used for testing of symptomatic patients and can detect SARS-CoV-2 infection up to one week before symptoms appear. A positive antibody response will indicate that a person has previously been infected with SARS-CoV-2. The Elecsys® Anti-SARS-CoV-2 test will help health care practitioners understand the extent of exposure and the spread of infection in a population, which is particularly useful as many cases are thought to be asymptomatic. During infection with a pathogen, the presence of an antibody response correlates to a certain level of immunity and protection from further infection.

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Workshops Oral Presentation Abstracts

Evaluation Mean/SD and How to Perform QC Cross-over Studies According to CLSI C24

Mr. Nico Vandepoele

Scientific and Professional Affairs Manager, Al Jeel

Learning objectives:

Explain at least 2 methods how to set up and monitor a mean and SD

Use a Levey Jennings chart to interpret the evaluation mean and SD

Describe the new simplified cross over study process according to the latest CLSI C24 guidelines.

One of the most important settings for the statistical process control in the quality control (QC) process in the laboratory are the target mean and the target standard deviation (SD). Even if we have the most stringent Westgard rules they won't detect unreliable results if this mean and SD target is not reflecting the actual instrument performance. An incorrect mean and SD can even create a lot of false rejections which can create a lot of unnecessary troubleshooting in the lab. One of the best tools to evaluate these setting is our Levey-Jennings chart which provides a quick visual overview of our test performance.

This presentation will review the basic definitions and concepts how to establish this target mean and SD. The presentation will also provide the latest guidance from the Clinical & Laboratory Standards Institute (CLSI) C24 'Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline – 4th Edition' how to establish this mean and SD when we start a new QC lot, also called a crossover study.

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Workshops Oral Presentation Abstracts

Beckman Coulter Total Solutions to Fight Against COVID-19 Pandemic

Dr. Moner Ragas

EMEA Scientific Manager

(Beckman- UAE)

Since outbreaks began at the end of 2019, the coronavirus has claimed more than 1 million lives across the globe. Diagnostic testing for COVID-19 is rapidly improving in quality every day, with many tests focused on diagnosing patients with active viral infections.

Both molecular and antigen tests are used to detect active infections by identifying viral genetic material (RT-PCR) or identifying unique markers of the pathogen itself (Antigen test). In addition, serological tests to detect the presence of antibodies in patient serum are key tools for understanding the immune response in those who have been previously infected and have developed antibodies to SARS-CoV-2.

Building on its strong commitment to the fight against COVID-19, Beckman Coulter has developed Emergency Use Authorized assays with the highest level of quality to help manage the pandemic and reduce social and economic impacts of the COVID-19 outbreak.

The presentation will be discussing:

- The current and future role of antigen and antibody testing in overcoming the COVID-19 pandemic and how governments are beginning to make use of these tests to re-open.
- The clinical value of Beckman Coulter SARS-CoV-2 immunoassays in identifying highly potent neutralizing antibodies.
- A "Menu That Matters" of comprehensive *in vitro* diagnostic tests commonly used for critically ill cases aimed to support patient management and provide faster treatment decisions.

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Workshops Oral Presentation Abstracts

Metabolic Syndrome, Diabetes Care and Improved Healthcare using HbA1c

Dr. Marvin Berman

*Manager Scientific Services
Abbott Laboratories, USA*

Metabolic syndrome is not a disease but is a group of risk factors that affect a person's health condition. The risk factors consist of high blood pressure, high blood sugar, unhealthy cholesterol levels (high triglycerides/Low Cholesterol) and abdominal fat. To be diagnosed with metabolic syndrome, a person needs to have at least three of these risk factors. Fortunately, metabolic syndrome can be controlled, largely with changes to your lifestyle. These risk factors increase your risk for Diabetes by five times. The causes of metabolic syndrome and the use of diagnostic tests to reduce these risk factors will be reviewed.

Type 2 Diabetes is a lifelong disease that keeps your body from using insulin correctly (Insulin resistance). The medical costs for Diabetes patients are projected to increase each year as diagnosed cases are expected to continue to go up worldwide. The ADA and other international organizations support HbA1c testing for detection of Diabetes. Using the HbA1c assay, an individualized treatment plan can be developed based on several risk factors such as life expectancy, disease duration and vascular complications. For example, while a younger patient may need to get their HbA1c level to less than 6.5%, an HbA1c level of 7.0 to 7.4% would be best for an older patient. The utility of different HbA1c methodologies will be compared. This discussion will include methods based on charge such as HPLC and methods based on structural differences such as clinical chemistry assays. The advantages and disadvantages of using these different HbA1c assay methods will be compared.

In conclusion, untreated metabolic syndrome will lead to an increase in Diabetes cases. The use of HbA1c detection methods will allow early detection of these Diabetic patients which can lead to quicker intervention and monitoring of the health/compliance of these patient



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Workshops Oral Presentation Abstracts

Extending the COVID-19 Testing Capacity with POC Solutions

Ms. Stephanie Penaud
EMA Product Manager, Becton Dickinson

All over the world, testing is a key component of health authorities response to fight against the Covid-19 pandemic. Sars-CoV-2 RT-PCR tests appeared early in the market but required specific equipment and highly skilled staff, thus limiting the testing capacity.

Today, with the new Antigen tests, it is possible to detect active infection directly at Point of Care, in 15 minutes. During this session, we will present the new solution from BD, the BD Veritor Plus System for rapid detection of SARS-CoV-2 that offers lab-quality results at the point of care, in a simple-to-operate, handheld instrument.

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الجمعية السعودية للكيمياء السريرية

1-3 December 2020

Poster Presentation Abstracts

Abstract #: 1

The Role of Oxysterols as Selective Oestrogen Receptor Modulators (Serms) At Promoting Tumour Growth in Adrenocortical Carcinoma

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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 steroidogenic 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 ER α . 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 (ER α 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 μ M) either alone or combined with hydroxyl-tamoxifen (OHT) as inhibitor (10 μ M 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 μ M) 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.

Poster Presentation Abstracts

Abstract #: 2

Review on Biotin Interference in Clinical Chemistry Immunoassays

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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 Streptavidin 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.

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Poster Presentation Abstracts

Abstract #: 3

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

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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 BTB 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 BTB 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 C_{18:1} (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.

Poster Presentation Abstracts

Abstract #: 4

Cytotoxic Effect of Metformin on Breast Cancer Cell Lines

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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 reprogramming 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.

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Poster Presentation Abstracts

Abstract #: 5

The Effect Of (Lysulin™) on Glycemic Control, Sudomotor Function and Other Components of Metabolic Syndrome in Patients With Type 2 Diabetes- Preliminary Results

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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.

Poster Presentation Abstracts

Abstract #: 6

Ethyl Glucuronide and Ethyl Sulphate: a review on their role in alcohol postmortem forensic toxicology analysis

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Background: The interpretation of alcohol results for post-mortem specimens can be difficult due to the possibility of post-mortem production of alcohol. Therefore, forensic toxicologists exploit ethanol biomarkers. Although there are a number of previous reviews discussing the uses of these biomarkers in clinical forensic toxicology related application i.e. driver under the influence of alcohol and workplace testing, no review has been published for the applicability of these biomarkers on postmortem investigation which is the subject for current review. The aim of this work is to review methods in the literature for the determination of ethyl glucuronide (EtG) and ethyl sulfate (EtS) in post-mortem specimens including their sample preparation and role in alcohol postmortem interpretation.

Methodology: A systematic review of most relevant methods of determination of EtG and EtS that were applied to real post-mortem investigation was undertaken. A search of ScienceDirect, PubMed and references from relevant articles published in the last 10 years was performed. A total of 24 articles covering the period 2006 until October 2020 was selected.

Results: Most of the detection methods that described for postmortem blood, urine, and few reports using vitreous humor and tissue specimens, their sample preparations, and measurement analyzers techniques are discussed, it has been found that method validation parameters were not conducted properly, mostly intended objective is to present data about ethanol biomarkers than insuring methods were valid to fit their purpose. The lack of relating the results of EtG and EtS with the cause of death due to ethanol intake or determined few hours of alcohol consumption before death may decreased the number of applications after a great starting from 2006-2010, however, at the beginning of 2020, ethanol biomarkers research has improved. A considerable number of the method were using LC-MS-ESI/MS techniques.

Conclusions: The number of available investigations in the literature are not scaling the importance of ethanol post-mortem alcohol formation issues. As most of studies using LC-MS techniques, it can be seen clearly that matrix effect (ME) can be the big challenges on the analytical method performance. Finally, more research on using tissue specimens are recommended for two main reasons: in case of highly decomposed bodies (no bodily fluid available) and it can be a complementary specimen to blood samples as most of the reports using tissues specimens were promising.

Poster Presentation Abstracts

Abstract #: 7

Molecular Basis of Ighg4-Related Low Serum Igg4 Subclasses In Down Syndrome

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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 donors (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 in our population with DS, but other factors exist that need to be identified.

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Poster Presentation Abstracts

Abstract #: 8

Biochemical Alteration in Blood Stress Marker and Other Vitals of Saudi Medicos in Pre And Post Real Time Cardiac Catheterization Procedure

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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 and 5.19 ± 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 and 342.98 ± 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.

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Poster Presentation Abstracts

Abstract #: 9

Identification of Abnormal Proteins in The Blood of Patients with Type2 Diabetes and Dry Eye Syndrome.

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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 NGH 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 biostatistical 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.

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Poster Presentation Abstracts

Abstract #: 10

Al Borg Medical Laboratories' In-House Novel Multiplex Rt-Qpcr For Detecting Sars-Cov-2

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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.

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Poster Presentation Abstracts

Abstract #: 11

Lean Six Sigma Methodologies Reduce Turnaround Times for Expedite Chemistry Tests

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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.



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Poster Presentation Abstracts

Abstract #: 12

Evaluation Of β -Hydroxybutyrate Assay in Serum or Plasma Using Kinetic Enzymatic Method (Randox Kits) On Roche Cobas C702 Analyzer

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Background: The β -hydroxybutyrate (β OHB) 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 β OHB 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 β OHB 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 β OHB 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 β OHB using Randox kits on automated COBAS c702 platform was acceptable. It provides reliable results for patients' samples testing.

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Poster Presentation Abstracts

Abstract #: 13

Analytical Performance of Point of Care Blood Gas Analyzer Gem Premier 4000

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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 (pCO₂), Partial Pressure of Oxygen (pO₂)], Electrolytes [Sodium (Na⁺), Potassium (K⁺), Chloride (Cl⁻), and Ionized Calcium (Ca²⁺)], Metabolites [Glucose (Glu), Lactate (Lac) and Total Bilirubin (TBil)], and the CO-Oximetry [Total Hemoglobin (tHb), Methemoglobin (MetHb), Carboxyhemoglobin (COHb), Oxyhemoglobin (O₂Hb) 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.

Poster Presentation Abstracts

Abstract #: 14

Beta-2 Microglobulin And Renal Failure In Multiple Myeloma

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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 Image 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 \pm 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.



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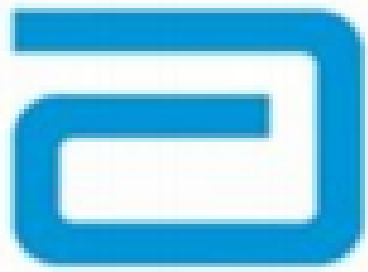
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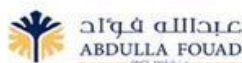


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