SHOW ISSUE 2019

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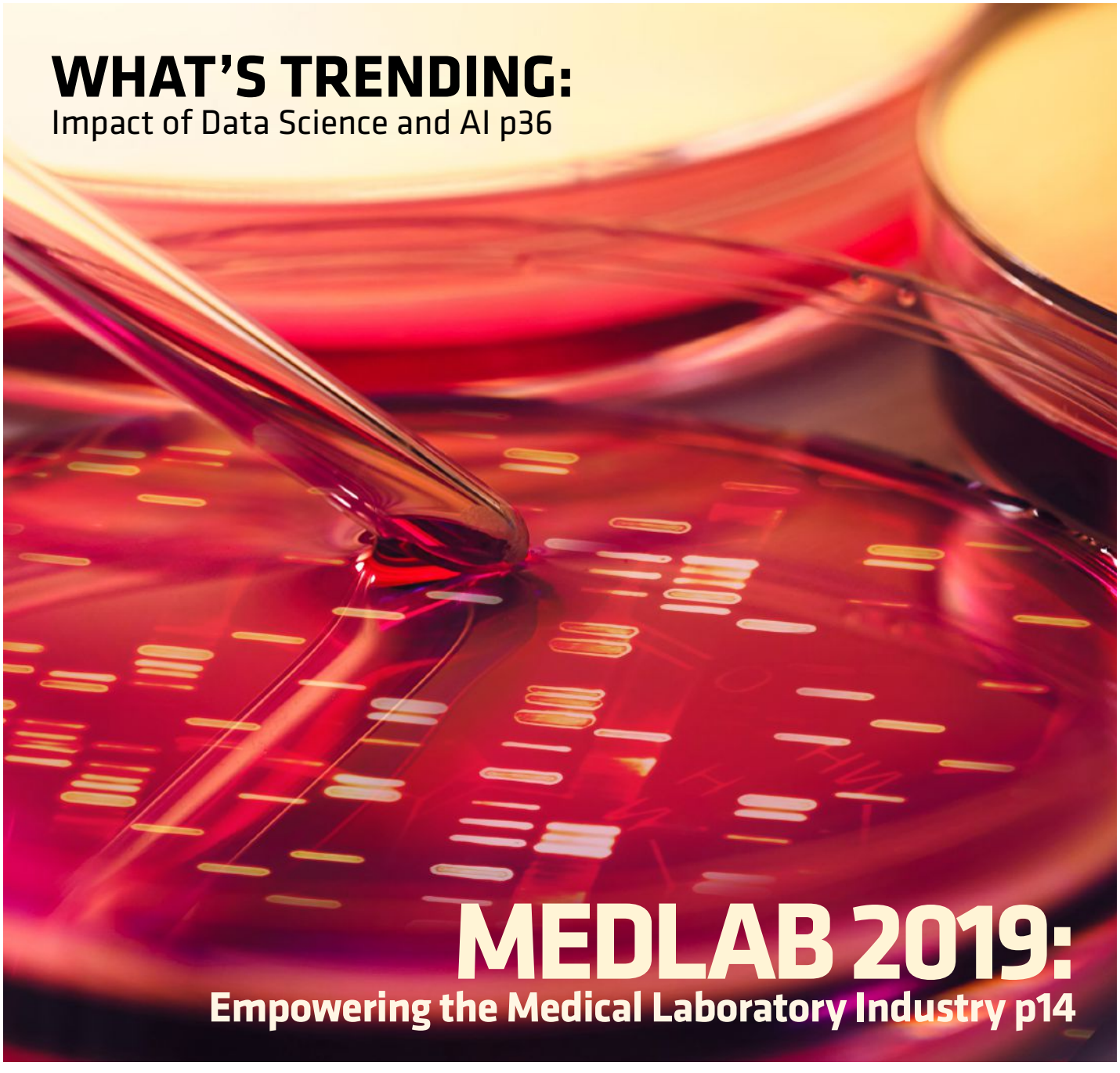
THE **OFFICIAL MAGAZINE** OF THE MEDLAB EXHIBITION



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CEA
Total PSA
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CA 125
CA 15-3
CA 19-9
HCG/ β -HCG
Tg(Thyroglobulin)
PAP
CA 50
CYFRA 21-1
CA 242
CA 72-4
NSE
S-100
SCCA
TPA-snibe
Pepsinogen I
Pepsinogen II
Gastrin-17
H.pylori IgG
β 2-MG
Calcitonin
Proinsulin
H.pylori IgA
H.pylori IgM
ProGRP
HE4
HER-2
*PIVKA-II
*AFP-L3

Drug Monitoring

Digoxin
CSA (Cyclosporine A)
FK 506 (Tacrolimus)

Inflammation Monitoring

hs-CRP
PCT(Procalcitonin)
IL- 6

Kidney Function

β_2-MG
Albumin

Hepatic Fibrosis

HA
PIIIP N-P
C IV
Laminin
Cholyglycine

EBV

EBV EA IgG
EBV EA IgA
EBV VCA IgG
EBV VCA IgM
EBV VCA IgA
EBV NA IgG
EBV NA IgA

Prenatal Screening

AFP (Prenatal Screening)
Free β –HCG
PAPP-A
HCG/ β –HCG
free Estriol

Bone Metabolism

Calcitonin
Osteocalcin
25-OH Vitamin D
Intact PTH
* β -CTX
*PINP

Thyroid

TSH (3rd Generation
T4
T3
FT4
FT3
Tg(Thyroglobulin)
TGA(Anti-Tg)
Intact PTH
Anti-TPO
TRAb
TMA
Rev T3

TORCH

Toxo IgG
Toxo IgM
Rubella IgG
Rubella IgM
CMV IgG
CMV IgM
HSV-1/2 IgG
HSV-2 IgG
HSV-1/2 IgM
*HSV-2 IgM
*HSV-1 IgG
*HSV-1 IgM

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Ferritin
Folate (FA)

138 Countries

9000 Units Globally

Cardiac

on)

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Troponin I
Myoglobin
NT-proBNP
Aldosterone
Angiotensin I
Angiotensin II
D-Dimer
LP-PLA2
hs-cTnI
hs-CRP
Direct Renin
H-FABP
BNP

Glyco Metabolism

C-Peptide
Insulin
ICA
IAA(Anti Insulin)
Proinsulin
GAD 65
Anti-IA2

Immunoglobulin

IgM
IgA
IgE
IgG

Autoimmune

TGA(Anti-Tg)
Anti-TPO
TRAb
TMA
ICA
IAA(Anti Insulin)
GAD 65
Anti-IA2
Anti-dsDNA IgG
ANA Screen
ENA Screen
Anti-Sm IgG
Anti-Rib-P IgG
Anti-Scl-70 IgG
Anti-Centromeres IgG
Anti-Jo-1 IgG
Anti-M2-3E IgG
Anti-Histone IgG
Anti-nRNP/Sm IgG
Anti-SS-B IgG
Anti-SS-A IgG
*Anti-CCP

Fertility

FSH
LH
HCG/ β –HCG
PRL
Estradiol
Testosterone
free Testosterone
DHEA-S
Progesterone
free Estriol
17-OH Progesterone
AMH
SHBG
Androstenedione
*PlGF
*sFlt-1

Others

Cortisol
GH(hGH)
IGF-I
ACTH
IGFBP-3

Infectious Disease

HBsAg
Anti-HBs
HBeAg
Anti-HBe
Anti-HBc
Anti-HCV
Syphilis
Anti-HAV
HAV IgM
HIV p24 Ag
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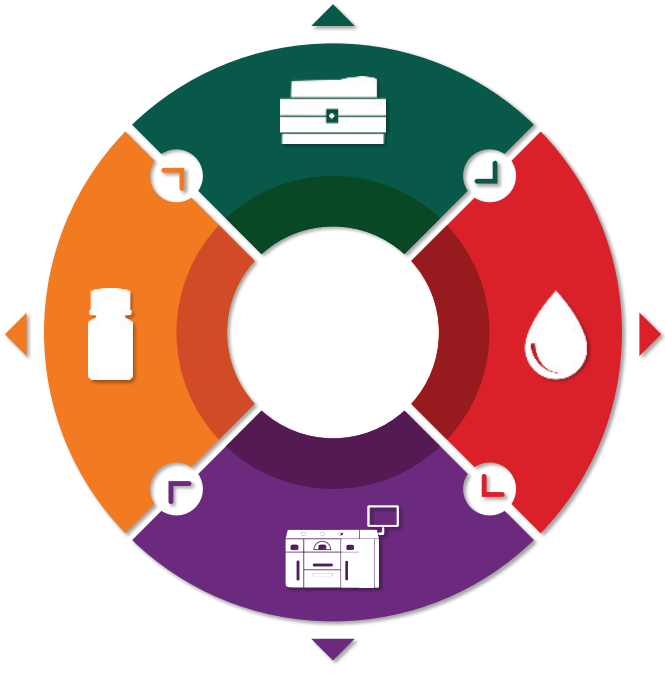

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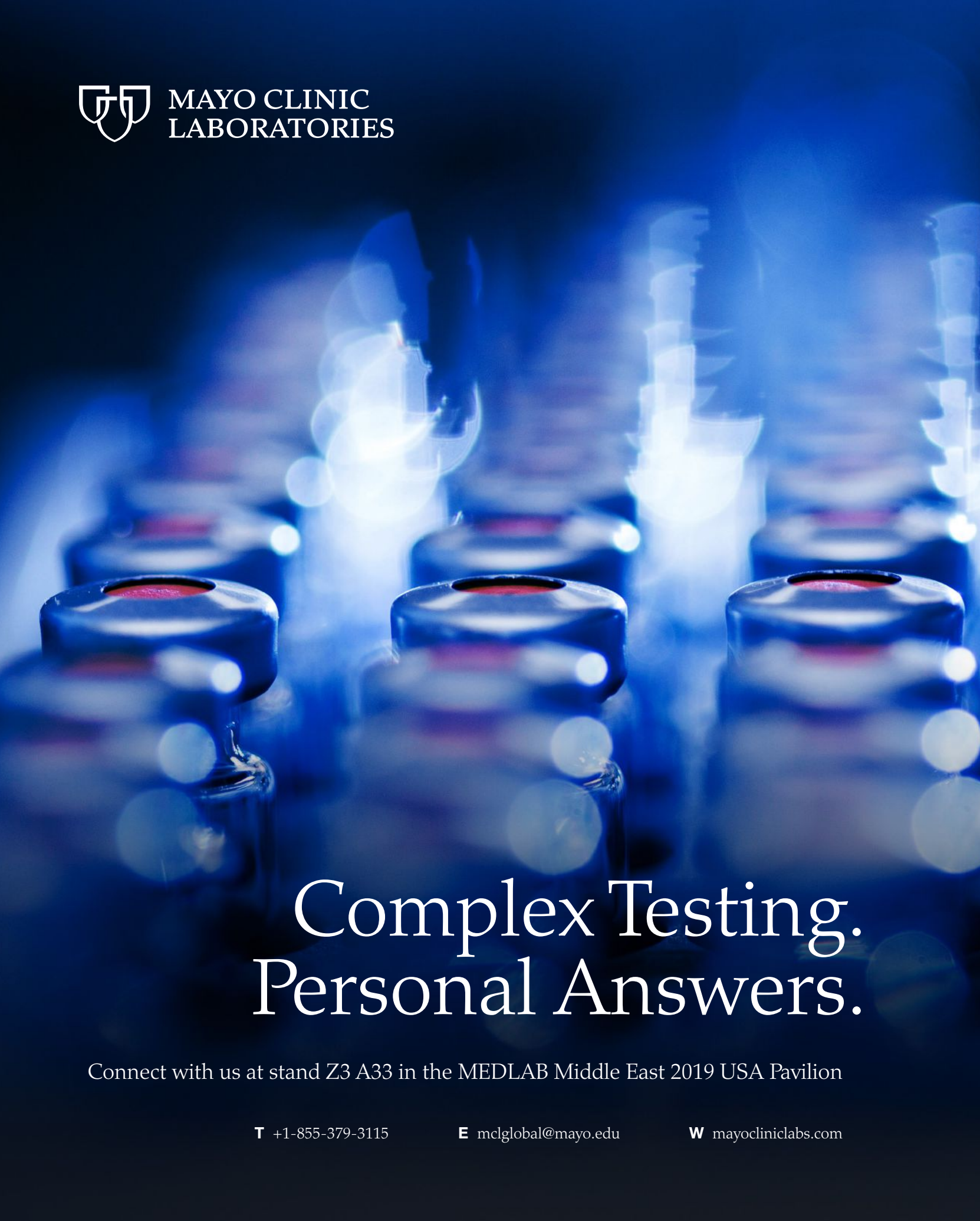
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letter from the editor

Lab of the Future

Welcome to special edition of MEDLAB Exhibition & Congress 2019! The issue is packed with features highlighting the latest laboratory management and diagnostics advancements and technologies that are transforming healthcare delivery globally.

In this issue, we hear from speakers at the MEDLAB Congress such as Robert L. Sautter *(page 32)* who discusses the importance of antibiotic stewardship programmes for microbiologists, infectious disease physicians, and pharmacists, in order to better use appropriate antimicrobials to treat patients.

Furthermore, in the current Big Data revolution, many long-existing technologies such as Artificial Intelligence (AI) are now being primed for use in the medical laboratory. In our pages, speakers from the newly launched AI conference at MEDLAB highlight the profound and promising prospects for improved efficiencies in relation to streamlined and automated care provision and services.

For instance, Dr. Mark Hoffman *(page 36)* examines the impact of data science on the clinical laboratory and how these advances have created exciting opportunities along with some challenges for the laboratory community. While Dr. Palat K Menon *(page 40)* shares his vision of the laboratory of the future and highlights how AI algorithms might work best alongside pathologists for higher efficiency and accuracy.

Lastly, Medlab Magazine is embracing the digital-first model and instead of bringing out just print issues, we will also publish digital magazines throughout the year. Plus, we will regularly report the latest news and trends on *www.medlabmagazine.com*.

We wish you a warm welcome to MEDLAB 2019 and hope you have a productive show, whether you are an exhibitor, visitor or a delegate.

Deepa Narwani

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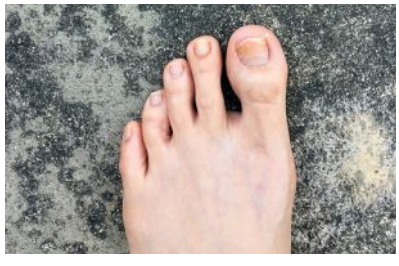
Colorectal Cancer Awareness

Fecal Occult Blood Analyzer

QUICK RUN (II)

Compactness with Multi-functionality



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MEDLAB 2019:
Empowering the Medical Laboratory Industry

The upcoming edition of the MEDLAB Exhibition continues to highlight advanced techniques for better health and hosts the region's only CME accredited multi-disciplinary Congress.

By MEDLAB Magazine Staff

The third stand-alone edition of the MEDLAB Exhibition and Congress is all set to connect and empower the international medical laboratory industry and will focus on developing the value of laboratory medicine in shaping the future of healthcare. The event will take place between February 4 to 7, 2019, at the Dubai World Trade Centre.

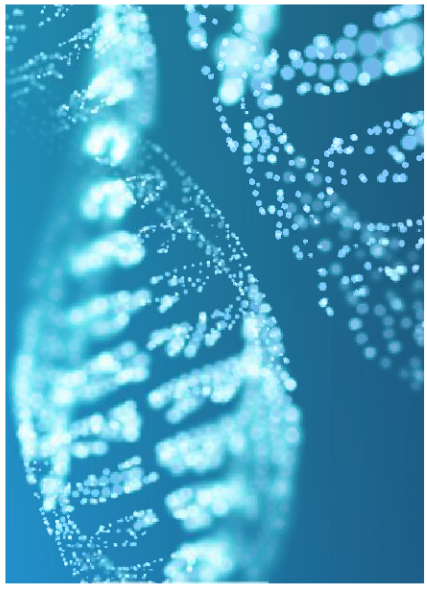
A must-attend annual event for the medical laboratory community, MEDLAB will welcome over 19,610 professionals and more than 678 companies from around 46 countries. The event brings together thousands of professionals, right from manufacturers to key opinion leaders who congregate to shape the future of the industry.

The exhibition offers access to high-performance devices at cost-effective prices that enable in better decision-making. It prides itself on bringing innovation from all continents to support the advancement of patient care. With this agenda, the event will showcase an array of the latest laboratory medicine solutions such as cutting-edge equipment, diagnostic tests, instruments, reagents, and disposables, among other items.

Pioneering Growth

One of the only exhibitions that provides access to a variety of audiences, right from distributors to medical laboratory professionals, MEDLAB has established itself as a one-stop-shop for generating viable leads and doing business within the MENA region.

The 2018 edition of the show demonstrated the significance to the diagnostics industry worldwide, with a seven per cent increase in overall attendees from 2017. Understanding this niche market's goals and challenges, the event benefited from a uniquely targeted campaign to enforce the theme of unifying the laboratory and clinicians, in order to improve patient care. The event welcomed 678 exhibitors and hosted 12



country pavilions, 46 exhibiting countries, 124 product categories, 17 (12 Laboratory and five Clinical) conferences, and 6,726 delegates.

While the first stand-alone event in 2017 hosted over 575 exhibitors from 38 countries, including representation from 12 country pavilions. Welcoming 20,420 attendees from 129 countries, the event allowed medical lab professionals the opportunity to meet, learn and do business with their relevant target audience.

Having introduced bespoke tracks to bridge the gap between lab professionals and clinicians, it was evident that the event fulfilled a critical need in the market, as four out of 11 tracks were sold out ahead of the first stand-alone show.

Bridging the Gap

Furthermore, MEDLAB hosts the region's only CME-accredited multi-disciplinary Congress. It is committed to supporting the education of all faculty and medical lab professionals and offers conference tracks that put emphasis on the core lab and specialist lab units.

MEDLAB Congress 2019 will host 11 multi-disciplinary conferences that will provide education as well as management solutions to help advance skills and improve laboratory functions. These will provide up to 31.5 CME credits and fresh insights from industry pioneers to build key skills as well as increase the quality of care.

Focusing on the implementation of quick and safe selection, performance and evaluation of results of new and established laboratory tests, the Congress has established itself as a learning and sharing platform for all medical laboratory workers to advance professionally and develop adaptive solutions for daily practice in the lab.

This year, the conferences will cover a wide range of topics from reviewing of basic laboratory procedures to identifying advanced mechanisms that will cater to the knowledge demand of every attendee. It will be led by a strong scientific committee, ensuring that current issues and innovation are at the centre of all programmes.

This edition, MEDLAB will explore the "Lab of the Future" as the UAE prepares to adopt the use of Artificial Intelligence (AI) in the medical laboratory. Reportedly, AI is predicted to add US$182 billion to UAE's economy by 2035 with the healthcare industry taking a US$22 billion slice of the gains.

The conference will explore the potential for AI to transform the medical laboratory industry in the UAE through improved efficiencies and how the diagnosis can be revolutionised through futuristic technologies such as data robots and "bloodless blood tests". The conference is a must-attend to understand how innovation and emerging digital health technologies will revolutionise the medical laboratory.

The event will host other conferences such as Laboratory Management, which will open with a plenary session to talk about the laboratory beyond 2020. It will be followed by two sessions – the leadership session that will focus on managerial issues and the lab operations

session, which will address technical skills and methods designed for laboratory technicians.

Also, the newly introduced Immunology conference will provide delegates with a unique opportunity to engage with immunology field experts. This new track will discuss the latest trends and issues concerning the widespread utilisation of immunological techniques for healthcare advancement. Also new, the Cytogenetics & IVF conference is aimed at improving services in the growing number of fertility centres and genetic labs in the region. It will feature developments in prenatal diagnosis to chromosome biology in epigenetics and evolution.

While the Haematology & Blood Transfusion conference will bring together leaders within the field of haematology and blood transfusion science to provide a broader overview of current key developments and best practices, supported by evidence-based education.

Leading the Way

Last year also saw the introduction of the "Heads of Lab Masterclass", a roundtable discussion facilitating senior laboratory decision-makers to meet and discuss both public and private laboratory concerns and challenges, providing leading manufacturers direct insight into the lab to offer viable solutions. The session received a great response and is back again this year. The topic is "Laboratory Medicine: Challenges and Opportunities" and will feature exceptional leaders in the laboratory.

The masterclass will discuss current and anticipated healthcare developments that may affect the future of laboratory medicine and how to deal with these changes, asses global and regional competition and provide an insight into technologies and solutions for the operational organisation of clinical laboratory services such as consolidation, integration, and networks. ML

CHAMPIONING CHANGE

Deepa Narwani speaks to MEDLAB 2019's internationally acclaimed "Laboratory Champions" who will be making key presentations at the show. Excerpts:

Outstanding Opportunities

Glen Fine will be discussing risk management principles for the medical laboratory on Monday, February 4. He shares: "I intend the talk to be specific and address issues that matter to the audience, including how to identify the most likely sources of error, evaluating the risk of harm, and developing risk mitigation strategies."

He will also be speaking at the National Reference Laboratory's (NRL) Symposium on CLSI's global reference standards on quality indicators and quality control for quantitative measurement procedures on February 5 and 6.

According to Fine, MEDLAB offers an outstanding opportunity for professionals to learn, grow, meet new colleagues, renew existing professional relationships, and see the latest advances in lab technology and growth areas.

"I also encourage attendees to extend beyond their "comfort zone" and to introduce themselves to others and build a network of associates you can text or call when you are having issues. This will be my fourth time attending the show. I have found it to be one of the top educational, networking and trade shows in the world. The large volume of attendees from around the globe, industry exhibitors, and educational topics are world-class," he adds.

Critical Role of Leadership

Patrick E. Godbey, MD, FCAP, President-elect, College of American Pathologists (CAP) Founder, CEO, and Laboratory Director, Southeastern Pathology Associates, Brunswick, Georgia, U.S., will be discussing "Laboratory leadership: A critical role inside and beyond the laboratory."

He says: "Specifically, I will be discussing leadership in the clinical laboratory, responsibilities of the laboratory director for ensuring that it is providing the necessary tests and quality for effective patient care, and common challenges in fulfilling the laboratory director role."

Dr. Godbey believes that MEDLAB provides a platform to interact with customers and meet professionals who are interested in partnering with the CAP on a journey toward achieving the highest quality laboratory medicine.

"I believe MEDLAB attendees have the opportunity to learn about CAP external quality assurance, inspection, accreditation, and other programmes designed to raise the level of accuracy and quality in the laboratory. Moreover, we see the event as an invaluable platform for speakers to address key challenges and opportunities in the field. Healthcare professionals can benefit immensely from this and share best practices. Attendees also have the opportunity to see what's new and innovative at the exhibition," he concludes.

Glen Fine

Dr. Patrick Godbey

MEDLAB ASIA PACIFIC 2019 :
Bringing Intelligence and Innovation Together

By MEDLAB Magazine Staff

The next edition of MEDLAB Asia Pacific and Asia Health is all set to take place from March 26 to 28. The event, which will be held at the Suntec Singapore Convention & Exhibition Centre, is one of Southeast Asia's premier international laboratory and healthcare exhibitions. The 2019 edition will host 14 inter-disciplinary scientific conferences, eight international pavilions, over 200 product categories, and more than 250 exhibitors.

The 2018 edition of the event hosted over 57 per cent healthcare and laboratory-specific dealers and distributors, alongside senior decision-making end users, enabling them to connect with new suppliers, business partners and customers looking to do business in Southeast Asia. It received over 250 exhibitors from 24 countries worldwide, including representation from 11 country pavilions.

Welcoming 4,358 attendees from 62 countries (eight per cent increase from the 2017 edition), the concentrated and targeted event allowed all medical lab and healthcare professionals the opportunity to meet, learn and do business with their relevant audience.

The conferences at the event experienced seven per cent year-on-year growth with 2,834 delegates attending the 15 multi-disciplinary CME-accredited conferences. Having introduced dedicated tracks to bridge the gap between lab professionals and clinicians, the event's clinical tracks were attended by lab professionals, doctors, general practitioners, oncologists, obstetricians, gynaecologists and other specialists throughout the show days.

For instance, the newly introduced Healthcare Procurement Conference, supported by the Procurement and Supply Institute of Asia - PASIA, focused on the recent Asian trends in buying for hospitals and other healthcare facilities. Attended by over 150 delegates, the conference hosted over 20 of the leading distributors from across the APAC to attend, speak and provide best practice on procurement regulations in the medical device and equipment industry.

Enhancing Skills

Now in its sixth year, MEDLAB Asia Pacific will provide a platform for leading companies to showcase current technologies and smart innovations in the field of laboratory and diagnostics. Furthermore, it will feature a multi-track, fully accredited, conference programme providing unparalleled education

and management solutions to help labs excel. With a number of expert speakers and laboratory professionals in attendance, the event provides an opportunity to explore the current technology and science driving today's diagnostics and patient care.

MEDLAB Asia Pacific is renowned for offering integral opportunities for the industry to showcase the latest laboratory management and diagnostics technologies to a worldwide audience, to advance their skills and improve lab services in today's highly competitive market.

The MEDLAB Asia Pacific Congress is the among one of the few dedicated medical laboratory scientific events in Asia providing multidisciplinary education for medical lab professionals, enhancing skills, productivity, and quality for sustainable care.

The Congress brings together clinical laboratory professionals from different types of laboratories and is attended by laboratory managers and leaders, clinical technicians, consultants, scientists who can connect and share their experiences and collective knowledge on all aspects of laboratory medicine and clinical research. In 2019, the event will also introduce roundtable discussions to advance technical, mechanical and diagnostic skills of laboratory technicians.

New Features

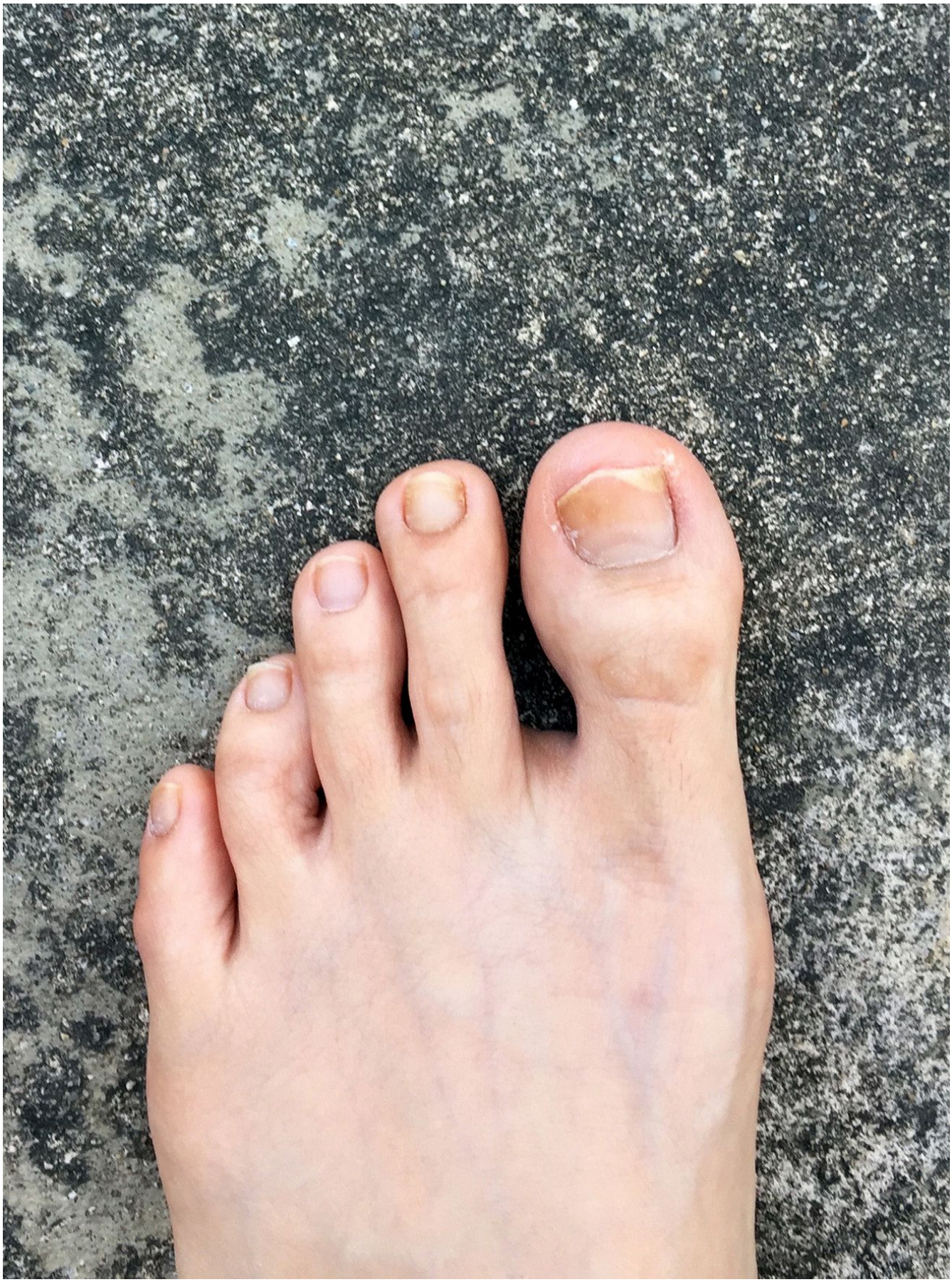
The upcoming edition has a whole host of new features such as the Artificial Intelligence Future in Health Zone, Patient Safety Zone, Hosted Buyer Programme, Innovation Zone, Business Matchmaking, and Oncology Zone.

The Hosted Buyer Programme is designed to connect international suppliers at MEDLAB Asia Pacific with prospective buyers across the region. Hosting high-level buyers with a considerable budget for new purchases, the programme will ensure not only a monetary return on investment (ROI) for suppliers but also an invaluable ROI for the time spent at the event.

While the Business Matchmaking portal will see suppliers being partnered with buyers, both trade and clinicians, based on their requirements. Product interest and purchasing power will be considered to further ensure a line-up of worthwhile meetings, that is both cost effective and time efficient for attendees. ML

Conference Agenda

Day 1 - 26 March	Day 2 – 27 March	Day 3 – 28 March
Laboratory Management	Clinical Chemistry	Haematology
Infectious Diseases	Molecular Diagnostics & Genetics	Laboratory Informatics
Roundtable Discussions **(NEW)**: ■ Quality control ■ Body Fluid evaluation ■ Method Validation ■ Role of Lab in patient safety ■ Reference Intervals ■ Lab Administration	Anatomic Pathology **(NEW)**	Point of Care Testing
	Networking Meeting Innovations in biomarkers	



Dermatomycosis Diagnostics by DNA MICROARRAY

By Dr. Jacqueline Gosink, EUROIMMUN AG, Luebeck, Germany

Itchy, scaly, painful, unseemly and all-round unpleasant, fungal skin and nail infections are a scourge of our times. They are caused predominantly by dermatophytes, but also by yeasts and moulds. The pathogens spread easily via contaminated surfaces such as clothes, shoes, showers, floors and carpets, as well as by direct contact. Fungal skin and nail infections are characteristically long-lasting, recurring and difficult to cure. Identification of the causative pathogen is essential for selecting the most effective treatment. The classical diagnostic methods of pathogen culturing and microscopy are, however, time-consuming and unreliable. Direct pathogen detection by PCR-based methods provides fast and accurate identification of the causative agent, enabling prompt implementation of targeted therapy. Multiplex testing by DNA microarray provides exceptionally high diagnostic efficiency, allowing as many as 56 dermatomycosis pathogens to be determined in a single reaction.

Dermatomycosis

Fungal infections of the skin, hair and nails, known as dermatomycoses, are extremely common, affecting around 20-25 per cent of the population worldwide. Elderly people and immunocompromised patients are especially at risk. Infections caused exclusively by dermatophytes are referred to as dermatophytoses or tinea. Tinea pedis, which occurs on the soles of the feet and between the toes, is the most common dermatophyte infection, followed by tinea unguium, which affects the nails. Rarer forms can occur on the neck, back, trunk, arms, legs, groin, hands, scalp, face or beard hair. Nail infections caused by dermatophytes or yeasts/moulds are called onychomycoses and are typically accompanied by deformation of the nail.

Dermatophytes encompass fungi of the genera Trichophyton, Epidermophyton, Nannizzia, Paraphyton, Lophophyton, Microsporum and Arthroderma. Dermatophytes are classified according to the major host and infection source into anthropophilic (human source), zoophilic (animal source) or geophilic (soil source) species. Around 70 per cent of human dermatophyte infections are caused by anthropophilic species. Trichophyton rubrum, in particular, is the most frequent cause of fungal skin infections worldwide. Zoophilic dermatophytes are commonly transmitted by pets, which are often asymptomatic. These infections can cause severe inflammatory reactions in humans. Geophilic infections are less frequent in humans and typically occur in outdoor workers.

Human pathogenic yeasts and moulds include Candida spec., Scopulariopsis brevicaulis, Fusarium spec. and Aspergillus fumigatus. Moulds and yeasts cause opportunistic infections, benefitting from damage to the skin or nail caused by an existing dermatophyte. In immunocompromised individuals, local fungal infections may develop into systemic mycosis.

Diagnostic Strategy

Dermatomycoses can be difficult to diagnose clinically, as they are heterogeneous and may resemble other dermatoses such as eczema, psoriasis, erysipelas, or autoimmune diseases such as Lichen ruber planus. In addition, diagnosis can be hampered by bacterial infections of the injured skin, ongoing treatments with corticosteroid-containing compounds or secondary contact allergies.

Nevertheless, accurate identification of the culpable pathogen is a prerequisite for selecting the most suitable medication, since different antifungal drugs have different activity spectra. Selecting effective treatment at the outset is especially important given the oftentimes long duration of therapy. In the case of nail infections, for example, successful treatment can take many months.

Classical laboratory diagnostics for dermatomycoses encompass detection of the pathogen by culture and/or morphological identification by microscopy. However, this procedure requires time, patience and expertise. Successful pathogen culturing, for example, can take up to six weeks. The procedure is also prone to uncertain or incorrect findings. In mixed infections, slowly growing species may be overgrown or overlooked. Furthermore, antifungal therapy started before the sampling can hinder the culture.

Direct Pathogen Detection

A faster and more reliable method for identification of the causative agent is PCR-based detection by DNA microarray, which identifies the pathogens directly by means of their genetic material. Nucleic acid-based detection can close the diagnostic ▶

gap of microscopy/culture and increase the sensitivity and specificity of mycological diagnostics. Molecular genetic detection also significantly shortens the time to diagnosis from weeks to hours.

The novel EUROArray Dermatomycosis provides direct detection and differentiation of the most important dermatomycosis pathogens in one test. The assay simultaneously detects 50 dermatophyte species and provides species identification for 23 of these as well as for six yeasts and moulds (Table 1). The direct detection ensures accurate results, even in cases of difficult-to-culture dermatophytes, mixed infections or dermatomycoses that have already been treated.

The EUROArray procedure is extremely easy to perform (Figure 1) and takes just three hours. Ready-to-use reagents and the small number of pipetting steps ensure a minimal work load. The analysis is performed on DNA isolated from patient sample material, such as skin scales, nail shavings or hair stubs. Defined gene sections of the pathogens are first amplified by multiplex polymerase chain reaction (PCR) and at the same time fluorescently labelled. The PCR products are then hybridised to complementary probes in the microarray system and detected using a special scanner (Figure 2). The evaluation and interpretation of results as well as the archiving of data are fully automated and thus objective. No in-depth knowledge of molecular biology is required to perform the test. The swift and unambiguous test result enables prompt therapeutic intervention and may also provide a pointer to the source of infection, in the case of zoophilic infections often a pet.

Clinical Evaluation

An evaluation study was performed using 409 clinical samples. The EUROArray Dermatomycosis yielded a good agreement with the pre-characterisation. In many cases, additional pathogens that were not included in the pre-characterisation were detected. The additional findings were confirmed by further independent tests or sequencing. Thus, the study confirmed the reliability and the broad detection capabilities of the EUROArray.

Perspectives

The incidence of fungal skin and nail infections is increasing worldwide and is expected to continue to rise. Growth in vulnerable populations, such as the elderly and those with chronic diseases like diabetes mellitus, may fuel the upsurge further. Furthermore, the geographic distribution of dermatophytes species and the epidemiology of infections is changing due to factors such as migration, travel, drug therapy, lifestyle and socioeconomic conditions. This necessitates a broad diagnostic analysis in cases of infection. Molecular genetic methods such as the EUROArray Dermatomycosis are ideally suited for this application, providing rapid, comprehensive and reliable results. This enables timely, pathogen-specific treatment, increasing the chances of curing the fungal disease. ML

FIGURE 1. EUROArray procedure

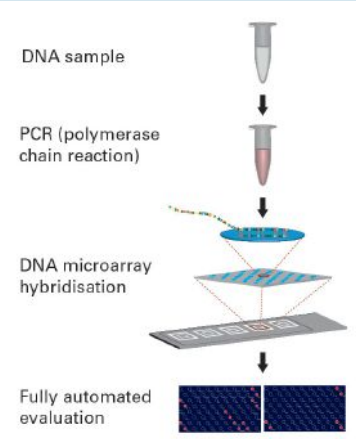


FIGURE 2. Evaluation of the EUROArray Dermatomycosis

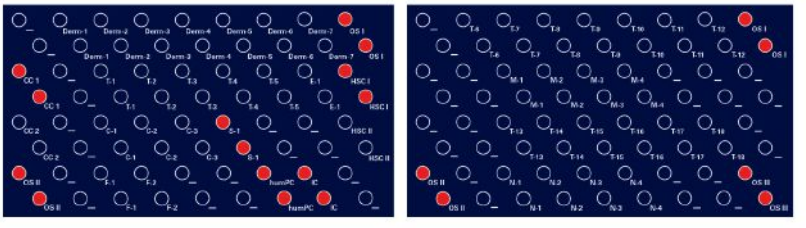


TABLE 1. Dermatophyte, yeast and mould species detected by the EUROArray Dermatomycosis

Dermatophyte species	
Anthropophilic	T. simii
T. tonsurans	T. quinckeanum* (T. mentagrophytes)
T. interdigitale	T. erinacei
T. schoenleinii	T. bullosum
T. concentricum	T. benhamiae* (A. benhamiae)
T. rubrum	T. verrucosum
T. violaceum	T. eriotrephon
E. floccosum	M. canis
M. ferrugineum	N. persicolor* (M. persicolor)
M. audouinii	**Geophilic**
Zoophilic	N. fulva* (M. fulvum)
T. equinum	N. gypsea* (M. gypseum)
T. mentagrophytes* (T. interdigitale)	N. incurvata* (M. incurvatum)

*new nomenclature (Hoog et al, Mycopathologia: 2017 Feb; 182(1-2):5-31)

Yeast species	**Mould species**
C. parapsilosis	F. solani
C. albicans	F. oxysporum
C. guilliermondii	Sc. brevicaulis

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1. Percentage of samples with numerical results that do not require additional intervention or handling, such as manual smear review, spun hematocrit, dilution, or other repeat/reflex testing. DxH series side-by-side results documentation.

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Can Probiotics Influence Fertility?

By Prof. Dr. Timur Gürgan, MD, Scientific Director, Gürgan Clinic Women's Health and IVF Centre, Ankara, Turkey; Bahçeşehir University, Department of Obstetrics and Gyneacology, Faculty of Medicine, İstanbul, Turkey, and Dr. Ziya KALEM, MD, Senior Clinician, Gürgan Clinic Women's Health and IVF Centre, Ankara, Turkey

Symbiotic relationship between microbial flora in human body and our body plays a key role in maintaining a healthy life. Microbiota of our body protects us against pathogens, supports our immune system and plays a role in the synthesis of certain necessary micronutrients. Human microbiota is composed of bacteria, fungi and viruses, and their number exceeds 10 trillion in total. This number is 100 times more than the number of other cells in our body. Researchers are able to determine the microbial diversity and rates in our body in a surprising accuracy with new-generation sequencing technique. Such developments have been the turning point in the understanding of relationship between microbiota and human health. Majority of today's studies are about

Intestinal microbiota protects intestines against the pathogenic invasion of bacteria by getting into competition for nutrients or producing antimicrobial proteins or peptides (bacteriocin).

gastrointestinal system and genitourinary system. While being less frequently, microbial communities in organs such as nose, nasopharynx, auditory canal, eyes and skin have been investigated.

Human intestinal microbiota is the most studied microbial community; it is complex and intensely related to its host (human). Intestinal microbiota is thought to have a role in many pathological conditions in human, and evidence supporting such theory is increasingly improving.

Human intestinal microbiota goes through a few developmental processes until gaining its final shape. First, foetus intrauterine is invaded by bacteria coming from mother's intestinal system and vagina. Next, it is subjected to mother's vaginal microbes during vaginal birth. Furthermore, it is known that breast milk is not sterile and host bacteria such as Streptococcus, Staphylococcus, Propionibacterium, and Bifidobacterium. In early postnatal period, intestinal microbiota is rich of Bifidobacteria, but they become less towards age 2 and child's intestinal microbiota becomes similar to adult's intestinal microbiota. Among children born by caesarean section, intestinal microbiota is different from children born by vaginal delivery in the first three to four months; this difference can be explained by reasons such as that children born by caesarean section don't contact mother's vaginal microbiota, mother's use of antibiotics and late breast-feeding.

Content of intestinal microbiota is affected by factors such as diet, smoking, age, body-mass index, haemoglobin level and antibiotics use. Diet is also thought to be the main source of intercommunity intestinal microbiota difference. Intestinal microbiome is capable of synthesising certain matters, which permeate into general circulation and affect organ systems. Indeed, some of the researchers call internal microbiome an actual endocrinal organ. Bacteria in intestinal microbiota can secrete agents such as serotonin, gamma-amino butyric acid, histamine, acetylcholine, dopamine and noradrenaline into circulation.

Importance of short-chained lipid acids presented as end product due to fermentation of carbohydrates by bacteria in the anaerobic environment of intestines has been emphasised in recent years. These are acetic acid, propionic acid and butyric acid. Great part of these products is absorbed by intestines and five to 10 per cent of them are discarded with faeces.

Intestinal microbiota protects intestines against the pathogenic invasion of bacteria by getting into competition for nutrients or producing antimicrobial proteins or peptides (bacteriocin).

It has been long known that microbiota of female reproductive system is very diverse. Traditionally, research used to focus on vaginal microbiota; however, evidence has been collected in the last 10-20 years on the fact that female reproductive systems including uterus are not sterile. It has been increasingly clarified that microbiota extends beyond uterine cavity, and according to some of the researchers, there may be bacteria found also in fallopian tubes of healthy women. Studies have recently begun on the relationship between reproductive system microbiota and fertilisation and successful pregnancy. So far, the relationship between clinically apparent infection and inflammation and impaired reproductive function has been clearly identified. Inflammation due to pathogenic invasion causes proinflammatory cytokines and growth factors to be secreted from immune system cells. Slight changes in microbiome may cause ambiguous changes in tissues, but such changes may be clinically important.

Lactobacillus which has probiotic attributes and prevents reproduction of other bacteria is prevalent in normal vaginal microbiota. Lactobacillus produces high amount of H2O2 and prevents other members of microbiota from becoming prevalent in tissue.

Reproductive system's microbiota is not only composed of free bacteria clusters. These bacteria mostly form three-dimensional biofilm structures. These structures function as a protective cover; they involve polysaccharides, nucleic acids and proteins. These biofilm structures prevent immune system from recognising the pathogens and reduce positive effects of antibiotics.

Biofilms usually form in vagina but can extend towards endometrial cavity and even fallopian tubes. Even though biofilms' role in pathogens of reproductive system is not fully known, what we need to have in mind is that the relationship between microbiome and reproductive system cannot be identified only with presence or absence of certain bacteria.

Microbiome can affect gametogenesis. It has been shown that some bacteria impair follicular development and suppress follicular response to gonadotropins.

Studies on vaginal microbiota of healthy women have been carried out under the management of human microbiome project. Samples were taken from three different areas (introitus, mid-vagina and posterior fornix) of vaginas of 113 healthy, volunteer women, and these samples were analysed with the 16S rRNA sequencing.

The samples taken from the same individual at different times differed scarcely by type of bacteria, and a very little difference was found between the samples from different individuals. The samples taken from different areas of vagina did not differ by type of bacteria, and Lactobacillus was prevalent. The fact that samples taken from the same individual at different times showed very little difference is the indicator that vaginal flora is stable. Vaginal microbiota is simpler than other parts of body in terms of content in a healthy woman; so, even small shifts may cause disease symptoms.

It has been believed that ascending colonisation of upper genital system via vagina is associated only with pathological conditions until recently. Uterine cavity has been considered sterile for a long time due to cervical mucus involving high levels of proinflammatory cytokines, immunoglobulins, and antimicrobial peptides and functioning as a protective barrier. However, upward bacteria transport is possible in a healthy reproductive system. For example, when we placed radio-labeled 1-2 ml human serum albumin in the posterior fornix of vagina, these ▶

were observed in uterus two minutes later.

As shown in a few studies, human follicular liquid can be cultured and hosts microbes. Follicular liquid was obtained during transvaginal oocyte retrieval in some of these studies, during laparoscopy in others. It has not been clarified whether bacteria are present in follicles before the retrieval of bacteria cultured from the follicular liquid or whether follicular liquid is contaminated during aspiration. It has been found that follicular liquid contains microbes similar to the ones in vaginal microbiota. These include Lactobacillus, Bifidobacteria, Enterobacteriaceae, Streptococcus and Staphylococcus. This finding reinforces the assumption that follicular liquid is not contaminated during oocyte aspiration and is colonised beforehand.

As mentioned before, parts (follicular liquid, endometrial cavity) playing a role in reproductive system and considered to have been sterile in the past have been understood not to be sterile and to have idiosyncratic microbiotas in molecular studies.

In bacterial vaginitis, reduction of Lactobacillus (Döderlein rods) dominance causes increased bacteria diversity (Gardnerella, Mycoplasma, and Prevotella). This increased diversity in bacterial vaginitis increases tendency to gynaecological infections such as Chlamydia, Neisseria gonorrhoea, Trichomonas, Human papilloma virus (HPV) and herpes simplex type-2. It is known that hydrogen peroxide produced by Lactobacillus have viricidal quality, and decreased Lactobacillus in bacterial vaginitis increases tendency to HIV infection. Again, subclinical endometritis was observed in 27 per cent of the patients with vaginal chlamydia infection and 26 per cent of the patients with vaginal gonorrhoea infection.

Similarly, to vaginal microbiome, it seems possible that imbalances in uterine microbiome can increase tendency to disorders such as infertility and pregnancy complications. Impaired uterine microbiome can cause early-late abortions, preterm labour and postpartum endometritis, affecting the reproductive system. Follicular fluids were studied during the oocyte retrieval for IVF, and differences were found in the composition of follicular fluid by diseases (polycystic ovary, endometriosis) and whether there is implantation.

In a study conducted on endometrial microbiota, the patients in which more than 90 per cent of endometrium's bacteria content were composed of Lactobacillus were compared with the patients in which the rate was less than 90 per cent, and implantation, clinical pregnancy, ongoing pregnancy and live birth rates of the patients with Lactobacillus dominance (more than 90 per cent) were found significantly higher than the other group.

If we were to accept effect of vaginal, uterine and follicular fluid microbiome on infertility, we would need to investigate possible treatment options. For instance, prophylactic antibiotics usage before embryo transfer in IVF cycles may reduce amount of microbial colonisation in upper genital tracts and be effective in pregnancy rates. Yet, contradictory research results have been reported to date.

As mentioned before, the most distinct characteristic of a healthy vaginal microbiome is the relative multitude of Lactobacillus. Beneficial effects of probiotic supplement on human health have been increasingly receiving recognition by physicians. Given the abundance and effects of microorganisms in reproductive system, it seems reasonable that beneficiary effects of probiotics might be positive on the reproductive system health. Since majority of bacteria in human body is present in intestines, great part of studies has investigated oral probiotics intake on intestinal health to date.

For the first time, Hilton et al. (1992) reduced the risk of relapse by seven times by giving 250 grams of yoghurt containing Lactobacillus acidophilus a day orally to the patients with recurring vulvovaginitis complaint. Later, it was shown that Lactobacillus rhamnosus inhibited the reproduction of Gardnerella vaginalis and candida albicans through high glycogen metabolism and lactic acid production in vitro. In recent years, several studies have been conducted on benefits of probiotic supplement and beneficial effects of probiotics directly on reproductive health are yet to be proven; however, orally-taken Lactobacillus rhamnosus and Lactobacillus fermentum have been shown to be hygienizing vaginal flora among 82 per cent of women with a vaginal dysbiosis history. Supporting the treatment with Lactobacillus rhamnosus and Lactobacillus reuteri following the antibiotics usage in bacterial vaginitis was reported to be increasing vagina-specific Lactobacillus iners and Lactobacillus crispatus. Based on these observations, certain bacterial strains can be utilised to regulate pre-conception vaginal microbiota, but further studies are required to find the ideal combination, dosage and way of application.

It was stated that probiotics might contribute to a healthy immune system as well as its contributions to the formation of a healthy microbiota in intestines. This result was based on the presence of quality meta-analyses supporting that probiotics can be used against conditions such as infectious diarrhoea, antibiotics-related diarrhoea and irritable bowel syndrome.

There are many studies in the literature concluding negative impact of impaired vaginal microbiota on fertility. However, studies on upper genital system's (endometrium, fallopian tubes, follicular liquid) microbiota which has been accepted to be sterile until recently are limited, and no study was observed in the literature on the treatment of upper genital system's impaired microbiota with probiotics. On the other hand, based on the assumption that vaginal microbiota can affect upper genital system's microbiota via adjacency, it can be concluded that probiotics used for impaired vaginal microbiota would indirectly affect upper genital system in a positive way. ML

For the first time Hilton et al. (1992) reduced the risk of relapse by seven times by giving 250 grams of yoghurt containing Lactobacillus acidophilus a day orally to the patients with recurring vulvovaginitis complaint.

Dr. Gurgan will be speaking on 'Repeated Implantation Failure: Investigation and Therapeutic Options' on February 7, as part of the Cytogenetics & IVF, at MEDLAB Exhibition and Congress

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The Promise of High-sensitivity Cardiac Troponins in the Rapid Exclusion Algorithm for ACUTE CORONARY SYNDROME

By Tan Hong Jie Gabriel, MBBS, Singapore, and Jack Tan Wei Chieh, MBBS, Singapore, MMed (Int Med), MRCP, UK

Chest pain is one of the leading presentations in the Emergency Department (ED), and the historically conservative approach to avoid missing a potential acute myocardial infarction (AMI) has led clinicians to admit or prolong the ED dwell time of many more patients than are subsequently found to have an AMI. This consequently leads to crowding in the ED, which is associated with adverse outcomes for all patients, with or without AMI.

Approximately 30 per cent of chest pain related ED visits will have a final diagnosis of a myocardial infarction (MI). Clinicians are obligated to exclude myocardial ischemia with a high degree of certainty. To manage costs and the adverse effects of overcrowding in the ED, it is of high priority to be able to rapidly and safely discharge patients with a sufficiently low probability for acute coronary syndrome (<0.5 per cent – 1 per cent).

The 2012 third universal definition of a MI is the detection of a rise and/or fall of cardiac troponins with at least one value above the 99th percentile upper reference limit (URL) in addition to at least one of the following: 1) symptoms of ischaemia; 2) new electrocardiogram (ECG) changes of ST-T segments, new left bundle branch block or development of pathological Q waves; 3) imaging evidence of new regional wall motion abnormality or loss of viable myocardium; and/or 4) identification of an intracoronary thrombus by angiography or autopsy.

To diagnose AMI, myocardial injury must be accompanied by clinical indicators of an ischemic mechanism. On the contrary, an AMI cannot be present in the absence of myocardial injury. Hence, a MI is easier to rule out than to rule in. In addition, sufficient time must be allowed for the release of myocardial structural proteins (i.e. cardiac troponins, cTn) into the circulation in measurable quantities to be detectable post-myocardial injury. Therefore, the absence of high-sensitivity troponin (hsTn)>99th percentile URL and ≥6 hours after the onset of ischemia has conventionally been used to rule out MI.

In the 1960s, aspartate transaminase (AST) was the first biomarker widely used in diagnosing AMI, followed by creatine kinase (CK) and lactate dehydrogenase (LDH) by the 1970s, all of which were not specific to cardiac muscle and hence detection of these were not specific to myocardial injury. Myoglobin, found in the heart and striated skeletal muscles, was later developed in 1978 as a cardiac biomarker as its serum level rises following acute myocardial injury. This was replaced in the era of electrophoresis advancement during which cardiac isoenzymes CK-MB, LDH 1 and 2 could be detected.

Troponin is a complex within the contractile apparatus of cardiac and skeletal myocytes discovered in 1965. It was detectable with a reliably sensitive radioimmunoassay developed in the late 1980s. Several generations of troponin assays have since been developed, each reportedly with increasing diagnostic utility as well as the ability to rule out MI. Cardiac troponin (cTn) is a collective term referring to serum troponins T and I, which are isoforms highly sensitive and specific to cardiac myocytes, the sensitivity for detection of which approaches 100 per cent when sampled 6 – 12 h after acute onset of chest pain. Therefore, to reliably rule out AMI, patients with acute chest pain have had repeat troponin samples 6 – 12 h after the initial assessment. Consequently, patients were increasingly admitted for observation.

The latest generation of hsTn assays is defined as assays that have a coefficient variant (CV) of 10 per cent or less, at the 99th percentile URL, with the ability to detect cTn levels in at least 50 per cent of the reference normal population. Compared with earlier-generation assays, hsTn can ▶

establish biochemical evidence of myocardial injury at a much lower concentrations (10- to 100-fold lower) and thus earlier after the onset of ischemia. It is also able to discriminate small changes in concentration starting within the normal reference range, above the limit of detection (LoD) of the assay but below the URL. Small dynamic increases (delta values) are associated with a higher probability of subsequent rises above the URL and future major adverse cardiac events (MACE); whereas stable concentrations of hsTn in the detectable range below the URL are associated with structural heart disease, atherosclerosis risk factors, and a higher risk of future MACE. Consequently, non-detectable or very low hsTn concentrations identify patients with lower cardiovascular risk.

Of the emerging applications for hsTn, the rapid rule-out of MI in the ED is the application most likely to be incorporated by clinicians. Accelerated diagnostic protocols (ADP) utilising hsTn can facilitate earlier triage while maintaining an acceptable negative predictive value (NPV). For example, the ADP developed by Meller et al (2015) utilising high-sensitivity troponin T (hsTnT) identified 35-40 per cent of patients to be at extremely low risk of MACE and hence ideal candidates for early outpatient management.

ST-elevation myocardial infarction (STEMI) is an ECG diagnosis in the context of a patient with typical cardiac chest pain, and clinicians do not wait for biochemical evidence of myocardial damage before emergency revascularisation is instituted. Non-ST-elevation myocardial infarction (NSTEMI), on the other hand, can be ruled out as early as four hours after symptom onset with existing hsTn assays, allowing shorter ED or inpatient stay for patients without raised levels of troponin and earlier intervention for those with a confirmed AMI.

ADPs incorporating the clinical history, electrocardiogram, and cTn concentrations provide a framework to rapidly evaluate and triage chest pain patients suspicious for ischemia. The National Institute for Health and Care Excellence (NICE) updated guidelines in 2016 on the evaluation of patients with suspected AMI recommended clinicians to consider ruling out MI if a patient has very low concentrations of cTn at presentation. They further recommended clinicians to apply the LoD as a threshold below which MI can be safely ruled out at presentation, provided patients are deemed to be at low risk of MI by an appropriate risk stratification system. Evidence from studies including both the Thrombolysis in Myocardial Infarction (TIMI) score and the Global Registry of Acute Coronary Events (GRACE) score were considered. Having cTn concentrations embedded in both scores were initially derived and validated in patients with confirmed MI for prognostication, but over time, these scores have been implemented to risk stratify patients with suspected MI as well. Although NICE ultimately recommended the TIMI risk score, it was yet to be validated with hsTn, using LoD at presentation alone.

In 2018, Carlton et al found when a hsTnT of <5ng/L (LoD) was applied alongside a TIMI score of 0 and a non-ischaemic ECG, the sensitivity and NPV were extremely high, at 99.5 per cent and 99.6 per cent respectively. For the high-sensitivity Troponin I, (hsTnI), using the LoD (<2ng/L) and a TIMI score of 0 alongside a non-ischaemic ECG, the sensitivity was 98.9 per cent and NPV was 99.5 per cent. These strategies would identify 17.9 per cent and 21 per cent of low-risk patients respectively.

The European Society of Cardiology (ESC) has previously advocated the use of a 0/3-hour algorithm in conjunction with the ECG and GRACE (Global Registry of Acute Coronary Event) risk score in clinical practice. However, a recent meta-analysis by Pickering et al (2017) have concluded that a single hsTnT concentration below the LoD in combination with a non-ischemic ECG provided excellent NPV (99.3 per cent) and sensitivity (98.7 per cent) for MI, hence may successfully rule out AMI in patients presenting to EDs with possible ACS without the need for additional risk score. Indeed, the ESC now advocates use of the LoD at presentation in conjunction with ECG, but do not recommend the addition of clinical risk scores. Nevertheless, application of clinical risk score is still widespread in most settings, probably due to the perceived assurance it provides diagnostically.

One of the most widely used risk scores, the history, ECG, age, risk factors, troponins (heart) score, was developed and validated in a population with suspected ACS. A recent meta-analysis of 11,217 patients demonstrated that this score had a sensitivity of just 96.7 per cent, below the threshold of 99 per cent, which most ED clinicians deem acceptable. It is unclear whether this score risk stratifies better than with hsTn alone, hence comparative studies between risk stratification thresholds of hsTn alone or in combination with risk scores are required to determine if patient safety can be improved.

The evolution of hsTn-based rule-out strategies in the ED is aimed at reliably excluding myocardial injury as early as possible through staged measurement of hsTn in conjunction with other clinical assessments for the probability of MI. Emerging components include movement of serial hsTn samples to earlier time points, addition of criteria for an absolute delta hsTn changes between measurements, and integration of very low decision limits well below the 99th percentile URL at the early time points. For example, the ESC 2015 practice guidelines also included an alternative (Class I) strategy, reducing the sampling interval from three to one hour when a validated hsTn assay with 0/1-hour algorithm is used. Such an algorithm incorporates all three components listed above, including a very low cut-off applied at the initial hsTn value aimed at excluding MI after the first sample in patients who arrive >three hours after symptom onset, and a delta criteria for patients with dynamic

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hsTn concentrations subjecting them to additional testing. These reports have shown that using very low hsTn on the first sample can reasonably exclude MI in 40-50 per cent of low-risk patients having presented >two hours from symptom onset. Similarly, a comparative study by Chapman et al (2017) between the High-STEACS (High-Sensitivity Troponin in the Evaluation of Patients With Acute Coronary Syndrome) 0/3/6-hr algorithm and the standard ESC 0/3-hr algorithm to rule out MI, also value added on the use of a very low 0-hour cut-off to facilitate earlier rule-out, and a delta criterion to exclude increasing values with absolute concentrations below the URL among patients requiring three-hour sampling.

Boeddinghaus et al (2017) moved the serial sample in the 0/3- hour algorithm forward to one hour and comparing the ESC alternative 0/1-hour strategy with other approaches using either a single cut-off at 0 hours or the one-hour strategy. They found that each of these approaches performed similarly in delivering an NPV >99 per cent, comparing favourably with the ESC 0/3-hour algorithm (NPV, 98.4 per cent) among patients presenting >two hours after symptom onset. However, among early presenters, the NPV (98.5 per cent) and sensitivity (94.2 per cent) were lowered with the use of the single 0-hour cut-off (5 ng/L). Hence, it is of utmost importance that very early presenters should have serial testing to support an acceptable NPV, as should patients with other high-risk indicators.

Although others have also advocated the use of the LoD as necessary to support an acceptable sensitivity with a single sample, a study by Carlton at el (2016) showed that use of LoD (1.2ng/L) ruled out fewer patients (18.8 per cent discharge rate), albeit with higher sensitivity of 99.0 per cent (95 per cent CI, 96.8 per cent – 99.7 per cent) and NPV of 99.5 per cent (95 per cent CI, 98.4 per cent – 99.9 per cent).

Undoubtedly, there remain several challenges in translating this diagnostic innovation into cost-effective healthcare with improved patient outcomes. Firstly, increased sensitivity of hsTn assays are usually accompanied with reduced specificities and low positive predictive values (PPV) for MI. Although there would be a lower likelihood of a missed MI, these assays would not be suitable for early rule-in decision-making. In other words, clinicians would need to be more prudent and cautious with positive tests given the advent of such assays. Secondly, the reduced specificity and low PPV for MI accompanying the improved analytical precision of the assays leads to greater rate of invasive investigation, i.e. coronary angiography without a proportionate increase in coronary lesion-specific therapy, i.e. revascularisation, although the improved analytical precision enables earlier clinical decision to admit or discharge a patient with suspected ACS. Thirdly, hsTn assays are impractical in the primary care setting due to the long turnaround times for results despite its usefulness in the context of low or intermediate clinical suspicion of MI, provided sufficient time has passed since symptom onset. Also, it is problematic for general practitioners to receive results in a timely manner for execution of an appropriate clinical response. Lastly, improved test precision without a greater discretion in clinical decision making and test interpretation may result in increased costs and inefficiencies, i.e. increased investigative burden of patients tested positive due to the many non-coronary causes of elevated troponin.

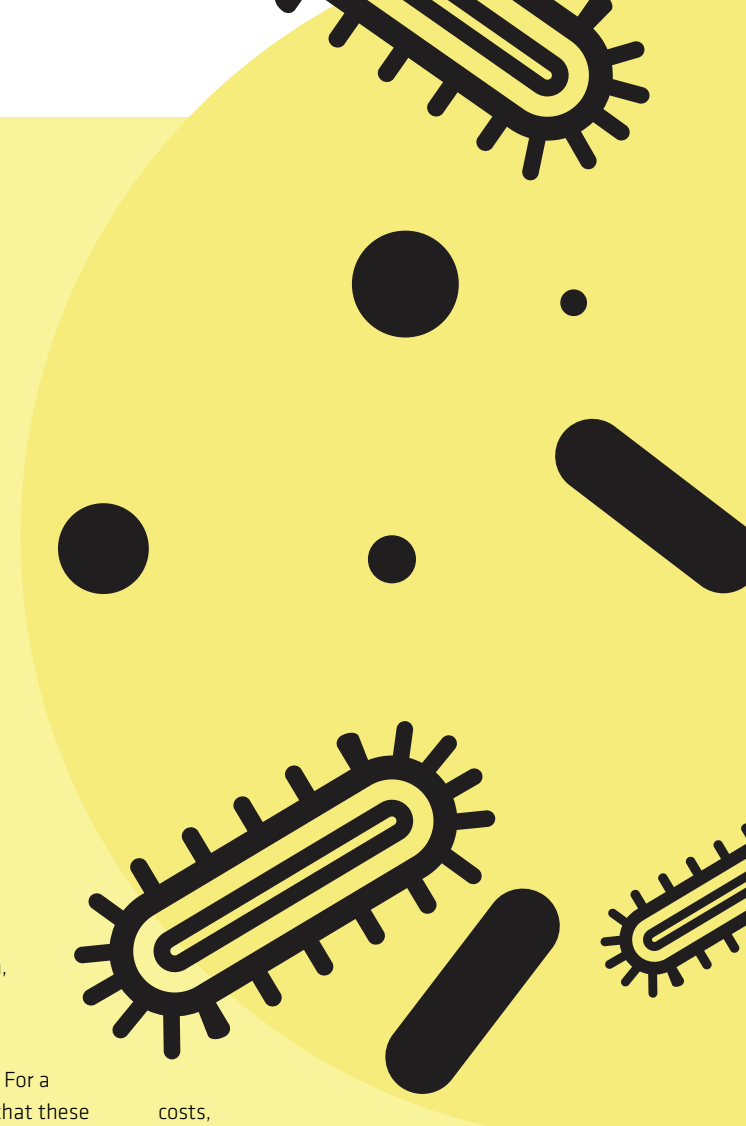
With emerging studies published worldwide optimising the potential application of hsTn, knowledge gaps have still remained to date. For example, there is lack of data among early presenters to provide confidence around and/or lead to revision of current algorithms. Future algorithms may possibly integrate the actual timing of sampling instead of assigning specific time points as per all current algorithms. The time-related rate of rise may become more crucial than the absolute or relative changes. Perhaps coupling hsTn with clinical probability tools such as cardiovascular risk scores or imaging such as CT coronary angiogram can improve diagnostic performance for ACS rule-out. Prospective randomised studies implementing these testing strategies are warranted in view that current studies are mostly observational with reported outcomes based on management according to local standards of care. In view of low cut-offs and small delta criteria optimising NPV but lowering PPV, future studies should also be directed at determining higher delta criteria to rule in MI. These issues should be addressed in the near future as we move toward evidence-based best practice.

In conclusion, hsTn has greater utility in the early rule-out of MI, potentially at 0-hour presentation for low risk cases clinical outcomes are also improved due to less likelihood of missed AMI in patients presenting with chest pain in the ED. Nevertheless, specificity and PPV remains its main shortfall as hsTn does not differentiate AMI from other non-coronary causes of myocardial necrosis. hsTn should be always be used in tandem with clinical judgement to enable appropriate interpretation of these assays. Lastly, consensus and continuous education in every institution employing hsTn are essential for clinical practice changes in testing strategies to harness the full potential of hsTn in further improving resource efficiency and patient safety. ML

References available on request.

MULTI-DRUGS RESISTANT ORGANISMS: ALARMING THREAT FOR INFECTIOUS DISEASE MANAGEMENT

By Tri Wibawa, Department of Microbiology, Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada, Yogyakarta, Indonesia

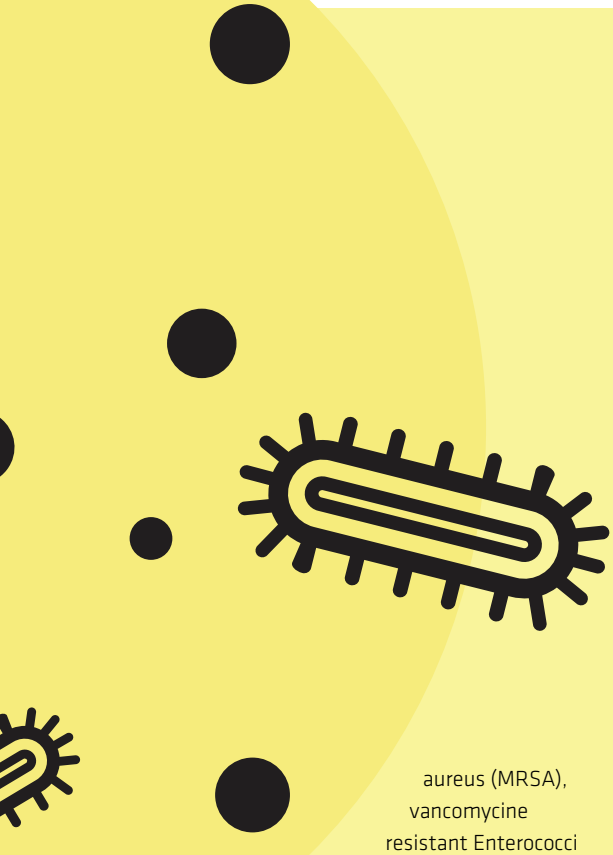


Infectious diseases are illness involving two organisms: a human being as a host and a microorganism as a causative agent. To manage infectious diseases doctors must consider both, otherwise it will not address all the biological characteristics of infectious diseases. Current approach of infectious diseases management is using antimicrobial agents to eradicate pathogens. The aims of antimicrobial agent administration are to eradicate or decrease the pathogens concentration below dose of infection. The microbe should be killed by drugs, which are available in the market. However, there are huge accumulated data of pathogens resistance against antimicrobial agents. In addition, the antimicrobial agent effect is influenced by the characteristic of the patients, since its administration does not mean the drugs will be able to reach the target organ, where the microbes are present, properly.

Mutation of the microbes is a random event, which eventually results in the change of the entire characteristics of the microbes, which is more exaggerated by the horizontal gen transfer. For a long time, it has been known that these mechanisms are responsible for the rise of antimicrobial resistance in microbes, though it is not uniformed in bacteria, fungus, and viruses (Richardson, 2017). A human as a host has been documented with genetic variation also. However, direct evidence of interaction between the two events of evolution in the microbes and humans may not yet be conclusive.

Multi drug resistant organisms (MDRO), a technical definition that is not uniform, refers to microbes that are resistant to many antimicrobial agents from different classes and inhibitory mechanisms. MDRO infections have clinical manifestations that are like infections caused by susceptible pathogens, with an exception in several cases. Options for treating patients with MDRO infections are often extremely limited, because of the shortage of antimicrobial agents left. On the other hand, the pipeline of antimicrobial invention has been in a droughty condition. It will result in increased lengths of stay, costs, and mortality. All together it will produce an interflow of infectious diseases management impediments (CDC, 2006).

There are two issues of MDRO management in the healthcare setting, containment for its transmission and treatment for infected patients. Containment of the MDRO transmission includes the community and healthcare associated transmission. Transmission of MDRO is a big concern since, by nature, the genetic determinants of drug resistance can be transmitted from bacteria in the various genus and species. It means that if we have extended-spectrum beta-lactamases (ESBL) producing Escherichia coli in the community or healthcare, we may expect that the ESBL associated genes spread to other Enterobacteriaceae in the same region. The same situation occurs in methicillin resistant Staphylococcus



aureus (MRSA), vancomycine resistant Enterococci (VRE), or carbapenem-resistant enterobacteriaceae (CRE) cases (Reinheimer et al., 2016).

Multifaced approaches are needed to contain the MDRO transmission in the healthcare setting (Backman et al., 2011; Barnes et al., 2014). Current recommendation for containment of the MDRO transmission includes several strategic planes i.e.: implementing antibiotics stewardship, focus on infection prevention fundamentals, enhance the role of microbiology laboratory, minimise the use of invasive medical devices, and enhancement of environmental cleaning and disinfection strategies. Antibiotics stewardship is a systematic programme that aims to ensure the prudent antibiotics prescription in bacterial infection cases. This will result in the reduction of selection pressure for bacteria that will eventually prevent the emerging of MDRO. Infection prevention fundamental for MDRO is related with the contact precaution procedure implementation, such as: hand washing and hygiene. One of the most important factors is to make sure that the infection prevention programme is in place and implemented. Microbiology laboratory is the unit that can detect the presence of MDRO in the hospital. It is always a case that prompts notification to the infection control officers, and clinicians will help to contain MDRO transmission. Minimisation of invasive medical device is another key factor of MDRO containment, through the daily basis review of the necessity of medical device use, such as: central line and urine catheters.

Implementing the MDRO transmission prevention programme is challenging. Factors that may contribute to the failure of such strategic plans are: poor human resource education and training (Dumyati et al, 2017); lack of involvement and communication among clinicians, nurses, infection control officers, microbiology laboratory, and healthcare management in implementing the programme; lack of surveillance infrastructure and implementation, including active surveillance culture to identify patients who are colonised with a targeted MDRO; monitoring of MDRO transmission base on the positive culture results of patients, which may not reflect the real transmission and circulation of MDRO (CDC, 2006).

Treating a MDRO bacterial infection case is challenging. This problem may be correlated with the situation that several – if not all – classes of antibiotics are resistant. There is limited choice for clinicians to kill bacteria by using common antibiotics. Although antibiotics is not the only answer, the effectivity of nutrition/energy balance, maintaining immune-protective barrier, preserving the flora normal, and other immunological intervention are not as effective as antimicrobial approaches.

One of the issues of antibiotics therapy for MDRO is whether to use monotherapy or combination of several antibiotics. It is controversial and inflicts debates from experts. The favouring opinion to the combination therapy is based on several considerations, such as: there is an in vitro and animal data that several antibiotics may have synergism effect to kill bacteria; it is a reasonable approach to prevent resistance of bacteria against other antibiotics; and it also increases the probability of appropriate empirical coverage. On the other hand, experts prefer to recommend antibiotic monotherapy based on several reasons: the cost, toxicity, and antagonism between combined antibiotics; studies combined different antibiotic combinations, which is not able to show the efficacy of specific antibiotic combination; and patients included in RCTs are not representative of the patient population seen in general practice (Paul and Leibovici, 2013). Furthermore, there is no comprehensive meta-analysis study that truly favours combination therapy.

However, it was interesting that the combination antibiotics therapy has been prescribed, at least occasionally, in 114/115 (99.1 per cent) hospitals, in France, Greece, Italy, Slovenia, Spain and selected hospitals in the U.S., which were involved in a cross-sectional, Internet-based questionnaire survey. It seems that combination therapy was the preferred treatment strategy for infections caused by carbapenem resistant Gram-negative bacteria (CRGNB) among hospital representatives, even though high-quality evidence for carbapenem-based combination therapy is lacking (Papst et al., 2018).

The controversies of antibiotic treatment in MDRO bacterial infected patients indicated that the problem of MDRO is obvious. The best approach must be a pre-emptive action to prevent generation and transmission of MDRO in the society and healthcare facilities. However, the three steps of MDRO check points e.g.: prevent generation, containment of transmission, and treatment of the patient is a vicious circle of antibiotics resistant. We need comprehensive action at every step of the way. ML

References available on request.

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STUFF WE SHOULD NOT BE DOING

A look at better ways to determine the appropriate tests to offer and also how to best minimise errors

By Robert L. Sautter, PhD HCLD/CC (ABB), Principle of RL Sautter Consulting LLC, Lancaster, South Carolina, and Kevin C. Hazen, Ph.D., D(ABMM), FAAM, FIDSA, Director of Clinical Microbiology and Professor of Pathology, Section Head of Bacteriology, Mycobacteriology and Molecular Microbiology, Duke University, Durham, North Carolina, U.S.

Laboratory testing is dependent upon preanalytical, analytical and postanalytical test phases. In the laboratory, we are focused upon the analytical phase and often ignore the preanalytical and postanalytical portion of testing. This is a drastic error, even though both the pre and post phases are more difficult to control, they account for many errors, and for delays in caregivers reacting to test results. Seventy per cent of laboratory errors are associated with pre-analytical errors. Much work has been done to speed the results of laboratory testing in the analytical phase, however if the results are not available to care givers soon after they are posted in the laboratory information system, then the effort expended to speed the testing will be wasted. When possible, electronic results sent directly to the caregiver will aid in care, i.e. TheraDoc system. Also, if test results can be in the medical record when the caregiver can review them or rounds with patients, it will speed appropriate care.

Over the years, we have often offered testing and methodologies that can be described as "we have always done it that way". The use of evidenced based medicine should replace that approach so that providers test the appropriate patient, use the best method to diagnose disease and also treat patients appropriately. Microbiologists, infectious disease physicians and pharmacists have recently been engaged in antibiotic stewardship programmes to better use appropriate antimicrobials to treat patients and not to use them on patients that do not need them. By doing so, a significant cost savings will be seen as well as better outcomes for patients. Too often laboratory medical and administrative staff make decisions in a void without using expertise from other disciplines. The use of multidisciplinary teams and diagnostic management teams offer a great advantage in treating patients and offering relevant laboratory testing.

In addition to some practices mentioned above, here is a look at some of the "stuff we should not be doing".

Examples:

1. Accepting samples that are not appropriate for testing either due to poor collection, storage, or from unapproved sources without proper validation studies.
2. Adding newer methodologies without addressing with affected medical professionals preanalytical specimen collection errors and other pre-analytical steps.
3. Shipping samples many hours to the

main laboratory if processing, testing or screening can be done locally. If they cannot be done in the laboratory, then in the point of care.

4. Adding new methodologies or procedures without discussing them with a multidisciplinary team including: Infectious disease, the physician specialty affected by the change and administration (i.e., the post-analytical impact of a new test).
5. Agreeing to perform AST on drug-bug combinations for which there are no standards.
6. Other "do not do" items will be discussed.

Antibiotic Stewardship and the Laboratory

The laboratory has played a key role in dispensing antimicrobial results as well as interpretation for clinicians, nurses and pharmacists. The explosion of antibiotic stewardship has occurred in the last few years with increasing full-time equivalents (FTE) as well as increasing budgets in pharmacy, infectious disease and nursing. However, since the Joint Commission issued a new standard for antimicrobial stewardship programmes in hospitals, critical access hospitals, and nursing care centres, the laboratory has been excluded from the "table". The members of the team as mentioned in the standard are an infectious disease physician, pharmacist, practitioners and infection preventionists. For several of the members of the team, "if available in the setting," are to be included. The laboratory, and in particular the microbiology laboratory, is excluded from the required active members. Ideally a doctoral level microbiologist should be on the team as is recognised by the Centers for Disease Control and Prevention (CDC). Although the Joint Commission states that they mimic the requirements for the team published by CDC, however, a member of microbiology laboratory or the diagnostic laboratory in general is not mentioned as key members of their stewardship team.

Laboratory Stewardship

Over the last 30 years an explosion in the cost of healthcare has occurred, and the laboratory is not exempt to this issue. In fact, an estimated four to five billion laboratory tests are performed annually with 30 per cent of them being unnecessary. The clinical microbiology laboratory is to provide appropriate tests to aid in diagnosis and therapeutic management of a patient with an infectious disease. Evidence-based approaches are key to this success as well as using a multidisciplinary team and also diagnostic management teams to treat patients. The clinical microbiologist should not only be dispensing test results but also should be key in determining which tests are useful in a patient scenario along with other caregivers. Many of the tests that could be ordered are not pertinent to the disease but rather simply just "ordered by habit". Stewardship programmes rely on the clinical microbiology laboratory to direct actions needed for effective stewardship activities.

Examples of those contributions to stewardship are: 1. preanalytical, analytical and postanalytical test phases all influence the value of a test result; 2. Rapid result reporting can be an extremely important parameter for care as it can lead to effective interventions; 3. Guidance in selection of tests and interpretive assistance of the results; 4. Implementation of the most currently effective testing modalities and interpretation of the results; reporting appropriate antibiotics associated with positive outcomes for the patient; 5. Detection of antibiotic resistance begins in the Clinical Microbiology laboratory.

By working with other healthcare specialties, the microbiologist can serve as a valuable resource to the healthcare system.

The clinical microbiologist plays an important role in antibiotic stewardship and contributes to the antibiotic and laboratory stewardship teams in many ways, some of which are detailed above. They should be part of hospital, state, regional and federal expert panels to come up with guidelines on all areas of microbiology, as demonstrated in North Carolina's CRE guidance. To that point, clinical microbiology should be represented on all committees discussing antibiotic resistance and stewardship and infection control, so the clinical microbiologist can describe how they can help. ML

References available on request.

At MEDLAB, Sautter will be giving a presentation on 'What We Should Not be Doing in Microbiology' and will expand upon how the microbiologist should approach these issues, on February 6. An additional talk will be given on how to build a consolidated laboratory.

Use of Multigene Panel Testing in MOLECULAR DIAGNOSTICS OF CANCERS

By Dr. Val Zvereff, Technical Director- Geneticist, National Reference Laboratory (NRL)

Cancer is a very complex disease associated with mutations in almost 1,000 known cancer related genes in humans. These mutations are, in the majority of cases, acquired and caused by environmental, occupational or some other factors. In approximately 10 per cent of cancer cases, however, mutations in cancer-related genes are hereditary.

Molecular (or genetic) testing plays an important role in cancer diagnostics. A good example of a molecular genetic test used to diagnose cancer is the DNA analysis of Breast Cancer susceptibility gene 1 (BRCA1) and Breast Cancer susceptibility gene 2 (BRCA2), mutations which can increase the risk of breast, ovarian, and several other cancers. This type of testing came into the limelight following Angeline Jolie's public disclosure of her BRCA1 pathogenic mutation, which resulted in a spike in breast cancer genetic testing that experts described as the "Angelina Jolie effect".

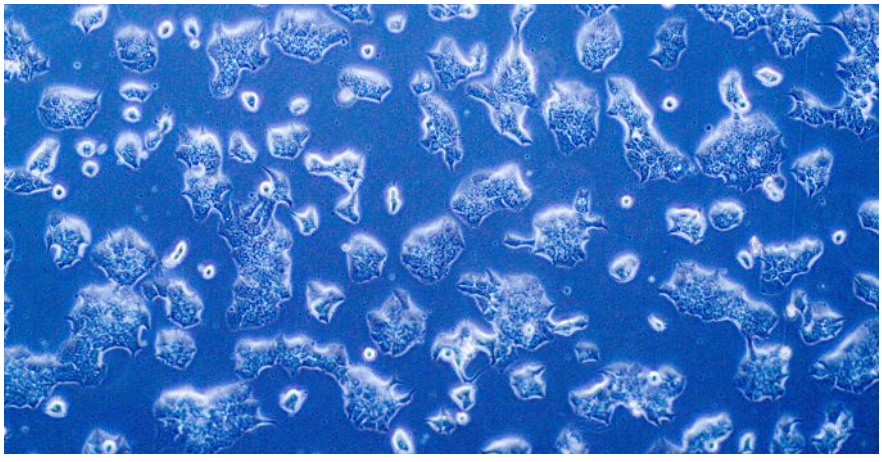
Traditionally, identification of genetic cancer risk has been performed through single gene testing in a stepwise manner using Sanger sequencing. The introduction of next-generation sequencing (NGS) in molecular diagnostics added more layers of complexity to clinical decision-making for clinicians. Presently, clinicians have to choose between single-gene testing, multigene panel (MGP) testing or even whole exome sequencing (WES) for their first-tier clinical diagnostic test.

A single-gene assay is indicated in cases when clinical diagnosis is obvious and only confirmation testing is required. Nevertheless, high cost, longer time, and the laboriousness of the approach shifted cancer testing to the MGP. MGP testing refers to the concurrent sequencing of multiple pre-selected genes for the detection of actionable DNA variants.

The introduction of MGP testing in cancer diagnostics quickly changed the clinical landscape for cancer patients and their families. Not only did it contribute to the management of the condition in patients, but it also helped with the risk management and reduction of the disease in risk group individuals.

There are many MGPs employed in cancer diagnostics today, some of which are used for the detection of pathogenic alterations in risk individuals or individuals with a history of breast cancer, the most common cancer among women and a high cause of mortality worldwide according to the World Health Organization. With the majority of cases of hereditary breast and ovarian cancers being caused by germline mutations in the BRCA1 and BRCA2 genes, many women at an increased risk of the disease and who had previously tested negative for pathogenic mutations in both genes had finally pathogenic variants of other breast cancer-related genes detected through the MGP approach. In fact, many studies highlight the utility of multigene panels in patients with history of negative BRCA1/2 genetic testing. One such study shows that using the MGP approach in patients who had previously tested negative for mutations in BRCA1 and BRCA2 genes improved identification of pathogenic variants in other genes that cause breast or ovarian cancer susceptibility at a detection rate ranging between 2.9 and 9.3 per cent. Another advantage of MGP is the decreasing cost of genetic testing due to NGS technology. Because the price of ordering a genetic test was the same regardless of the number of genes on the panel, test selection is dependent only on patient and provider preferences, rather than price.

Despite the many documented advantages of the MGP approach, the technique has still faced certain criticism by the scientific and clinical community. In MGP testing, genes without strong ties to the corresponding cancer syndrome can be added to the panel, which increases the risk of overestimating the clinical implications of a result. Additionally,



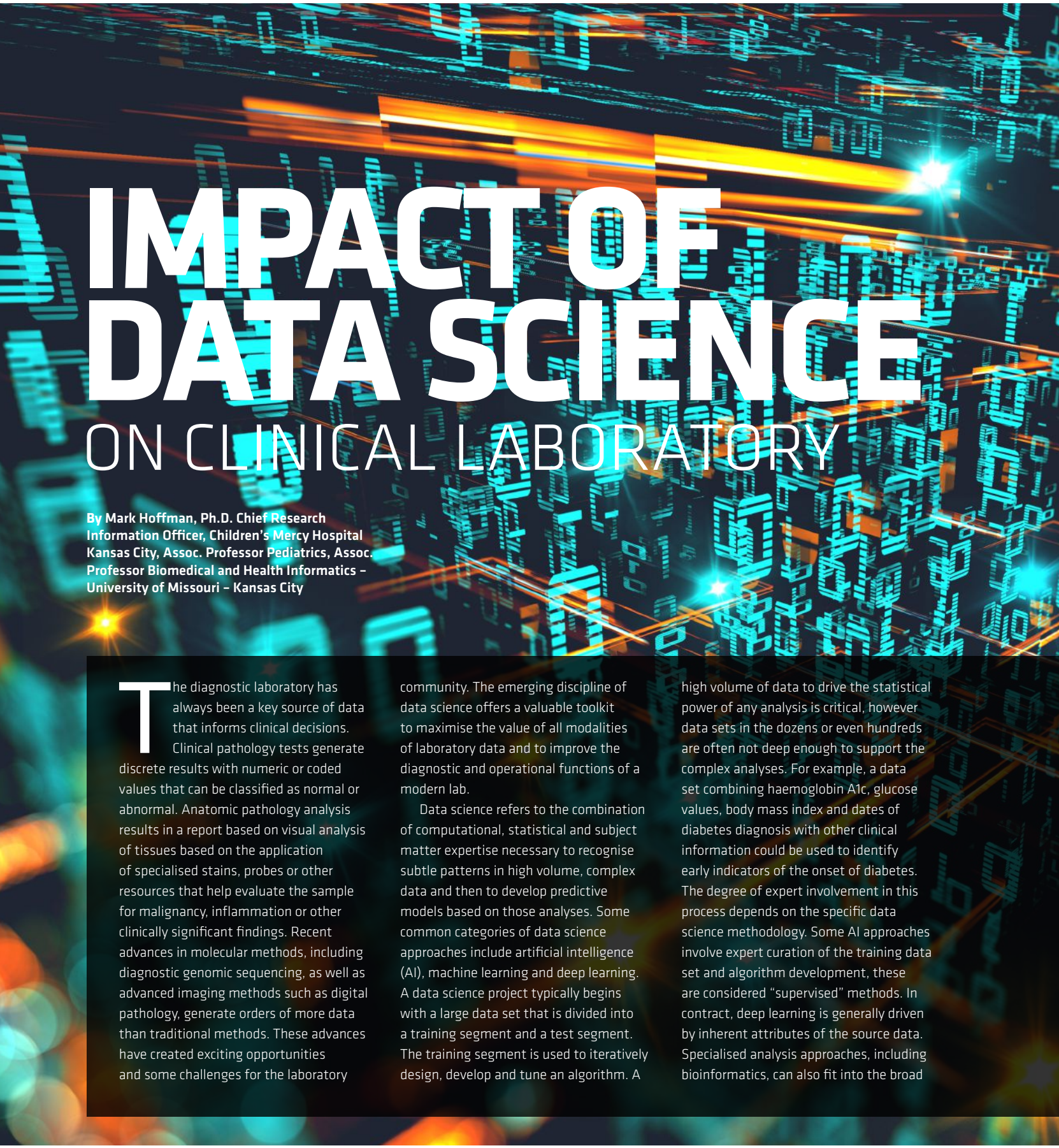
this type of testing can increase the detection rate of variants of uncertain clinical significance (VUS) for which management is unclear. This highlights the importance of variant annotation and interpretation pipelines to prioritise the variants properly. Other problems and challenges associated with MGP testing include the identification of secondary findings, whereby unexpected deleterious variants in genes associated with conditions other than the ones originally tested for are detected. This may be useful however if the patient's family history is unknown or limited.

Whole exome sequencing (WES) is another molecular genetic testing approach that is used when MGP does not help. In fact, one important disadvantage of targeted multigene panels is that they may become outdated relatively quickly. During the time in which a panel is developed and validated for clinical use, new studies identifying newly characterised disease genes are already being published. As such, an advantage of WES is the ability to sequence the entire protein-coding regions of the human genome, at once, allowing for the assessment and analysis interpretation and re-interpretation of alterations in all genes. WES also allows the analysis of a significantly larger number of genes at a reasonable cost, the potential to identify novel genes, and the ability to sequence the exomes of multiple family members simultaneously if needed.

As a matter of comparison, MGP provides nearly 100 per cent coverage in targeted genes, WES has a unique advantage of analysing a much broader gene list, including newly reported disease genes. A recent study demonstrated that WES improved diagnostic rate in 8 per cent of patients who first underwent multigene panel testing. Phenotype-driven WES interpretation also greatly reduced the rates of uncertain results. As such, if high cancer risk is present but the specific syndrome is uncertain, WES can be the method of choice. It is worth to mention that WES shares with MGP increased rate of detection of VUS and incidental (secondary) findings.

The choice between the different genetic testing approaches depends on each case. The MGP approach is ideal for analysing specific mutations or genes that have suspected associations with disease. In addition, focusing on individual genes or gene regions provides higher depth of sequencing than WES, which then enables the identification of rare variants. WES, on the other hand, allows for a comprehensive analysis of the whole exome, which is especially important if genes of interest are unknown. This method is also highly likely to play an increasingly important and powerful role in cancer diagnostics. Although the choice of testing approaches for the identification of genomic risks might raise some questions, it is certain that the use of multigene testing in the clinical setting has re-defined both the optimal care of patients with cancer and the management of unaffected individuals. This is made possible because it ultimately allows for surveillance programmes, planning strategies of prevention and early intervention for enhanced patient management. It is very important that any future progress made in the genetic testing space is accompanied by a deep understanding and awareness of its implications of its potential by both physicians and patients. ML

References available on request.



IMPACT OF DATA SCIENCE ON CLINICAL LABORATORY

By Mark Hoffman, Ph.D. Chief Research Information Officer, Children's Mercy Hospital Kansas City, Assoc. Professor Pediatrics, Assoc. Professor Biomedical and Health Informatics – University of Missouri – Kansas City

The diagnostic laboratory has always been a key source of data that informs clinical decisions. Clinical pathology tests generate discrete results with numeric or coded values that can be classified as normal or abnormal. Anatomic pathology analysis results in a report based on visual analysis of tissues based on the application of specialised stains, probes or other resources that help evaluate the sample for malignancy, inflammation or other clinically significant findings. Recent advances in molecular methods, including diagnostic genomic sequencing, as well as advanced imaging methods such as digital pathology, generate orders of more data than traditional methods. These advances have created exciting opportunities and some challenges for the laboratory community. The emerging discipline of data science offers a valuable toolkit to maximise the value of all modalities of laboratory data and to improve the diagnostic and operational functions of a modern lab.

Data science refers to the combination of computational, statistical and subject matter expertise necessary to recognise subtle patterns in high volume, complex data and then to develop predictive models based on those analyses. Some common categories of data science approaches include artificial intelligence (AI), machine learning and deep learning. A data science project typically begins with a large data set that is divided into a training segment and a test segment. The training segment is used to iteratively design, develop and tune an algorithm. A high volume of data to drive the statistical power of any analysis is critical, however data sets in the dozens or even hundreds are often not deep enough to support the complex analyses. For example, a data set combining haemoglobin A1c, glucose values, body mass index and dates of diabetes diagnosis with other clinical information could be used to identify early indicators of the onset of diabetes. The degree of expert involvement in this process depends on the specific data science methodology. Some AI approaches involve expert curation of the training data set and algorithm development, these are considered "supervised" methods. In contract, deep learning is generally driven by inherent attributes of the source data. Specialised analysis approaches, including bioinformatics, can also fit into the broad

category of data science.

The incorporation of pathology information into electronic health records creates the opportunity to query this data for subtle patterns. At the local level, data analysis can help in quality control, for example in determining whether there has been drift in the results from an instrument indicating a need for calibration. Some analyses require more data than is available from a single organisation. Initiatives in which de-identified electronic health record (EHR) data is aggregated from multiple organisations can provide a valuable resource for gaining new insights into the role of laboratory data in clinical decision making. For example, we recently used this approach to demonstrate that magnesium, both high and low levels of magnesium, in patients with a myocardial infarction correlates with higher mortality. We have also used aggregate EHR data to demonstrate that A1c tests are frequently ordered for sickle cell patients, a practice that should be avoided. The unstructured data found on the text content of pathology reports can also be evaluated using natural language processing methods. EHR data analysis is increasingly recognised as an important source of phenotype information to complement genomic analysis.

Data science is also being applied to automate the analysis of diagnostic images, including pathology slides. The application of data science methods such as deep learning to these images has the potential to improve the accuracy of interpretation and to assist in the recognition of subtle but potentially significant patterns that elude the human eye or brain. AI based methods use pathologist annotations of slides to train an algorithm. Early efforts in this area include the use of deep learning to recognise micrometastases of breast cancer in lymph node biopsies and demonstrated increased sensitivity and reduced time to review. Other work has explored the use of data science to enhance blurry regions in slide images and to support quality control.

Molecular diagnostic testing has become standard practice in diagnostic laboratories. Increasingly, clinical full exome or genome sequencing is also becoming widely available for the management of cancer and the diagnosis of complex cases that do not yield to traditional methods. These methods generate massive volumes of high complexity data. For example, a genomic analysis for a single patient can generate more than one terabyte of data. Data science methods assist in the analysis of these raw sequences as laboratories search for variants that may be clinically significant. Recent advances in single cell sequencing will introduce another major shift in the volume of data that will ultimately be applied to reach a diagnosis. Genomic analysis has had many notable successes in single variant, Mendelian conditions, and in assisting in the management of cancer. Common chronic diseases with known hereditary, polygenic, influences remain difficult to characterise and will require the continued application of data science and bioinformatics methods to identify multifactorial contributions to diseases such as diabetes and asthma.

Data science methods have a wide variety of applications relevant to the laboratory. First, they can enhance the diagnostic capacity of the lab by offering novel means to improve accuracy and speed. Second, with the increasing complexity of data generated by laboratory processes such as high-resolution images and genomic data, subtle patterns are increasingly likely to elude human perception. Data science can help augment the clinical expert as they navigate these new sources of diagnostic data. Third, emerging methods will support the integration of lab data with other clinical data to develop comprehensive predictive algorithms capable of early detection of disease risk or identifying optimal treatment strategies in support of precision medicine. Finally, there are numerous applications of data science that can promote the administrative process of operating a clinical lab. For example, understanding subtle patterns in test utilisation can help in inventory management. Likewise, models that predict patients at risk of being a no-show for specimen collection can help manage call centre reminders.

Laboratory professionals seeking to apply data science to address complex questions can take a number of approaches. The best approach is to form a collaborative team with computational and statistical experts to address a clearly defined problem. The team would identify and characterise the data available to them as they design their strategy. The team approach helps mitigate concerns that laboratorians have to become programmers to participate in data science. For those who do want to develop some of the technical skills, high quality online data science training resources such as those provided by Coursera or edX provide an excellent starting point for learning more about the principles and methods of data science. Open source applications such as R and Python are widely available to perform complex data analysis, as are commercial packages. Laboratories that embrace data science will be well positioned to engage in the next generation of diagnostic technologies and methods. ML

Hoffman will be speaking on 'Data Science with 4 Billion Clinical Laboratory Results' on February 4, as part of the Artificial Intelligence Conference at MEDLAB Exhibition and Congress

Development of AI-powered Imaging Biomarkers to REDUCE MEDICAL COSTS

By Brandon B. Suh, Chief Executive Officer, Lunit, Inc.

Rising medical costs have become a huge social burden throughout the world, having grown four to five times on average during the past three decades. The situation in the U.S. has been the most extreme with eight to nine times in growth rate, translated into total medical costs that totalled $3 trillion, amounting to 17.8 per cent of the gross domestic product in 2015.

The two main causes of high medical costs are one, the high price of medical services, and the high number of diagnostic tests performed. As a good example, in 2006 the total number of CT scans taken in the U.S. was 62 million, compared to three million taken in 1980, a 20-fold increase in just 25 years.

The issue with overutilisation of diagnostic tests is truly remarkable. Up to 30-50 per cent of diagnostic tests in the U.S. is considered to have been unnecessary according to various reports. There are various reasons for this, but the bottom line is there is lack of objective guidance for these new diagnostic tests, and due to the fee-for-service payment system and defensive medicine associated with the medical liability environment in the U.S., it's only natural diagnostic tests are often overutilised.

Government policies, exemplified by the Patient Protection and Affordable Care Act of 2010, play an important role in shaping healthcare expenditure. Beyond policy, a potential solution to reduce medical costs is to use informatics to provide quantified objective guidance, as suggested by the Institute of Medicine of the National Academy of Sciences.

Biomarkers Validated to Save Medical Costs

Genomic Health's Oncotype Dx and Heartflow's CT-FFR are both good examples of biomarkers that have been successfully commercialised, reimbursed both by private and public insurance in reference to extensive evidence supported by favourable results from various prospective clinical studies.

Oncotype Dx is a molecular test based on genomic analysis that predicts individual response to chemotherapy in early breast cancer patients. Because historically around 50 per cent of hormone-receptor-positive early breast cancer patients received adjuvant chemotherapy in which only two per cent would benefit from the therapy, there has been a significant cost-inefficiency involved. Studies show application of Oncotype Dx reduced approximately 60 per cent of unnecessary chemotherapy.

Heartflow's CT-FFR is the only image-based analytics widely accepted as a biomarker on the market that predicts fractional flow reserve values through analysis of coronary CT angiography images based on computational fluid dynamics. Among stable angina patients, approximately 60 per cent of patients undergo invasive coronary angiography to evaluate the coronary vessels, in which only a small minority are found to have significant coronary stenosis subject to revascularisation. According to various studies, Heartflow's CT-FFR helped avoid unnecessary invasive angiograms in 61 per cent of patients.

AI-powered Imaging Biomarkers in Radiology Can Save Medical Costs

The high-performance level achieved by newly developed AI-powered data-driven solutions can be attributed to the power of deep learning technology. Semi-supervised learning has been mainly applied, in which only a small proportion of trained data are annotated by experts to guide the training process, in turn allowing the AI algorithm to discover subtle image features and patterns hardly recognised through ordinary human vision associated with target lesions to be detected, interpreted, and diagnosed.

In Lunit, a Seoul-based start-up company, we believe AI-powered imaging biomarkers that accurately evaluate and generate objective quantification for specific tasks of imaging, e.g. breast cancer assessment in mammography, are a viable solution to significantly reduce medical costs. Lunit's research and development efforts involve a wide variety of image modalities that include chest x-ray, mammography, chest CT, digital breast tomosynthesis, coronary CT angiography, as well as digital pathology, in which accuracy levels have reached 97-99 per cent in ROC AUC, significantly exceeding expert-level accuracy.

Among the 40 million mammograms performed each year in the U.S., on average around 10 per cent are recalled for a subsequent cancer detection rate of around five per cent, meaning a 95 per cent false positive rate. It can be estimated that from these unnecessary recalls, around $4 billion is wasted each year. Lunit's mammography product, Lunit INSIGHT MMG, claims to be 98 per cent accurate (ROC AUC), and depending on the level of trust ultimately given by radiologists, the recall rate is expected to be significantly reduced by more than 50 per cent. If Lunit INSIGHT MMG is applied to all mammograms taken annually, this may lead to over $2 billion medical costs saved per year in the U.S. alone. Similar estimations for all products currently being developed by Lunit leads to an approximation of more than $20 billion in medical cost potentially saved per year by Lunit's products combined.

Digital Pathology: A New Promising Frontier

A great majority of research in medical image AI has been focused on radiology images, but with recent technological advances that enabled high throughput scanning of pathology slides, AI applied to digital pathology images has garnered much interest in recent years.

The digitisation of tissue slides marks the inception of a new era when a myriad of new information will be at disposal for pathologists. This is especially true because pathology slides entail vast amounts of data, involving 10+ gigapixels when digitised at 40x magnification. Historically pathologists, responsible to review such slides through microscopes, were forced to simplify the overall characterisation of the tissue for consistent description that needed to be accurately conveyed and perceived. Even so, the discordance rate between pathologists has been reported to be high, ranging from four per cent for clearly cancerous cases like invasive carcinoma to 48 per cent for marginal cases like atypia.

Through AI-powered comprehensive, consistent, and quantitative analysis of digital pathology slides, diagnostic, prognostic, and predictive histomorphological features that have not been previously characterised may bring unprecedented clinical value. H&E slides, historically used to simply detect the presence of disease (e.g. cancer or not), and classify the basic types of disease (e.g. adenocarcinoma vs. squamous cell carcinoma), may be used to collect more information pertinent to even making treatment decisions, such as whether a cancer patient may respond to chemotherapy or not, hence functioning as imaging biomarker.

In fact, histomorphological features based on traditional pathology and AI-based analysis have both been shown to reflect the biological nature of cancer, and highly predictive of survival. Lunit's preliminary research has demonstrated high level of correlation (R>0.7) between AI-powered analysis of H&E slides with RNA sequencing data of genes related to tumour proliferation, which is the foremost factor predictive of chemotherapy response.

Alike Lunit, many companies, both newly founded start-ups like PathAI, Paige.ai, and Proscia, and relatively older image analytics companies such as Indica Labs, Definiens, and Visiopharm, have been active in their own ways to find means to develop clinically useful AI-powered solutions in digital pathology.

The Future of AI-powered Imaging Biomarkers Is Bright

AI-powered imaging biomarkers will need to be properly validated through clinical studies before they can be widely used clinically. Nonetheless, the potential benefit is clear: valuable information through accurate, consistent, and objective analysis of images may be easily used and applied clinically for more cost-efficient diagnostic and therapeutic decision making. The data-driven nature of AI is what makes it so effective, but what is more remarkable is its applicability in readily available data, especially imaging data, already deeply incorporated in routine clinical practice, allowing it to be inherently cost-efficient. ML

References available on request.

EFFECT OF ARTIFICIAL INTELLIGENCE IN THE CLINICAL LABORATORY

By Dr. Palat K Menon MD PhD MBA, Director & COO Thumbay Labs, Thumbay Medicity, Ajman, UAE

In the clinical laboratory, Chemistry and Haematology departments have been the earliest to adapt robotics and algorithms into its workflow. As early as 1984, the "EXPERT", a consultation system-building tool, which is a knowledge-based Artificial Intelligence (AI) programme was developed at Rutgers University for enabling sequential laboratory testing and interpretation.

AI technologies are now commonly termed 'knowledge engineering' and the intelligent computer software that embodies knowledge are called 'expert systems'. Because it has been rather difficult to develop practical applications of automatic learning, expert systems often don't include the ability to learn by themselves. Nevertheless, such expert systems are able to make decisions based on the accumulated knowledge with which they are programmed and are therefore commonly included within the definition of AI systems. An ever-increasing number of publications in the area of AI show the increasing interest and scope of its application in healthcare. A quick search of Pubmed reveals almost 83,000 publications related to AI in healthcare over the past few years.

With the staggering increase in volume of patient healthcare data, a constant increase in patient expectations and scarcity of resources, AI will be the engine driving improvements across the care continuum. Doctors will adapt to and use AI technology in their day-to-day work. Nurses and other healthcare workers augmented by AI can deliver a higher level of care for a larger populace.

With rapid advances in pathology such as paradigm shifts in digital pathology, next-gen sequencing, precision medicine and personalised treatments, pathologists will be the first point where clinical decisions will be made. Computational Pathology applies to computational models, machine learning and visualisations to make the lab output both more useful and easily

understood for the clinical decision maker. Computational pathology has clinical value in all aspects of medicine via a focus on computational methods that incorporate clinical pathology, anatomic pathology (including digital imaging), and molecular/genomic pathology data sets.

Continuous remote sensing of patients using "wearables" such as glucose monitoring devices, oximetry, temperature, heart rate and respiratory rate monitors connected to a central computing device via the ubiquitous "Internet of things" will be the norm, with AI aided "ambient computing" changing the way futuristic patient care will be provided. Prediction of sepsis is an important diagnostic conundrum where early appropriate therapy can save lives. A randomised controlled trial by Shimabukuro et al at the UCSF Medical Centre in 2017 used a machine learning-based predictor, which resulted in significant decreases in length of stay and in-hospital mortality rate. The study demonstrated the superiority of using an algorithmic predictor relative to the hospital's current Electronic Health Record native, rules-based, severe sepsis surveillance system. AI enhanced microfluidics and compact small interactive POCT labs are set to alter the way diagnostics is carried out. An example is the "Maverick Detection System" from Genalyte. Using biological probes bound on silicon biosensors chips, it binds macromolecules in the serum, the binding of which detected by a change in light resonance, which is determined photometrically. They plan to detect up to 128 analytes using disposable chips from a single sample.

Tumour DNA changes are important since it influences therapy. Following Next-Gen Sequencing, large amounts of genomic data are generated, which are then analysed by a combination of computational tools and human experts to understand the types of genetic mutations present in the tumour. These act as a guide to prognosis and personalised therapy. Newer methods of analysis involve machine learning, which automates the tumour DNA diagnostic process and improves the accuracy of that identification as compared with existing techniques enabling accurate prescription of mutation-specific therapies.

Today's clinical labs are already using advanced robotics to test minute volumes of blood, serum and other body fluids from thousands of samples in a day to give highly accurate and reproducible answers to clinical

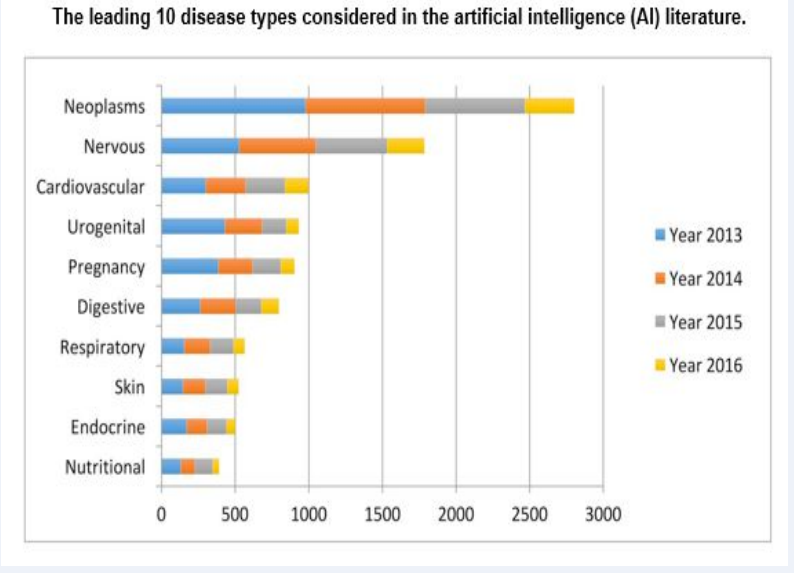
questions, in scales almost difficult to emulate humanly. These machines are driven by conventional algorithmic programmes, which represent and use data, iterate repetitively and exhaustively using a decision sequence, using numbers and equations, finally presenting a number or result within confidence limits. In the future, robots used in the clinical laboratory will be heuristic (self-learning), using inferential processes, with numerous ways to derive the best decision possible even allowing for missing information. Artificial Intelligence programmes combined with data bases, data mining, statistics, mathematical modelling, pattern recognition, computer vision, natural language processing, mixed reality and ambient computing will change the way our laboratories generate and display clinical information in the future.

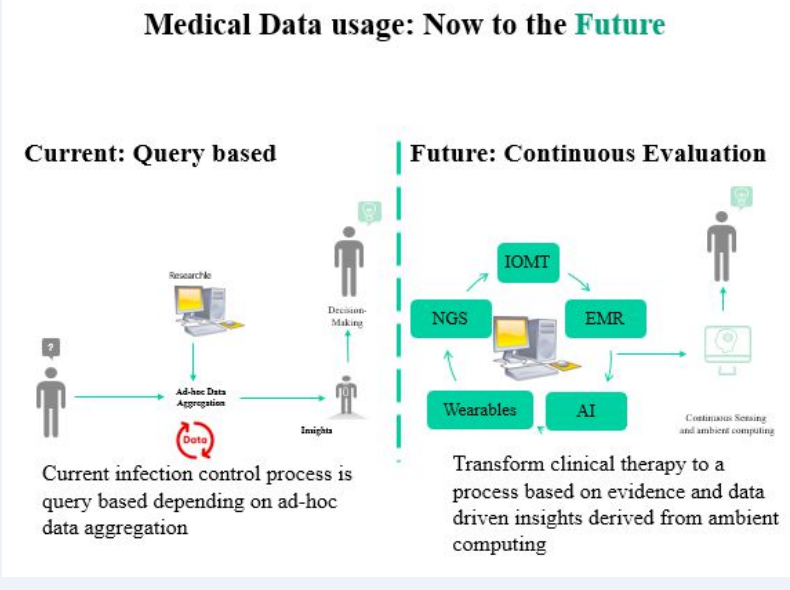
The Future

Pathologist augmented with AI is the future. AI will help leverage human knowledge, wisdom, and experience. Findings suggest that instead of replacing doctors, AI algorithms might work best alongside them in healthcare. AI and machine learning software are beginning to integrate themselves as tools for efficiency and accuracy within pathology. Software is being developed by start-ups, often in tandem with prominent educational institutions or large hospital research laboratories, addressing different diseases and conditions, most notably forms of cancer. A review of the functionalities of AI and machine learning software in the field of pathology reveal predominant usage in whole slide imaging analysis and diagnosis, tumour tissue genomics and its correlation to therapy, and finally companion diagnostic devices. The ICU of the future will have AI programmes, which will concurrently evaluate the continuous streams of data from multiple monitors and data collection devices to pool their information and present a comprehensive picture of the patient's health to doctors autonomously adjusting equipment settings to keep the patient in optimal condition.

I would like to conclude by quoting a concept on "Singularity" by Ray Kurzweil dated to occur by 2045. Technological singularity is a hypothesis that AI will trigger logarithmic technological growth, resulting in unfathomable changes to human civilisation. The changes to healthcare and longevity once we attain "Singularity" is beyond our current understanding.

He said: "2029 is the consistent date I have predicted for when an AI will pass a valid Turing test and therefore achieve human levels of intelligence. I have set the date 2045 for the "Singularity", which is when we will multiply our effective intelligence a billion-fold by merging with the intelligence we have created." ML





Dr. Menon will be giving an introduction on 'AI and Blockchain' on February 4, as part of the Artificial Intelligence Conference at MEDLAB Exhibition and Congress

IN THE KNOW

Haemolysis: A Challenge in the Preanalytical Phase

By Dr Christa Seipelt, PhD, Product Manager Diagnostic Products, Sarstedt AG & Co. KG, Germany

Blood sampling via intravenous catheters frequently occurs because patients in intensive care already have intravenous catheters in place, and patients admitted to accident and emergency units (A&E) are immediately set up with intravenous catheters – providing easy access to blood.

However, studies have identified this route as a cause of haemolysis (rupture of erythrocytes causing haemoglobin release into the plasma or serum), as well as meaningful biases in blood analyses. Poor blood sampling will not only delay treatment, waste lab time, result in incremental material costs for re-testing and, potentially, cause discord between doctors and nurses – usually responsible for blood collection. Therefore, understanding why samples can become useless is essential for better healthcare. It was found the risk is even greater in blood collection when intravenous catheters are used combined with primary evacuated blood collection tubes, and less with blood collection tubes with manual aspiration.

The S-Monovette® blood collection system combines two blood collection techniques –aspiration and vacuum – and presents advantages in collection from intravenous catheters or cannulae. An essential part of the clinical decision making is laboratory diagnostics, given that the total testing process goes along with a high degree of quality.

Several indications of evidence attest that the manually intensive activities of the pre-analytical phase are more sensible to uncertainties and errors than those belonging to the analytical and post analytical phases. This inherent vulnerability is mostly attributable to inappropriate, incorrect or mishandled procedures used for obtaining blood specimens (Lippi et al Clinical Biochemistry 46 (2013) 561-564).

The researchers pointed out that among various pre-analytical non-conformances that can be encountered in routine laboratory practices, sample haemolysis represents the primary source of problems, in terms of prevalence and likelihood of sample rejection. The in vitro haemolysis is occurring during, or after sample collection, once potential sources of haemolytic anaemia have been ruled out. The greatest number of haemolysed specimens is taken in A&E where the relative prevalence can be as high as 10-30 per cent (Lippi et al Clinical Biochemistry 46 (2013) 561-564, cited Literature 4-6).

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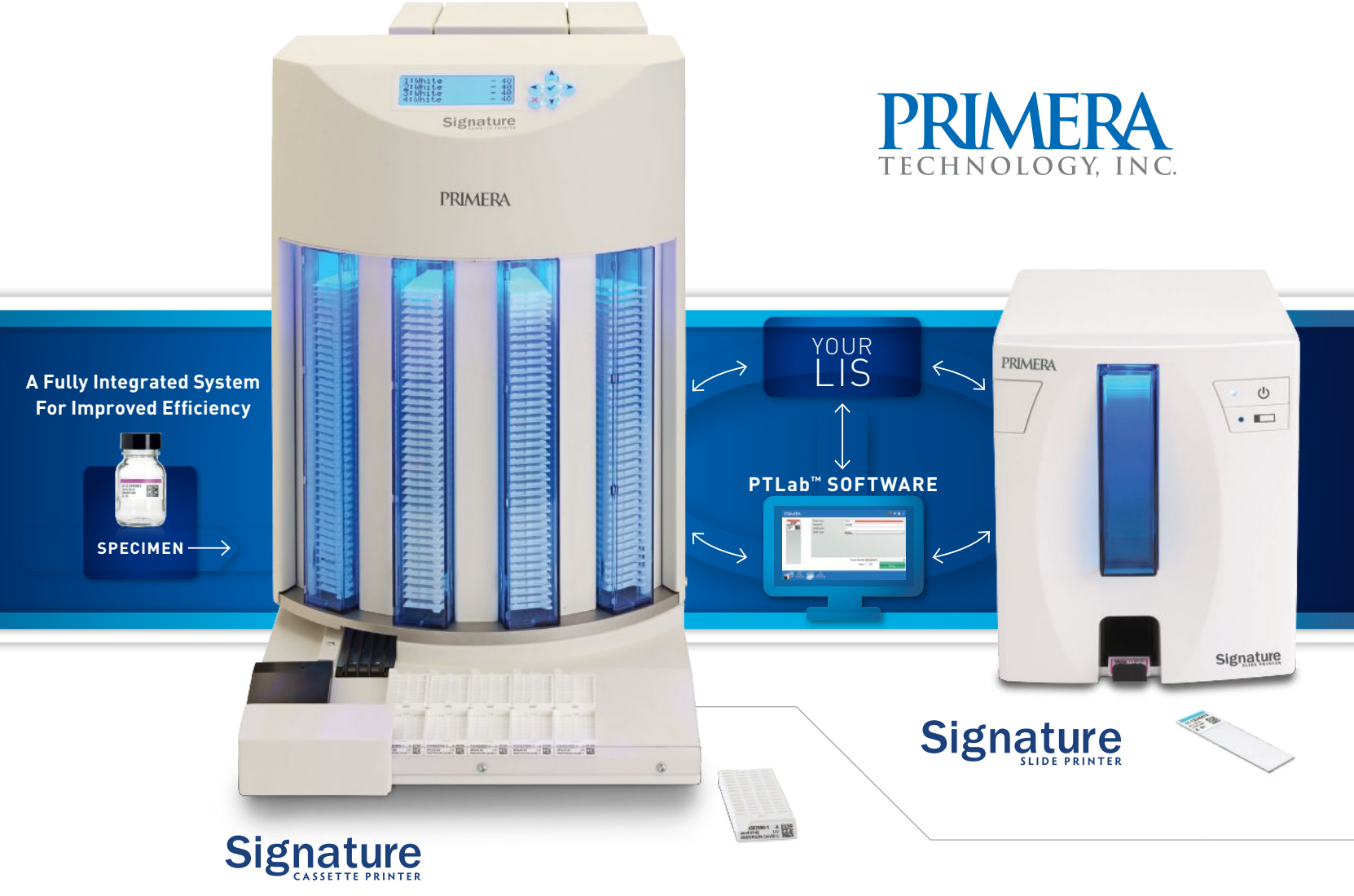

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IN THE KNOW

Randox: Tailored to Meet the Needs of the Individual

By Emma Callaghan, Marketing Executive, Michael Mulligan, Senior Marketing Executive, and James Crilly, Marketing Team Leader, Randox Laboratories, 55 Diamond Road, Crumlin, County Antrim, United Kingdom

As a world leader in the in-vitro diagnostic industry with over 35 years' experience, Randox is leading the charge in moving from a one-size-fits-all approach towards decisions, practices and products tailored to the needs of the individual. This innovative approach to diagnostics has facilitated the development of revolutionary products designed specifically to enhance a patients' quality of life.

Evidence MultiSTAT

The Evidence MultiSTAT is a fully automated immunoanalyser that enables on-site simultaneous detection of 21 classical, prescription, and synthetic drugs from a single sample using Biochip Array Technology. Testing panels are available for blood and urine samples with as little as 200ul sample volume required and results available in under 20 minutes ensuring efficient and accurate drug screening. This revolutionary multi-analyte testing platform allows clinicians to achieve a complete immunoassay profile with highly accurate results and a 98 per cent agreement with confirmatory methods. Randox has the world's largest toxicology test menu, comprising over 500 drugs and drug metabolites.

Molecular Quality Control

Our third-party range of molecular quality control solutions for infectious disease testing comprises hundreds of characterised viral, bacterial and fungal targets. These controls cover a wide range of transplant associated diseases, respiratory infections, sexually transmitted infections and more.

As whole pathogen controls, our range is designed to mimic the performance of patient samples and can be used to effectively monitor the entire testing process including extraction, amplification and detection.

For more information about our molecular infectious disease testing controls, please visit: https://www.randox.com/molecular-infectious-disease-controls/ or contact us at: acusera@randox.com

Molecular EQA

Dedicated to improving the quality of molecular diagnostic assays used in the detection of infectious diseases, our molecular EQA range, is one of the largest in the field of molecular diagnostics.

With access to over 90 EQA programmes including Blood Borne Viruses, Respiratory Diseases, Gastrointestinal Diseases, Multi-Pathogen/Syndromic Infections and more, there is something for every laboratory.

For more information about our molecular EQA for infectious disease testing, please visit: https://www.randox.com/qcmd-molecular-eqa/ or contact us at: acusera@randox.com

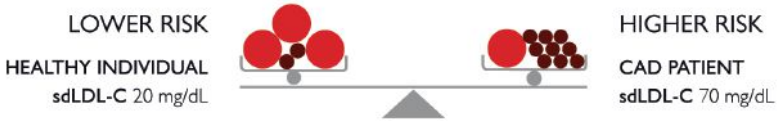
Extend Your Lipid Profile with sdLDL Cholesterol – A vital CVD Risk Marker

Small-dense LDL Cholesterol (sdLDL-C) is particularly atherogenic as it can easily permeate the inner arterial wall. Research indicates that individuals with a predominance of sdLDL-C have a three-fold increased risk of myocardial infarction.

Figure 1 highlights that although the overall LDL-C levels are 140mg/dl in both patients, the CAD patient has 50mg/dl more sdLDL-C particles than the healthy individual, increasing the CAD patients' risk of myocardial infarction. Randox utilise the "Denka Seiken" method, which produces results in as little as 10 minutes, facilitating faster patient diagnosis and treatment plan implementation.

For more information about the Randox sdLDL-C assay, please visit: www.randox.com/sdLDL-cholesterol or contact us at: reagents@randox.com

Figure 1 - Assessment of LDL cholesterol levels in two patients



Direct HbA1c Testing Using RX Series Clinical Chemistry Analysers

The concentration of HbA1c in the blood of diabetic patients increases with rising blood glucose levels and is representative of the mean blood glucose level over the preceding six to eight weeks.

Randox now offers a direct HbA1c assay for the rapid direct measurement of HbA1c in human blood. This assay is available to be used on the RX daytona +, RX imola and RX modena clinical chemistry analysers, which are capable of performing medium to high throughput testing. This direct HbA1c assay adds to the comprehensive test menu of niche and high performing assays already available at Randox.

The latex enhanced immunoturbidimetric method makes the test simple and quick to perform as only one assay is now required. Human error inaccuracies are removed as offline preparations are no longer required and are preformed on-board the RX series analysers.

For more information about our direct HbA1c assay, please visit: https://www.randox.com/hba1c-rxseries/ or contact us at: therxseries@randox.com

IN THE KNOW

BioSystems Launches BA200 Benchtop Analyser

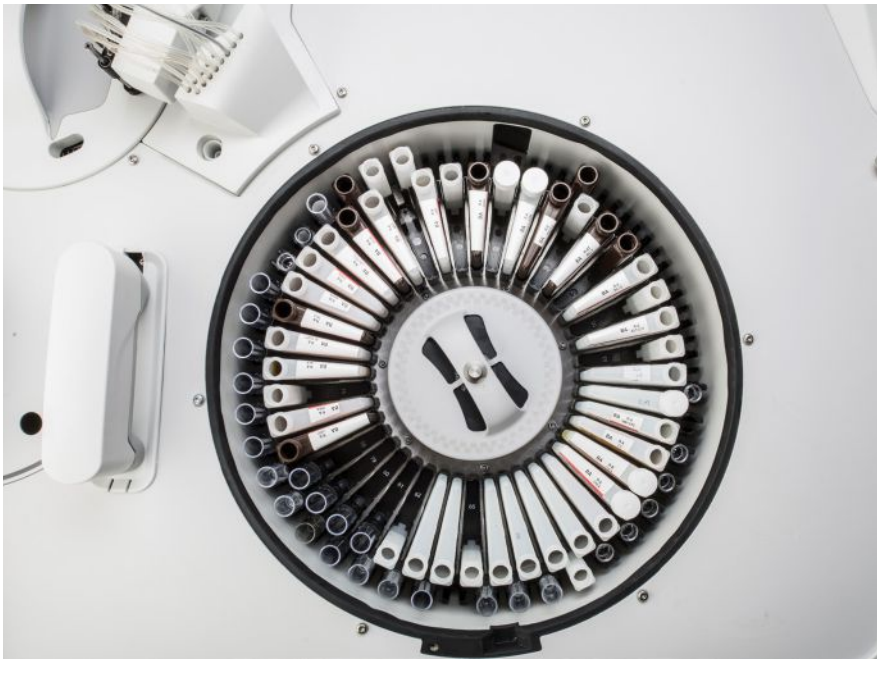
Article provided by BioSystems

BioSystems is introducing BA200, a benchtop analyser with a real throughput of 200 t/h with any combination of methods and parameters, (or up to 360 t/h including 4-channel ISE option), washing station, barcode identification and ISE capabilities.

Offering the highest loading capacity of its segment, with 88 positions barcoded that could be adjusted with specific adaptors to be used either as reagent, sample (primary or paediatric tubes), standard or control, it provides maximum configuration flexibility to adapt to the workload of any small or medium size laboratory, from routine to special chemistries.

A BioSystems' patented LED light source allows a precise focus in the reading spot area with no energy loss, increased signal and a sustained performance over its lifetime, over 50,000 hours of continuous without change of intensity, reducing their maintenance to almost zero. Also, the newly developed Dynamic Baseline procedure allows multiple readings to be made as the rotor is spinning to obtain highly accurate blank readings used to offer higher reliability for low absorbance values, thus improving significantly the CV per cent of the test at low values.

Finally, the BA200 system also introduces a dedicated range of reagents in package size adequate to small and medium laboratories (but also fully compatible with BA400 system), ensuring the highest performance and on-board stability.



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Clinical and molecular pathology, microbiology, medical engineering and life sciences are drivers of innovation for all areas of medicine. The MEDICA LABMED FORUM 2019 will highlight recent detection techniques in expanding medical fields such as new biomarkers and continous monitoring. On November 21, a special event will bring together innovative companies and young scientists to discuss career opportunities in the in vitro diagnostics and life science industry.

Doctors and patients, health policymakers and healthcare providers, media representatives and all other visitors of the world's largest medical trade fair are invited to four exciting focal days with top-class lectures and panel discussions. The MEDICA LABMED FORUM is organised by Prof. Dr. med. Georg Hoffmann, Trillium Medical Publishing House and German Cardiac Center Munich.

The conference language is English. The event take place each day from 10:30 a.m. to 4 p.m. in hall 1 and is free of charge for trade fair visitors.

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IN THE KNOW

Hipro: Providing High-Quality Diagnostic Systems

Article provided by Hipro Biotechnology Corp.

Hipro Biotechnology Corp, founded by Mr. Hao on September 29, 2006, is a high-tech enterprise based on international advanced medical technologies and brilliant self-innovations to provide first class products all over the world. Hipro focuses on R&D, manufacturing, marketing, and relevant services of point-of-care products. Day in day out, Hipro is committed to innovate in the field of accurate diagnostic system including instrumentation, reagents, service, as well as data management. Distributed in 25 countries through a network of distributors, we can guarantee our customers a superior service and a product portfolio that meets the demand.

Hipro has a world-class high capacity manufacturing facility (10000 sq.m.) with 1,500 sq.m. current GMP plants and strict quality control system. The quality system is ISO 13485 and CE certified by TUV Rheinland.

Hipro is a leading specialist in the development and manufacturing of diagnostic system solutions of the highest quality, trusted by customers all over the world for over 19 years. The product portfolio comprises more than 40 parameters including Biochemistry, Nephelometry, Fluorescence and Turbidimetric reagents for routine and special diagnostics including the third party calibrators and controls. The Hipro instrumentation product range covers automated immunoassay analysers, semi-automated analysers and other POC instruments for patient-near testing.

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IN THE KNOW

Sustained Operational Excellence, Ready For The Future

Article provided by Abbott Diagnostics

Abbott Diagnostics' latest initiative 'Welcome to the Collaboratory' sets out a new vision for laboratories and their place in healthcare systems. The results of a global study show that labs need to take a new and different approach, moving from a manufacturing site of data to the decision-making engine room. This transition will require labs to find a new way of working together with stakeholders across the system, breaking down the barriers between departments and even within labs – physical and cultural barriers, as well as disconnected data and workflows – and collaborating to optimise their productivity and achieve operational excellence.

Innovation in Action

A prime example of a lab taking on this challenge is the Somedi Lab, a private lab located within the Somedi polyclinic in Heist-op-den-Berg, Belgium, which provides services to both the clinic and local general practitioners. Somedi is constantly looking to the future, adopting new innovations to help improve its workflows and increase speed and efficiency. Previously, manual protocols, combined with the use of different types of analyzer, resulted in complicated work schedules and increased training needs, but a move to automation has resulted in streamlined and simplified processes. The lab invested in Abbott Alinity cc (dual) and Alinity ii (dual) analyzers linked to an Accelerator a3600 automation system, the first facility in Benelux – and one of the first in the world – to choose this configuration.

Alinity cc and ii connected to the Accelerator a3600 track system

Jaimie Breugelmans, pharmacist clinical biologist, said: "Previously, our work schedules were quite complex, but the implementation of the Abbott system has allowed us to consolidate all our test parameters onto the Alinity analyzers, standardizing the software and simplifying the lab workflows. Our automated workflow is now much leaner."

Guided by Clinicians' Needs

Around 90 per cent of the samples received at the laboratory come from general practitioners, who look to Somedi Lab for high quality results and specialized advice. The laboratory performs a wide variety of tests daily and the test portfolio has been selected based on direct communication with clinicians, follow-up of ever-changing request patterns, and evidence-based medicine, plus the availability and cost-efficiency of the analytical technology.

Breugelmans added: "The platform's flexible design ensures that we can include additional parameters and add extra modules at a later date without extending the track length and add a pre-analytical system for aliquoting or a post-analytical system for archiving."

A Streamlined Workflow Without Barriers

Automation has allowed Somedi Lab to rationalise its processes, handling the routine daily workload and stat samples more efficiently.

Mathias Blommaert, senior medical laboratory technician, explained: "The way the track system links the analyzers together is very helpful; before it took three people to manually load and run the analyzers, but now, with automation, just one person is required, freeing up staff to unpack samples and load them onto the sample processing system."

All the Support You Need For Success

For Somedi Lab, the secret to successfully implementing new technology has been good collaboration and communication, backed by 24/7 technical support.

Breugelmans concluded: "Innovation and the future are inextricably linked at Somedi, and the a3600 track and the Alinity analyzers are a good example of this. We now have a flexible system that is ideal for today and ready for the future. The switchover went very smoothly, without any delays in reporting results or loss of quality, and we have established a real partnership with Abbott that will continue into the future, which is reassuring in a changing clinical biology environment."

For more information, visit corelab.abbott or email to wired@abbott.com.

Abbott conducted a global study with thousands of healthcare executives, physicians and patients about the role they expect the laboratory to play in the future. The results were surprising:

- 93 per cent of executives want the lab to LEAD healthcare analytics
- 77 per cent of physicians want additional interpretation from the lab to help with diagnosis
- 69 per cent of patients are not satisfied with the meaning of their lab results

POCT Application: An Ideal Tool Beating Disease Burden in Developing Countries

Article provided by Fapon Biotech Inc.

Despite developing countries accounts for 90 per cent of the global disease burden, searching for the right disease diagnostic tool remains challenging owing to the poor infrastructure-based healthcare system. Integration of POCT in different healthcare facilities will help doctors making informed decisions more efficiently by obtaining a faster, accurate and comprehensive result.

Assuming that primary disease burden ranks to epidemics is no longer valid in developing countries given the chronic diseases have accounted for 50 per cent of the disease burden and shown high potential to grow. The recent breakthroughs of POCT application in chronic diseases offer accurate, detailed and fast disease evaluation beyond the walls of central laboratories. Since the quality of test results has a strong correlation with the quality of samples, POCT ensures accurate test results can be obtained by eliminating potential sample deterioration with no further sample handling process. Moreover, the flexibility of using different disease-specific test groupings in single POCT platform offers fast and rounded analysis has shown comparable accuracy to central laboratory CLIA systems. For instance, the test combination of cTnI, CK-MB and myoglobin for suspected AMI demonstrates a high correlation with only 15-20 minutes to result.

To a more specific context, the EDs are facing problem to provide consistent quality care with the continuously rising patient volume, POCT with excellence in time and accuracy is the top choice to doctors in achieving better clinical outcomes. Accordingly, POCT enables a 40 per cent decrease in turnaround time. With an extreme user-friendly three steps from sample to result procedure, the average reporting time is 23 minutes compared to central laboratories in 60 minutes. Most important, POCT provides excellent speed with no loss of accuracy. Cardiac markers like cTnI and D-Dimer have shown high diagnostic accuracy with high sensitivity and specificity in benchmarking the central laboratory CLIA systems. Hence, the utilisation of POCT in EDs will dramatically accelerate doctors' decision-making time and result in quicker treatment initiation and shorter stay time for patients.

Fapon POCT Lateral Flow Immunofluorescenct Assay Solution

Fapon Biotech Inc. is a leading IVD reagent raw materials and one-stop solutions company founded in 2001. As one of the top IVD raw material suppliers in Asia, Fapon's antibodies, antigens and enzymes have edged out many international top brands and rewarded favourable reputation, forming strong partnerships with more than 700 IVD manufacturers around the world.

Fapon POCT solution applies the fluorescence-based immunochromatographic methodology with the high-affinity biotin-streptavidin fluorescent complex to obtain stronger signals. This exclusive **self-developed amplification system results in 5 to 10 times higher in sensitivity** than other conventional amplification techniques. Fapon's POCT solution contains a selection of **single, mid and auto channel analyzers** with **a wide test menu**, presenting a powerful diagnostic solution to various application scenarios. By having **≤ 10mins to result** and a **≥0.95 clinical correlation to central lab systems**, fast and accurate evaluations could be made to assist doctors decision making in achieving better clinical outcomes. The POCT only requires an ease of use **simple 3 steps operation** from test sample to result, without doubt, a fine tool to boost and optimise the entire workflow. For further convenience, Fapon's innovative reagent cartridge allows **the use of different samples** (serum/plasma/whole blood/human urine) without pre-treatment. To date, Fapon's POCT Solution offers **11 test categories in total 42 assays** to assist doctors' decision making in disease areas such as Cardiac, Inflammation, Renal Injury, Pregnancy, Thyroid, Hormone, Diabetes, Brain Injury, Metabolism, Stomach and Lung.

IN THE KNOW

Analyticon Biotechnologies AG: Your Partner for In-Vitro Diagnostics

Article provided by Analyticon Biotechnologies AG

Analyticon Biotechnologies AG, based in Lichtenfels, Germany, is a routine diagnostic corporation, serving to improve the health and well-being of people through development, manufacturing and marketing of exclusive high-quality diagnostic products, solutions, highly-responsive services and support.
The company was founded 1980, so for 39 years, Analyticon has been a reliable and trustworthy partner in In-Vitro Diagnostics. In our fast growing and agile organisation, we are working in multinational teams at the headquarters and around the world in close personal contact with all partners.

Urilyzer® Flex: The Solution for Routine Urinalysis Laboratories

At MEDLAB 2019, Analyticon will present its new system Urilyzer® Flex for semi-automated urine test strip and automated urine sediment analysis. The system is based on the Urilyzer® 500 Pro and the Urilyzer® Sed and provides a throughput of up to 60 samples per hour at a considerably lower invest compared to fully automated systems. A four-step procedure allows for an efficient workflow and a time to result in less than five minutes. The system is based on automated microscopy and offers high resolution bright field images in high

power field (400x) and low power field (100x) magnification that support an easy change from manual microscopy into automation. Visit them at MEDLAB 2019, booth Z5.E39.

INSTAND

Society for Promoting Quality Assurance in Medical Laboratories e.V.

INSTAND e.V. is one of the world's leading organisations for external quality assessment (EQA) in laboratory medicine, located in Düsseldorf, Germany. As a non-profit organization, it constitutes an interdisciplinary and independent scientific medical society with a unique and historically grown network of outstanding experts in the different fields of laboratory medicine. As a recognized member of national and international scientific bodies, INSTAND e.V. works in close cooperation with national and international organisations that are shaped by their joint commitment for standardisation and quality control.

INSTAND e.V. periodically organises national and international symposia, training courses and workshops. The high level of quality of INSTAND's work is documented by its recent accreditation in accordance with DIN EN ISO/IEC 17043.

Internal as well as external quality control and quality assurance have formed the backbone of INSTAND e.V.'s activities over several decades. In recent years, external quality assessment has played an ever increasing role in improving the inter-laboratory reliability and comparability of diagnostic results in the application of the different assay or test methodologies of various manufacturers.
Promoting these processes on a national and international level is a declared aim of INSTAND e.V.

All our efforts and activities are for the improvement and assurance of patient care and patient safety.

For further information or participation in our External Quality Assessment schemes, please have a look on our website: www.instand-ev.de

Contact:

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DTM Medical Presents Efficient Specimen Identification Solutions

Article provided by DTM Medical

DTM Medical, German distributor of printing solutions and services with more than 20 years of experience, is presenting its product portfolio for the medical market at MEDLAB 2019. It is showcasing the Signature Cassette and Slide Printers of Primera Technology, among other products, at its stand Z6.G31.

The Signature Cassette Printer, designed for use in pathology and histology labs, prints high-resolution text, graphics and bar codes directly onto tissue cassettes. This eliminates handwriting making specimen identification safe and accurate as prints don't rub off and are crystal clear.

There are two models available for the Signature Cassette Printer. The SCP-M is the manual version, loading one cassette at a time by the operator. The SCP-R is fully robotic instead, operating a robotic arm, which picks a cassette and puts it in the printer.

The Signature Slide Printer increases the efficiency and accuracy of any lab by printing directly on the slides. It is the world's only colour slide printer, producing on-demand, full-colour or black printing text, graphics, linear and 2D barcodes.

Slides are chemical and UV resistant to withstand processes, commonly used in laboratories, making them reliably identifiable even after several years.

For more information: http://dtm-medical.eu.

IN THE KNOW

Socorex: Partner in Precision

Article provided by Socorex

Socorex is a Swiss manufacturer specialising in precision volumetry. The liquid handling programme includes electronic and manual micropipettes, repeaters, dispensers, pipette controllers, automatic syringes, pipette tips, reservoirs and related accessories.

The most ergonomic and high-performance Acura manual pipette line is particularly attractive to laboratories demanding state-of-the-art features at budget-conscious prices. Calibrex is a line of robust bottle top dispensers with excellent chemical resistance, high performance and easy maintenance. For more information visit our booth at MEDLAB 2019 or log onto www.socorex.com

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IN THE KNOW

Mubadala to Deliver Laboratory Services to NMC Group

The partnership ensures a coordinated and seamless continuum of care for patients through a comprehensive test menu, an efficient logistics network and best practice connectivity solutions.

Article provided by National Reference Laboratory (NRL)

National Reference Laboratory (NRL), a Mubadala Healthcare network provider and NMC Group, one of the largest private healthcare companies in the UAE, recently announced that they have signed a Laboratory Services Agreement making NRL the exclusive provider of best-in-class laboratory testing to patients at 31 NMC healthcare facilities across the UAE.

NMC patients will now have direct access to NRL's comprehensive, specialist test menu of more than 4,700 tests, which is one of the largest laboratory test menus globally thanks to NRL's partnership with LabCorp, the world's leading diagnostics company.

Eng. Abdulla Al Shamsi, Head of Mubadala Healthcare said: "Through our world-class network of healthcare providers, we are very pleased to work alongside private healthcare companies to provide laboratory tests and services that have a transformative impact on patients, allowing us to collaborate in improving patient outcomes and positively impacting the healthcare sector across the UAE."

Chief Executive Officer at National Reference Laboratory, Abdul Hamid Oubeisi added: "We are pleased to have been selected by NMC Group as their trusted partner in the provision of high-quality laboratory diagnostic services. As one of the most experienced providers of laboratory solutions in the country and the region, we are looking forward to bringing our proven track record of testing and world-class logistics to the patients of NMC Group to ensure their treatment journey is optimised through swift and accurate laboratory testing."

As a result of the agreement, patient samples collected from 10 of NMC's largest hospitals and medical centres, including both NMC Royal Hospitals and NMC Specialty Hospitals in Abu Dhabi and Dubai, will be exclusively handled by NRL, the largest network of CAP-accredited laboratories in the Middle East.

L-R: Abdul Hamid Oubeisi, Chief Executive Officer at NRL, Abdulla Al Shamsi, Head of Mubadala Healthcare, and Prasanth Manghat, Chief Executive Officer and Executive Director of NMC Health Plc

Commenting on the collaboration, Prasanth Manghat, the Chief Executive Officer and Executive Director of NMC Health Plc., said: "As the largest private-sector healthcare provider in the region and one of the leading fertility service providers globally, we work closely with the government and its various bodies collaboratively. This step will further help to serve the UAE's healthcare goals as we endeavour to consistently invest in new innovative technologies and partnerships. It is our mission to lead the healthcare sector and provide best-in-class services to the residents of the UAE."

NRL's robust logistics network will guarantee uncompromised sample integrity and timely sample collection from NMC Group's country–wide network, ensuring reliable and fast test results.

Additionally, best practice connectivity solutions, including a web-portal and a two-way real-time interface between NRL's Laboratory Information System and the Electronic Medical Records (EMR) of the NMC Group, will ensure test ordering and results delivery are as efficient and accurate as possible.

This paper-less system will help reduce the risk of human error and work duplication, and enhance quality and patient outcomes.

Via the interface connection, physicians will be able to access and order from NRL's comprehensive test menu 24/7, and laboratory results will be reported in real-time and automatically stored in each patient's unique EMR.

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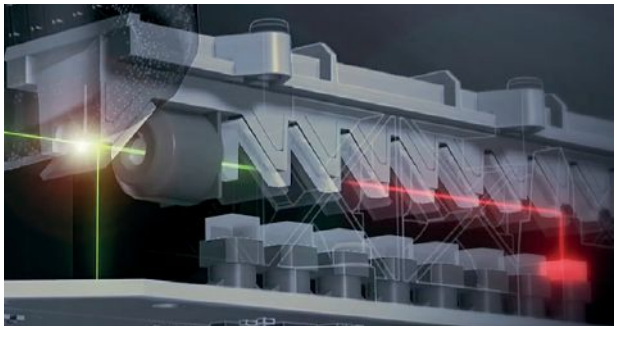

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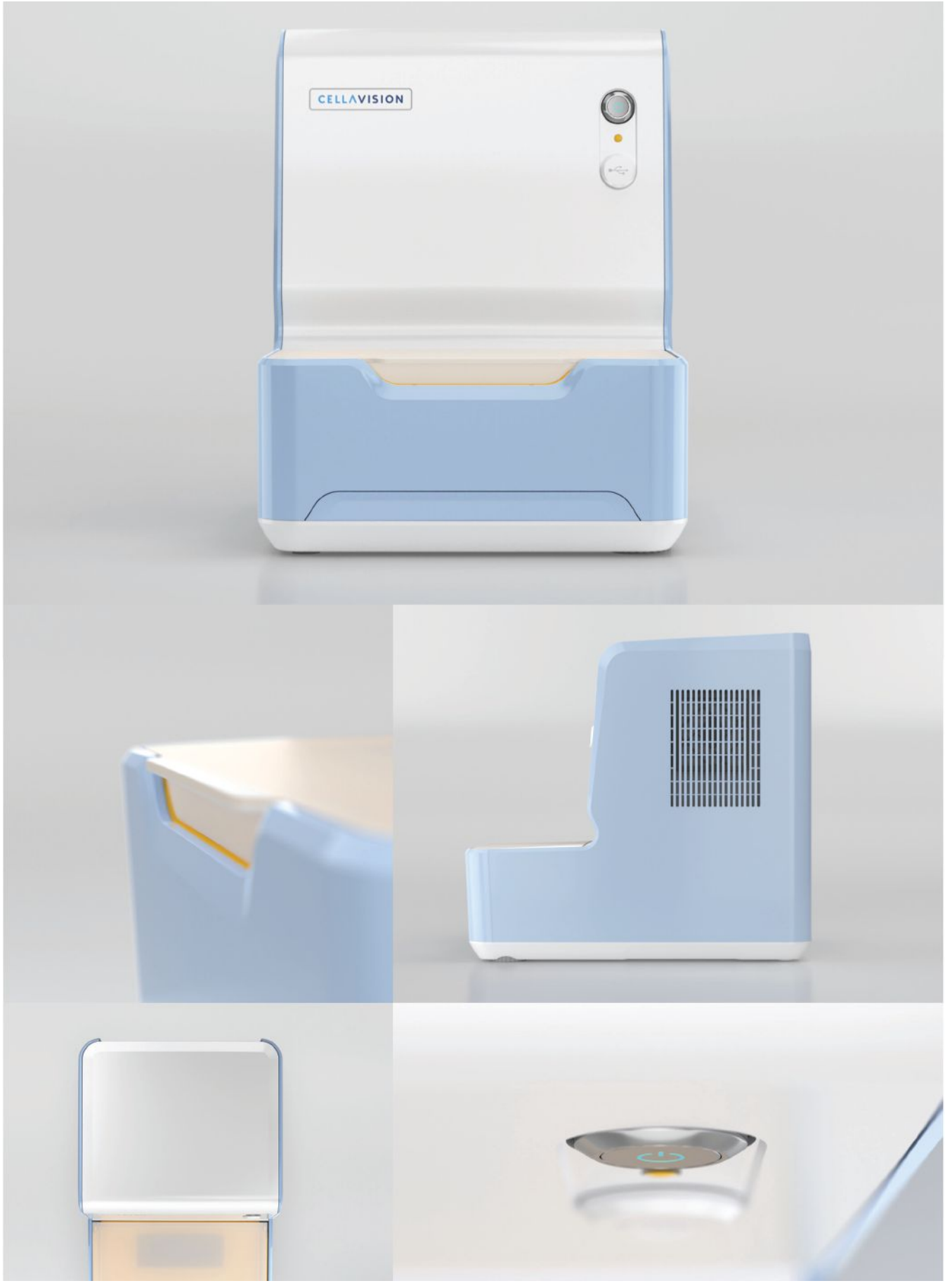
CELLAVISION

IN THE KNOW

DIGITAL CELL MORPHOLOGY

Helping labs work smarter and perform better

Article provided by CellaVision

Two decades ago, the Swedish Medtech company CellaVision introduced a revolutionary technology that has helped hematology labs all over the world modernise the process of performing blood cell differentials. This year at MEDLAB, they are launching a new analyzer that will enable smaller labs to implement the digital methodology that so many large labs have come to regard as standard practice.

The process of performing blood cell differentials is widely regarded as one of the more challenging aspects of routine hematology testing. It's time-consuming, laborious and the quality of output is entirely dependent on the proficiency of the Medical Technologist performing the analysis. In addition, the process is linked to considerable inter-observer interpretative challenges as well as a reliance on access to Pathologists for expert consultations.

In light of these challenges, it is perhaps not surprising that an ever-growing number of labs are stepping away from the microscope to implement the CellaVision alternative solution.

CellaVision's technology and methodology – known as Digital Cell Morphology – takes a more modern approach to performing blood cell differentials. It effectively removes many of the repetitive and laborious aspects of the process to give the Technologist time to focus on what really matters – the detection of abnormal cells and the delivery of first-class service to clinicians and patients.

The methodology is as simple as it is ingenious. The microscope is replaced by a CellaVision analyzer into which bar-coded slides are uploaded. During slide processing, the analyzer identifies the monolayer, locates cells, and takes an image of each cell found, after which it analyses and pre-classifies them using advanced image processing. The pre-classified and pre-characterised cells are then presented on a computer screen for convenient review and validation by the Medical Technologist.

MULTIPLE IMPLEMENTATION BENEFITS

Digital Cell Morphology by CellaVision provides four key benefits; the improved EFFICIENCY that comes with automating manual processes, enhanced QUALITY of results by promoting consistency and standardisation; improved CONNECTIVITY that facilitates collaboration within and between labs; and a general advancement of staff PROFICIENCY in performing cell differentials. Let's explore some of these themes in greater detail.

When performing differentials using manual microscopy, there are several sub-processes that take up valuable technologist time. Using CellaVision's automated methodology it's possible to reduce turnaround time in the lab. This enables labs to take on a greater volume of samples and improve utilization of manpower resources.

CellaVision technology introduces and establishes a more standardised testing methodology that makes it easier for labs to manage quality and ensure that cell differentials are performed with consistent accuracy and reliability.

With CellaVision's digital process, the task of performing cell differentials can be connected with the outside world. A Medical Technologist in a small lab can now collaborate and consult with colleagues, supervisors and morphology experts in other locations. Slides processed in one lab can be reviewed in another and challenging slides needing a second opinion can be reviewed remotely by a morphology expert in minutes.

CellaVision's methodology promotes staff proficiency and competency by providing built-in reference cell images, by presenting cells side-by-side in complete groups, and by establishing a collaborative environment where technologists learn from real-time consultation with more experienced colleagues and morphology experts.

With close to 4,000 installations around the world, CellaVision is now introducing a new product that will make it possible for labs of all sizes to implement Digital Cell Morphology.

INTRODUCING: CELLAVISION DC-1*

CellaVision DC-1 is a new smaller CellaVision analyzer that will prove a real game-changer for low-volume hematology labs as it enables smaller labs to implement the best-practice digital methodology for performing blood cell differentials.

CellaVision DC-1 is a semi-automated single slide system and although smaller, it offers the same set of proven operational and clinical benefits as CellaVision's larger analyzers. It can be placed in a small autonomous lab or in a satellite site of a larger laboratory network. In either setting, DC-1 promises the same advantages to small labs that large labs have enjoyed for many years: an automated and simplified process of performing blood differentials.

EXPERIENCE CELLAVISION DC-1AT MEDLAB 2019.

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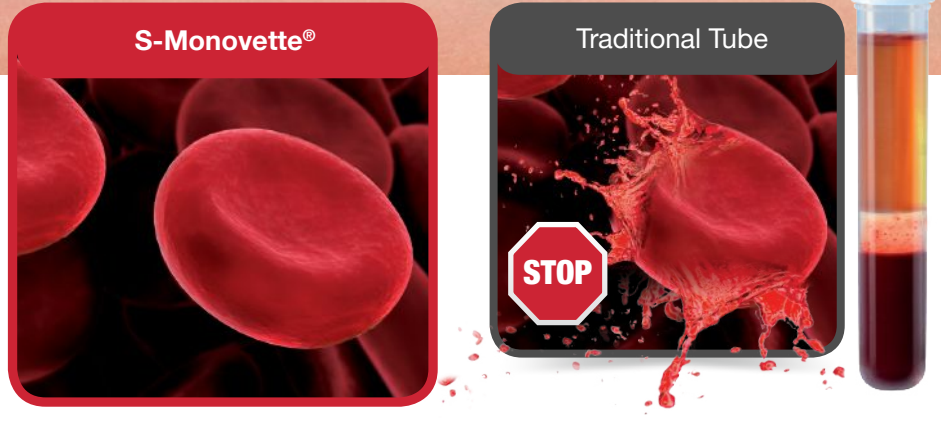

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