OCT/NOV 2019

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Medlab Middle East 2020

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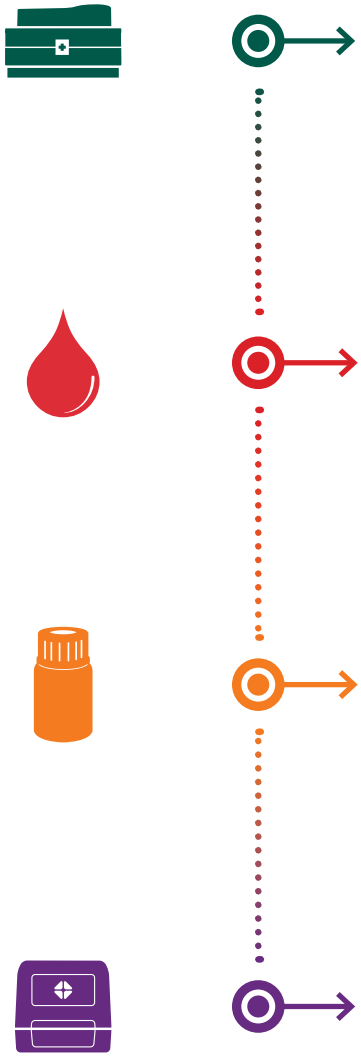

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By Informa Markets

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Enhancing diagnosis

Welcome to the October/November edition of Medlab Magazine! In this issue, we take a closer look at the upcoming Medlab Middle East 2020 that will host over 600 exhibiting companies, 15 country pavilions, 12 CME conferences and will welcome over more than 4,550 delegates. Find out about all the latest show developments in store on *pg 08.*

From 2020, Medlab Magazine will have a brand-new look and will be renamed as Omnia Health Magazine. The print and digital mediums of the publication will continue reporting the latest advancements transforming the laboratory industry and feature exclusive content around all our international shows. Take a sneak peek on *pg 10.*

Furthermore, we take a look at how the determination of autoantibodies plays a key role in the diagnosis of diabetes mellitus type I, the insulin-dependent, autoimmune-mediated form of diabetes *(pg 12).* We also shed light on the clinical utility of Full Blood Count (FBC) and its parameters *(pg 16).*

Also, find out how the advent of simple molecular genetic tests to detect the major polymorphisms associated with primary lactose intolerance has significantly enhanced the diagnosis of this common condition *(pg 26).*

We hope you find the articles to be informative and enjoy reading this issue.

Deepa Narwani

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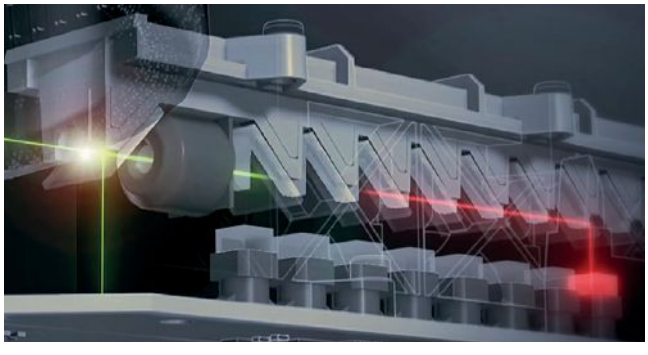

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Medlab Middle East 2020:
Transforming tomorrow's diagnostics

The upcoming edition of the exhibition will embrace the power of live experience for business, alongside the only CME accredited multi-disciplinary congress.

By Medlab Magazine Staff

The exhibition offers access to high-performance devices at cost-effective prices that enable better decision-making.

Medlab Middle East is the only clinical laboratory industry event that offers manufacturers the opportunity to meet a diverse audience of buyers from all around the world. From distributors to senior end-users, the 2020 edition is set to welcome over 25,800 laboratory and trade professionals in search of the latest innovations. Being present at the event is important to stay connected and benefit from this rapidly evolving industry.

The show will take place at the Za'abeel Halls 1 to 6, Dubai World Trade Centre, from February 3 to 6 2020. The exhibition will host over 600 exhibiting companies, 15 country pavilions, 12 CME conferences and will welcome over more than 4,550 delegates. The exhibition is free to visit for healthcare and laboratory trade professionals.

Global healthcare expenditures are expected to continue to rise at an annual rate of 5.4 per cent between 2017-2022 of which the global clinical laboratory services market is expected to reach a value of US$33.45 billion. At Medlab Middle East, you can join manufacturers from over 35 countries to connect and discuss products to match your latest requirements, budgets and interests. Offering access to high-performance solutions from advanced technology to affordable alternatives, there's an extensive range of products to explore at the show.

The exhibition offers access to high-performance devices at cost-effective prices that enable 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.

Transformation Hub

Staying true to Medlab Middle East's overall aim of shaping the future of healthcare by developing the value laboratory medicine, the 2020 edition is launching the all-new Transformation Hub.

A dedicated area amongst the busy exhibition floor will become home to medical laboratory SME's of the world, providing a platform to showcase the industry's latest gadgets, equipment and technology.

At the heart of the Transformation Hub is the Transformation Talks, a special feature engaging potential buyers in educational sessions, where manufacturers introduce new launches and in-demand solutions. Some of the key areas that will be highlighted at the hub include automation, information technology and laboratory measurement testing and technology.

Medlab Congress

An international scientific committee is underway in developing the 2020 conference programme where 120 plus thought leaders considered pioneers in the clinical laboratory will deliberate on technical skillsets, research findings and recommendations on multi-disciplinary topics from laboratory management to microbiology, clinical chemistry, haematology and more. The agenda will continue to offer CME accreditation and host the most diverse speaker line-up of international laboratory medicine specialists.

The CME accredited multi-disciplinary conferences will bring together a diverse line-up of high calibre international laboratory medicine specialists. For instance, the Heads of Laboratory Masterclass will offer attendees the opportunity to connect and network with colleagues from the industry and discuss key challenges.

Some of the newly introduced conferences include the **Blood Transfusion Medicine Conference**, which will be supported by The International Society of Blood Transfusion and the Saudi Society of Transfusion Medicine. This expert-led agenda will feature a host of renowned international blood specialists who will share novel insights that will transform attendee's breadth of expertise, update their diagnostic skills and support the provision of excellent care to every patient.

Technological innovation in healthcare is growing at an increasingly fast pace across specialties, and the laboratory is no exception. It offers great potential to improve working efficiency, patient care and experience, however, adaptation and implementation of innovations come with challenges. This newly launched conference on **Laboratory Innovation** will aim to ultimately support the better provision of solutions for existing healthcare problems.

One of the other new features is the **Roundtable Discussions** – focused scientific group discussions on selected administration and technical topics in the medical laboratory, these will allow participants to gain in-depth knowledge, directly from a facilitator and share amongst other professionals the challenges and best practices in providing efficient diagnostic services.

The event will also host free-to-attend industry workshops offering visitors a chance to hear from manufacturing companies about innovations and recent product launches. Furthermore, the Education Zone will allow visitors to discover clinical researches and projects in laboratory medicine through poster display and oral presentations. Additionally, 'Career Talks' will provide a platform for young laboratory professionals to learn about opportunities for career planning and further education.

Tom Coleman, Group Exhibition Director, Informa Markets Healthcare, said: "The 2020 dates for Medlab Middle East are on calendars of clinical laboratory and trade pioneers across 135+ countries. It's been a very successful few years in Dubai since we branched off as a stand-alone show from Arab Health, and the upcoming edition under the newly introduced theme 'Transforming diagnostic innovations' is gearing up to put on a top-notch experience for all stakeholders – see you there."

For more info visit www.medlabme.com.

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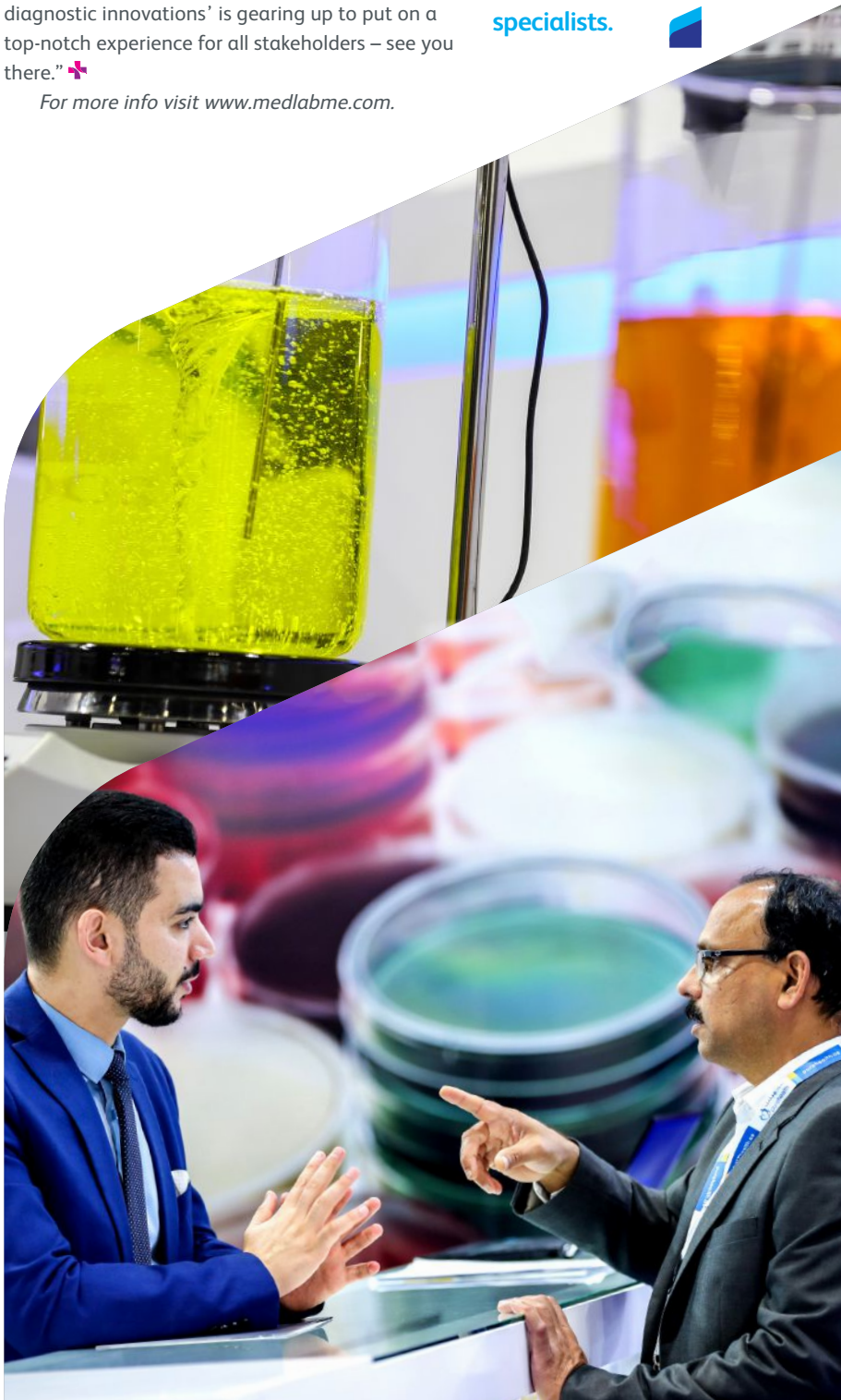


Medlab Magazine to be renamed as Omnia Health Magazine

Here is a sneak peek into our brand-new look in 2020!

At Informa Markets – Healthcare Group, our vision is to become the 'Global Information Hub' for the B2B healthcare industry and with more and more people logging in online to consume industry news and developments, we felt it's time to make a change and embrace the digital future.

From 2020, Medlab Magazine, the GCC's leading publication for laboratory news and developments, will be rebranded as Omnia Health Magazine. This move has been made to establish the magazine as the official publication for all the events under the Informa Markets – Healthcare Group. The print and digital mediums of the publication will continue reporting the latest advancements transforming the healthcare industry and feature exclusive content around all our international shows such as Arab Health, Medlab Middle East, Africa Health and FIME, among others.

Omnia Health will bring out two print issues with digital extensions and four exclusively digital magazines, along with topical supplements and 12 dedicated e-Newsletters that will be circulated to a global audience. Additionally, the most recent news and developments from across the globe will be reported weekly on www.omnia-health.com/news and promoted on our social media channels.

Omnia Health Magazine strives to provide commentary and analysis to key decision-makers

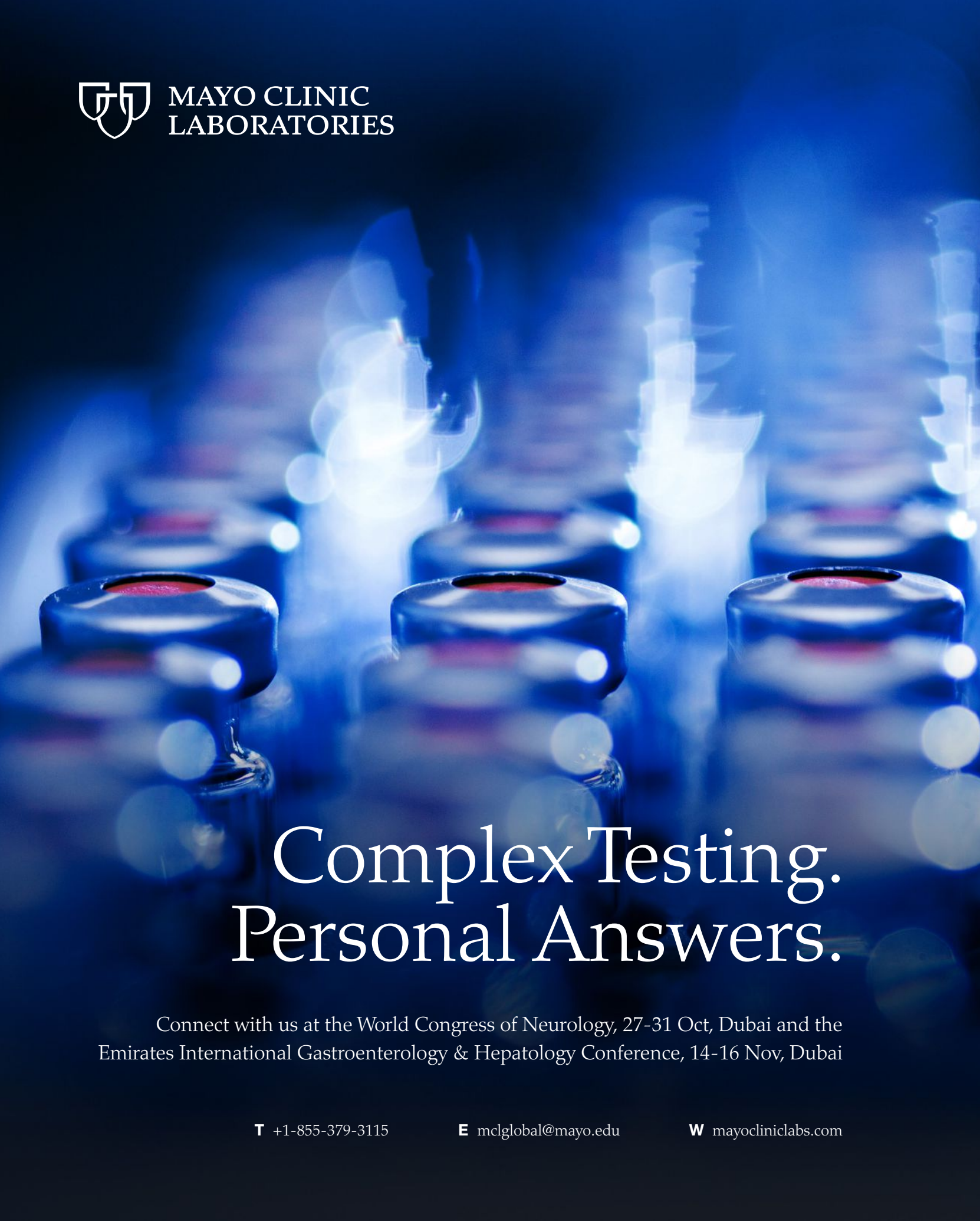
in the healthcare and laboratory industry. The B2B publication will cover topics related to the Investment, Management, Economics and Technological aspects of healthcare. Both our print and digital platforms have been designed to deliver the latest news in the industry and will offer a crucial insight into the trade.

The brand-new website *(pictured)* has been designed to focus on the user experience and will offer engaging content and optimised design and text that is user-friendly, to make it more accessible and interactive. The website will also feature embedded videos, webinars and whitepapers to give a more visual and engaging experience. It will host up-to-date analyses and reports on market developments and provide constant updates on new projects, products and technologies that will make it a must-read for healthcare professionals.

Omnia Health's online content platform will complement the digital Omnia Health Global Medical Directory that features products from leading medical and healthcare companies from around the world. Omnia Health is on the path to becoming a powerful business intelligence tool that will support all stakeholders in the healthcare industry grow.

Currently, Omnia Health is coming together, evolving, changing and growing, and we hope you'll be part of our exciting journey!

Omnia Health
By Informa Markets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Anti-zinc transporter 8 antibodies

Enhancing the diagnosis of diabetes mellitus type I

By Dr. Juliane Brock, EUROIMMUN AG, Luebeck, Germany

The determination of autoantibodies plays a key role in the diagnosis of diabetes mellitus type I, the insulin-dependent, autoimmune-mediated form of diabetes. Anti-zinc transporter 8 antibodies (ZnT8A) represent a new addition to the repertoire of autoantibody biomarkers. They complement existing serological parameters such as anti-islet cell antibodies (ICA), anti-glutamic acid decarboxylase antibodies (GADA), anti-tyrosine phosphatase antibodies (IA2A), and anti-insulin antibodies (IAA). A broad serological analysis of different autoantibodies significantly increases the detection rate for diabetes mellitus type I. Various autoantibody testing strategies are employed depending on the age of the patient.

Diabetes mellitus type I

Diabetes mellitus type I is an autoimmune disease in which the beta cells of the pancreatic cells of Langerhans are selectively destroyed, reducing the body's ability to produce insulin and thus regulate blood sugar levels. The disease mainly occurs in childhood or at the start of puberty, but may also occur in adults. The prevalence of diabetes mellitus type I, for example in Central Europe, amounts to approximately 0.4 per cent. Latent autoimmune diabetes in adults (LADA) is a special form of the disease, which occurs from around age 25. It is characterised by a mild course, which slowly progresses into an insulin-dependent stage. LADA is frequently first confused with the non-autoimmune-mediated diabetes mellitus type II due to its slow progression. In order to make a clear diagnosis, the detection of disease-specific autoantibodies is indispensable in both diabetes mellitus type I and LADA.

Disease development

The destruction of beta cells starts already years before the actual manifestation of diabetes mellitus type I, which occurs only when around 80 per cent of beta cells are destroyed. The production of disease-associated autoantibodies also starts in the early phase of the disease. The titer first rises rapidly and in the later stage decreases somewhat. Thus, autoantibodies represent important early markers, indicating the disease even before it manifests. Moreover, they have a prognostic value and can indicate if a person, for example a first-degree relative of a patient, has an increased risk of diabetes mellitus type I. The disease is treated with exogenous insulin, and an earlier start of therapy is associated with a better prognosis and less secondary organ damage. The destruction of the beta cells cannot, however, be stopped and patients remain insulin-dependent.

Disease-associated autoantibodies

ICA: Encompass all antibodies which are directed against the endocrine cells of the pancreas. They have a prevalence of 80 to 90 per cent in diabetes mellitus type I. The target antigens of ICA are predominalty glutamic acid decarboxylase, tyrosine phosphatase and zinc transporter 8.

GADA: Have a prevalence of 60 to 80 per cent in newly diagnosed patients. They often occur in very high concentrations and persist for a long time. GADA or ICA are suitable for delimitation of LADA from diabetes mellitus type II in young adults.

IA2A: Have a prevalence of 50 to 80 per cent in newly diagnosed patients and often occur together with other disease-specific antibodies. They have a high diagnostic sensitivity in children and young adults in terms of rapid progression to manifest type I diabetes mellitus.

ZnT8A: Are present in 60 to 80 per cent of patients at the beginning of the disease and are found in 26 per cent of patients in whom no GADA, IA2A or IAA are detected. They have a high prevalence in children, starting from three years of age and reaching a peak in late adolescence. ZnT8A have a high prognostic value, since they seem to correlate well with the mass of the beta cells. This means that in children of diabetes mellitus type I patients, the risk of developing the disease is higher if ZnT8A are present. Positivity for ZnT8A appears to reflect a more aggressive disease process both before and after diagnosis. In LADA patients, ZnT8A might indicate that the patient is in transition from a non-insulin dependent to an insulin-dependent stage.

IAA: Are present in the majority of paediatric patients. They are only relevant in adults if they occur together with other specific antibodies, since their formation may be induced by exogenous insulin and they may be present in healthy individuals.

Predictive value of autoantibodies

Generally, the risk of suffering from diabetes mellitus type I increases with the number of specific autoantibodies in serum. A strong affinity and high titers of these antibodies further increase the probability. Age also plays a decisive role in the estimation of the disease risk. The earlier the disease-associated autoantibodies occur, the higher the 10 year-risk of falling ill is and the faster the progression to manifest diabetes mellitus type I.

The connection between the number of different autoantibodies and the disease risk was demonstrated in a series of prospective studies from Zeigler et al. with over 13,000 children at high risk of developing diabetes mellitus type I (Figure 1). In 15-year-old subjects without autoantibodies the disease risk amounted to 0.4 per cent. In individuals of the same age with one autoantibody the disease risk was 12.7 per cent, with two different autoantibodies 61.6 per cent, and with three different autoantibodies 79.1 per cent.

Diagnostic strategy

The diagnostic procedure in diabetes mellitus type I depends strongly on the patient's age. Experts recommend investigating GADA first in both paediatric and adult patients. If no GADA are detected, children under the age of 10 years should be tested for IAA and ZnT8A, and children over 10 years for IA2A and ZnT8A. Adult patients who do not exhibit GADA should be investigated for ICA. Since some patients exhibit only one type of autoantibody, a comprehensive investigation of autoantibodies is always recommended.

ELISAs for detection of GADA, IA2A and ZnT8A

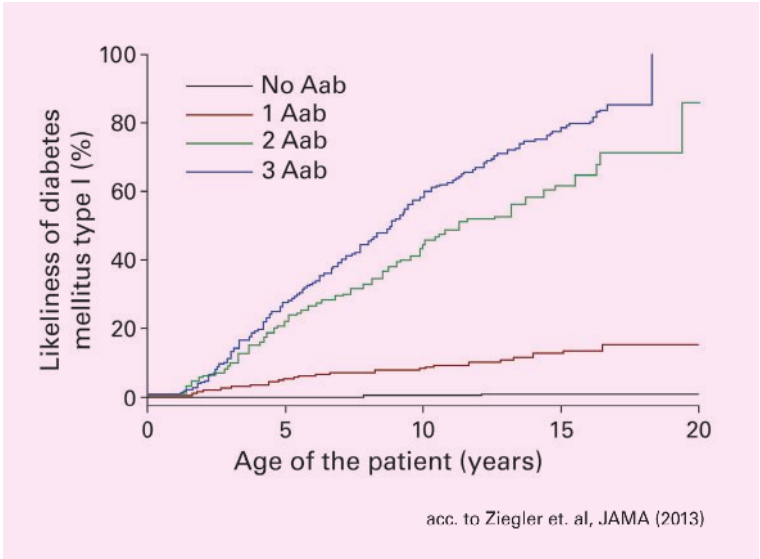
Formerly, the radioimmunoassay (RIA) was the gold standard for the determination of GADA and IA2A. Nowadays, reliable ELISA test systems are available, which provide comparable performance to RIA. They are, moreover, simple to perform and do not require the use of radioactive reagents. Studies with clinically characterised patient sera have verified the excellent agreement of the EUROIMMUN Anti-GAD ELISA (97 per cent) and Anti-IA2 ELISA (98 per cent) with the corresponding RIAs.

ZnT8A can be determined using a newly

▼**Table 1.** Prevalence of ZnT8A in different cohorts

Panel	n = 869	Anti-ZnT8 ELISA
Diabetes mellitus type I (paediatric)	227	163 (72 %)
Diabetes mellitus type I (adult)	94	51 (54 %)
LADA	51	16 (31 %)
Healthy blood donors (paediatric)	100	2 (2 %)
Healthy blood donors (adult)	297	3 (1 %)
Addison's disease	23	2 (9 %)
Rheumatoid arthritis	26	0 (0 %)
Graves' disease	24	1 (4 %)
Hashimoto's thyroiditis	24	0 (0 %)

▼**Figure 1.** Increasing likeliness of diabetes mellitus type I with rising number of different specific autoantibodies (Aab)



developed ELISA. In a study with sera from 50 diabetes mellitus type I patients, 76 per cent of the sera were determined as positive in the Anti-Zinc Transporter 8 ELISA. 94 per cent of samples were positive in at least one of the three ELISAs. In a further study, 869 sera from diabetes patients, healthy blood donors and patients with other autoimmune diseases were analysed with the Anti-Zinc Transporter 8 ELISA (Table 1). ZnT8A were detected in 72 per cent of paediatric and 54 per cent of adult diabetes mellitus type I patients, as well as in 31 per cent of LADA patients. Study subjects with other autoimmune diseases, in contrast, exhibited ZnT8A only in isolated cases.

RIA for detection of IAA

Detection of IAA is only reliable by RIA, since only in the liquid phase are all relevant epitopes of the antigen freely accessible for the heterogenic IAA. In a study encompassing 50 patients with newly manifest diabetes mellitus type I aged from 9 to 35 years and 100 sera from healthy blood donors, the Anti-Insulin RIA yielded a very good specificity of 95 per cent at a sensitivity of 46 per cent.

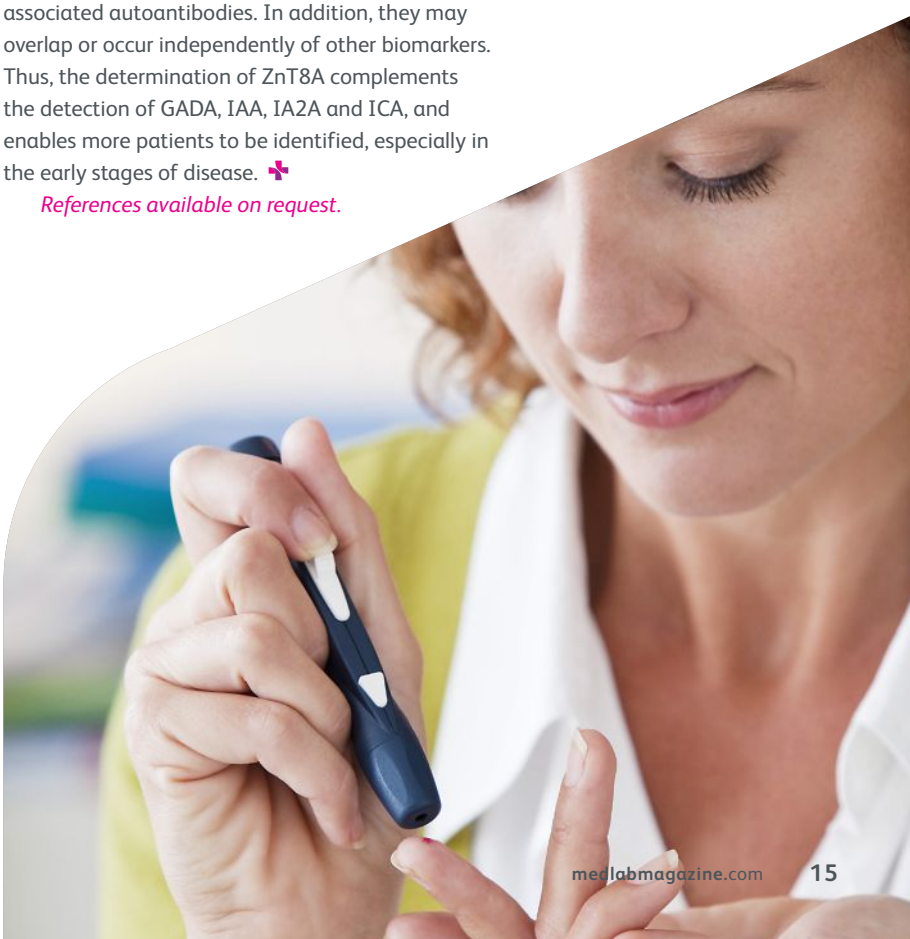
IFA for detection of ICA

The indirect immunofluorescence assay (IFA) using the substrate pancreas enables a comprehensive investigation of all ICA. In the commercial IFA from EUROIMMUN, frozen sections of primate pancreas are used for the antibody detection. ICA react with the endocrine part of the pancreas tissue and manifest with a smooth to granular cytoplasmic fluorescence of all islet cells.

Perspectives

A range of autoantibodies serve as diagnostic and predictive biomarkers for diabetes mellitus type I and LADA, in particular for differentiating these autoimmune disease forms from non-autoimmune diabetes mellitus type II. The discovery of ZnT8 as a major target of autoantibodies has significantly enhanced the diagnostic repertoire. ZnT8A occur with a similar prevalence to classic diabetes-associated autoantibodies. In addition, they may overlap or occur independently of other biomarkers. Thus, the determination of ZnT8A complements the detection of GADA, IAA, IA2A and ICA, and enables more patients to be identified, especially in the early stages of disease. ✜

References available on request.



The clinical utility of FBC and its parameters

By Dr. Chitranga Kariyawasan, Consultant Haematologist, Sri Jayewardenepura General Hospital (SJGH), Sri Lanka

A full blood count (FBC) is a blood test which measures a large number of blood parameters, most notably the Haemoglobin, white cell count (WCC) and Platelet count.

FBC is a common blood test that's done:

- To review overall health.
- To diagnose a medical condition.
- To monitor a medical condition.
- To monitor medical treatment.

FBC components

Haemoglobin

It is the oxygen-carrying pigment of red cells. There are millions of haemoglobin molecules in each red cell. This blood component carries oxygen from the lungs to the body tissues.

Normal levels in men and women are 14-18 g/dl and 12-16 g/dl respectively. (This would differ according to the populations, with those in the western countries having a higher Haemoglobin {Hb} in contrast to the Asian populations).

A low Haemoglobin is called anaemia, and has a variety of causes, including chronic (over a long time) blood loss, destruction of red cells, decreased blood cell formation in the bone marrow, defective production of haemoglobin, or chronic illness.

Clinically: It causes tiredness, shortness of breath on exertion and possibly postural light-headedness.

A high Haemoglobin is called erythrocytosis and may be caused by smoking, chronic lung disease or a blood condition called polycythaemia vera (PV). This is a proliferative disease of the bone marrow, which causes an increase in total RBCs and haematocrit as well as an elevation in white cells and platelet count. Clinically it causes plethoric face, headache, itchiness of the body, hyperviscocity symptoms and hypertension.

Red blood cells: RBCs are the number of erythrocytes in 1 cubic mm of whole blood. The RBC count will be low with iron deficiency, blood loss, haemolysis and bone marrow suppression. Increases may be found when one moves to a higher altitude or after prolonged physical exercise and can also reflect the body's attempt to compensate for hypoxia.

Normal levels in men and women are 4.6 million to 5.9 million and 4.1 million to 5.4 million, respectively.

Haematocrit: The test for haematocrit measures the volume of cells as a percentage of the total volume of cells and plasma in whole blood. This percentage is usually three times greater than the haemoglobin. After haemorrhage or excessive intravenous fluid infusion, the haematocrit will be low. If the patient is dehydrated, the haematocrit will be increased (erythrocytosis) and as mentioned above in the condition called Polycythaemia Vera and other secondary causes of erythrocytosis.

Normal levels in men and women are 42 to 47 per cent and 37 to 44 per cent respectively.

Mature RBCs have a lifespan of about 120 days. In haemolytic anaemia, the cell life span may be shorter.

Reticulocyte: These are the new cells released by the bone marrow. The reticulocyte count is therefore used to assess bone marrow function and can indicate the rate and production of RBCs. Normal to slightly low reticulocyte counts may occur with anaemia demonstrating an underproduction of red cells (such as with iron or folate deficiencies), elevated levels may indicate blood loss, haemolysis or response to haematinics.

Normal levels are 0.5 to 2 per cent.

Reticulated Hb (RHE/CHr) – a special parameter found in the more recent analysers

Measuring the haemoglobin content of reticulocytes, also known as reticulocyte haemoglobin (CHr) equivalent, is a way of diagnosing and monitoring iron deficiency anaemia. It is the fastest way to detect changes in iron status. Since red blood cells have a 120-day lifetime, detecting iron deficiencies and changes in the iron status of erythropoiesis is only possible relatively late using classical haematological parameters such as Hb, MCV and MCH.

Reticulocytes as mentioned before, are swept into the blood stream from the bone marrow and usually mature over the course of two to four days. Measuring the haemoglobin content of the reticulocytes means you can look at the current iron supply to erythropoiesis and judge the 'quality' of the cells. This lets you detect changes in iron status far earlier than through the haemoglobin content of mature red blood cells.

Immature reticulocyte fraction (IRF)

This parameter shows early haematopoietic recovery post chemotherapy and is more useful than the current practice of using the absolute neutrophil count.

Indices

Indices measure the average characteristics of the erythrocyte. The indices usually noted include the mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), the mean corpuscular haemoglobin concentration (MCHC) and red cell distribution width (RDW).

MCV: This measures the average size of the RBC and can be calculated by dividing haematocrit by RBC count X10. Low values indicate the cells are microcytic (small cells) and are often evident with conditions such as iron deficiency, lead poisoning and thalassemia. High values greater than 95 FL indicate macrocytic cells (large cells), and are found with such conditions as megaloblastic anaemia, folate or

Normal levels of RBC in men and women are 4.6 million to 5.9 million and 4.1 million to 5.4 million, respectively.

Reticulocytes are swept into the blood stream from the bone marrow and usually mature over the course of two to four days.

A very low WCC would raise concern that the immune system is overwhelmed by infection.

Vitamin B12 deficiency, liver disease, post-splenectomy, chemotherapy or hypothyroidism. The MCV can be normal with a low haemoglobin if the patient is hypovolemic or has had an acute blood loss.

Normal values are 80-95 FL.

MCH: Is the average weight of haemoglobin per red cell. Normal level is 27 to 32 picograms (pg).
MCHC: Is the average concentration of haemoglobin per erythrocyte.

Normal levels can be seen with acute blood loss, folate and Vitamin B12 deficiency; these cells will still be normochromic. Hypochromic or "pale cells" will be seen with conditions such as iron deficiency and thalassemia.

The MCV can be normal with a low haemoglobin if the patient is hypovolemic or has had an acute blood loss.

Normal levels are 32-36 per cent (g/dl)

RDW: This index is a quantitative estimate of the uniformity of individual cell size.

Elevated levels may indicate iron deficiency or other conditions with a wide distribution of various cell sizes such as in mixed deficiency anaemia, response to haematinics and certain haemolytic anaemias. Normal levels are 11.5 to 14.5 per cent.

White cell count (WCC)

WBCs, also known as leukocytes, are larger in size and less numerous than red cells. They develop from stem cells in the bone marrow.

A very low WCC would raise concern that the immune system is overwhelmed by infection and may not have enough white blood cells to fight the infection effectively. This is particularly true in the setting of recent chemotherapy, and may occur early on in any infective illness.

A high WCC is often due to an infection, which may or may not be severe. Other causes include a seizure, steroid medications such as prednisolone, or as a non-specific "stress response" to pain or illness.

If very high, it may be due to severe infection, or less commonly due to an acute or chronic form of leukaemia.

Normal levels of WBCs for men and women are 4,000 to 11,000/cubic mm.

The differential white cell count is done to establish the percentages of the five different types of cells and establish their relationship in the clinical conditions they have an association with. It adds up to 100 per cent and usually includes neutrophils, basophils, eosinophils, monocytes and lymphocytes.

Neutrophils

Besides increasing during inflammation and infections, it increases with conditions such as stress, necrosis from burns and heart attack.

Normal levels range from 40 – 70 per cent, absolute count – 2500 – 7000/cumm.

Eosinophils

It is found in areas such as skin and the airway in addition to the bloodstream. They increase in number during allergic and inflammatory reactions and parasite infections.

Normal blood levels range from 02 – 04 per cent, absolute count 100 -400/cumm.

Basophils

These are so called when found in the blood, are also known as "mast" cells when found in the tissues. Tissue basophils are found in the gastrointestinal and respiratory tracts and the skin. They contain heparin and histamine and are believed to be involved in allergic and stress situations. They may contribute to preventing clotting in micro-circulation.

Normal blood levels range from 0 -1 per cent, absolute count 0- 100/cumm.

Monocytes:

These arrive at the site of injury in about five hours or more.

Normal levels, which vary depending on the source, range from 2 – 8 per cent, absolute count 200 - 800/cumm.

Lymphocytes

These fight viral infections. Lymphocytes have a key role in the formation of immunoglobulins (humoral immunity) and also provide cellular immunity.

Normal levels range from 20 – 40 per cent, absolute count 1500 -3500/cumm.

Platelet count

It measures the platelet number, and are small elements formed in the red bone marrow. They are actually fragments of megakaryocyte cytoplasm (precursor cell to the platelet). They help to control bleeding, not function.

MPV (mean platelet volume) – indicates average size of the platelets in blood.

PDW (platelet distribution width) – indicates platelet variation and this could result in falsely low results (pseudothrombocytopenia).

A low platelet count is thrombocytopaenia, and may be due to a variety of causes, including Idiopathic v.

Thrombocytopenia does not result in serious bleeding, unless the platelet count is below 50. It helps to decide platelet transfusions especially when the platelet count is below 10.

A high platelet count called Thrombocytosis may occur as a reactive response to bleeding, haemolysis, infection, inflammation and malignancy or may be due to a clonal cause such as in myeloproliferative neoplasms namely essential thrombocythemia.

The normal level of platelets is 150,000-400,000/cubic mm.

IPF (immature platelet fraction) – is a new parameter present in the more sophisticated analysers. It is a very useful indicator of the presence of immature platelets in circulation. This is a very good indicator of the marrows ability to produce platelets in patients when presenting with thrombocytopenia. This marker has been utilised in the diagnosis of patients with immune thrombocytopenia and also to identify dengue in patients who are in the recovery stage.

Summary

The above explain the many clinical utilities of the parameters depicted by the FBC.

Lymphocytes have a key role in the formation of immunoglobulins and also provide cellular immunity.

Digital transformation of the medical laboratory

By Deepa Narwani, Editor

Dana Drissel

Technological innovation in healthcare is growing at an increasingly fast pace across specialties, and the laboratory is no exception. Against the backdrop of increasing digitisation, various processes and structures have to be reconsidered in the laboratory of the future. Network-capable laboratory devices with intelligent and smart functions, complex holistic automation concepts and efficient interface solutions are indispensable for the start of the new era.

For instance, computational tools can enable laboratory managers to address the developing complex medical environment. Kaon Interactive's Laboratory Design Tool (LDT), for example, offers companies the opportunity to share newly configured labs with internal stakeholders, to gain consensus buy-in on floorplans, equipment purchases, workflow efficiencies and more. In just minutes, the LDT enables laboratory managers, instrument sales and marketing teams, and lab scientists to configure entire laboratories and immediately immerse users in a newly designed lab.

To achieve this, the Kaon LDT offers three unique ways to visualise and experience a new, engaging, 3D, interactive laboratory layout: interactive 3D, untethered Virtual Reality (VR) and scalable Augmented Reality (AR) with real-time 3D object placement (instruments, consumables, chairs, workstations, windows, doors, pipette drying racks, sinks, etc.).

Users start configuring their lab either by free drawing a layout themselves or selecting from pre-defined labs that meet their specific business needs. Once a floorplan has been selected or created, instruments and furnishings may be added from a library of objects, using a simple drag-and-drop action. These 2D floor plans instantly become 3D immersive at the touch of a button.

The Kaon LDT is customisable to allow data-driven product and workflow suggestions for unique laboratory layouts, revealing differentiated value through calculated impact such as assay volume, energy and space requirements, and even staffing modifications. It also helps demonstrate future layout evolutions by supporting comparisons between existing and new workflows, validating proper fit and flow, optimising space, improving efficiency, lowering operational costs, reducing sample loss contamination, and more.

Excerpts from an interview with Dana Drissel, Vice President of Marketing, Kaon Interactive.

What has been the impact of advancements such as Point-of-care-testing (POCT), Big Data, and personalized medicine on the laboratory industry?

The ultimate goal of "Big Data" is to provide timely insight that is used to improve the effectiveness and efficiency of organisations. Within a laboratory, companies now have the ability to analyse collected data using visualisations and other techniques to uncover insights around their people, processes and systems. The challenge is then how to act on these key findings in real time to create effective clinical management, optimal patient care and improve the overall laboratory process.

According to you, how essential is automation in labs today?

Lab automation not only decreases human error associated with sample preparation, but it also increases efficiency in the lab by allowing the user to track samples. This type of productivity is imperative in today's labs to reduce costs and increase walk away time for scientists.

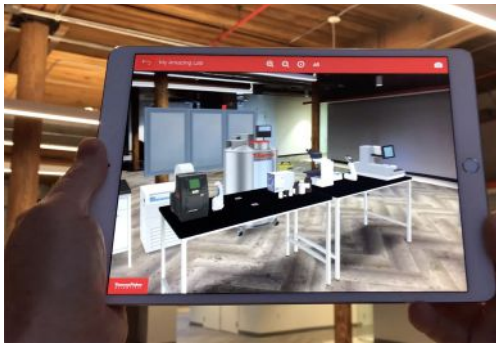
Tell us about Kaon's Laboratory Design Tool. What are its applications?

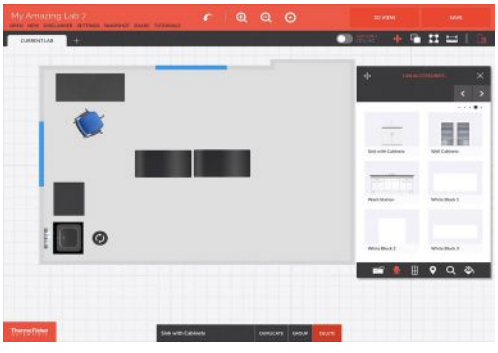
Kaon Interactive's LDT is a first-of-its-kind interactive laboratory plan and design tool that uses 3D, augmented reality and virtual reality to visualise laboratory configurations and communicate the unique benefits of lab products and services. It can be used to plan any medical lab or operating room design prior to purchasing equipment or committing to construction plans. The LDT empowers multiple constituents within the laboratory ecosystem to visualise complex instruments, equipment and workflows in a "virtual" layout. It's customisable to allow data-driven product and workflow suggestions for unique laboratory layouts, revealing differentiated value through calculated impact such as assay volume, energy and space requirements, and even staffing modifications. It also helps demonstrate future layout evolutions by supporting comparisons between existing and new workflows, validating proper fit and flow, optimising space, improving efficiency, lowering operational costs, reducing sample loss contamination, and more.

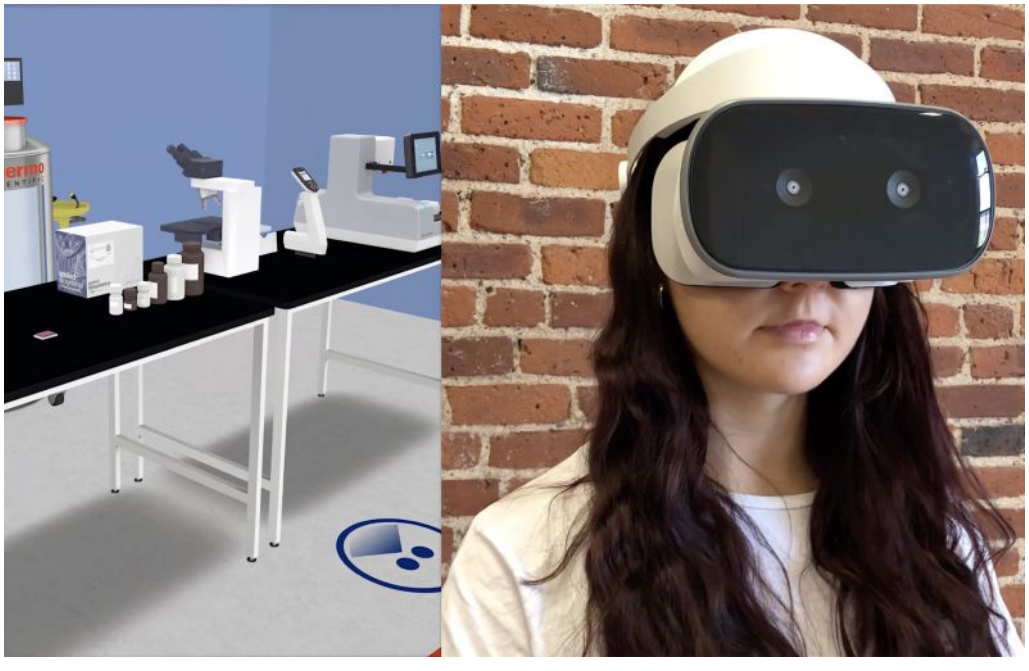
What are the challenges faced by the laboratory industry currently and what does the future look like?

What we were hearing within the life sciences industry is that many labs were mapped out via Post-It note or simple drawings. As you can imagine, that allows much room for error and only gives a mental picture of the final product. We wanted to personalise the experience and designed the LDT to bring a lab to life via 3D, augmented reality and virtual reality to help designers truly "visualise" it in the early planning stages. What's more, it allows you to virtually transport into the space, getting a feel for the room, the spacing, flow, etc., allowing for a uniquely memorable experience. We predict that visual interactive applications like the LDT will become a requirement in the digital transformation for B2B enterprises, including life sciences companies.

The LDT empowers multiple constituents within the laboratory ecosystem to visualise complex instruments, equipment and workflows in a "virtual" layout.







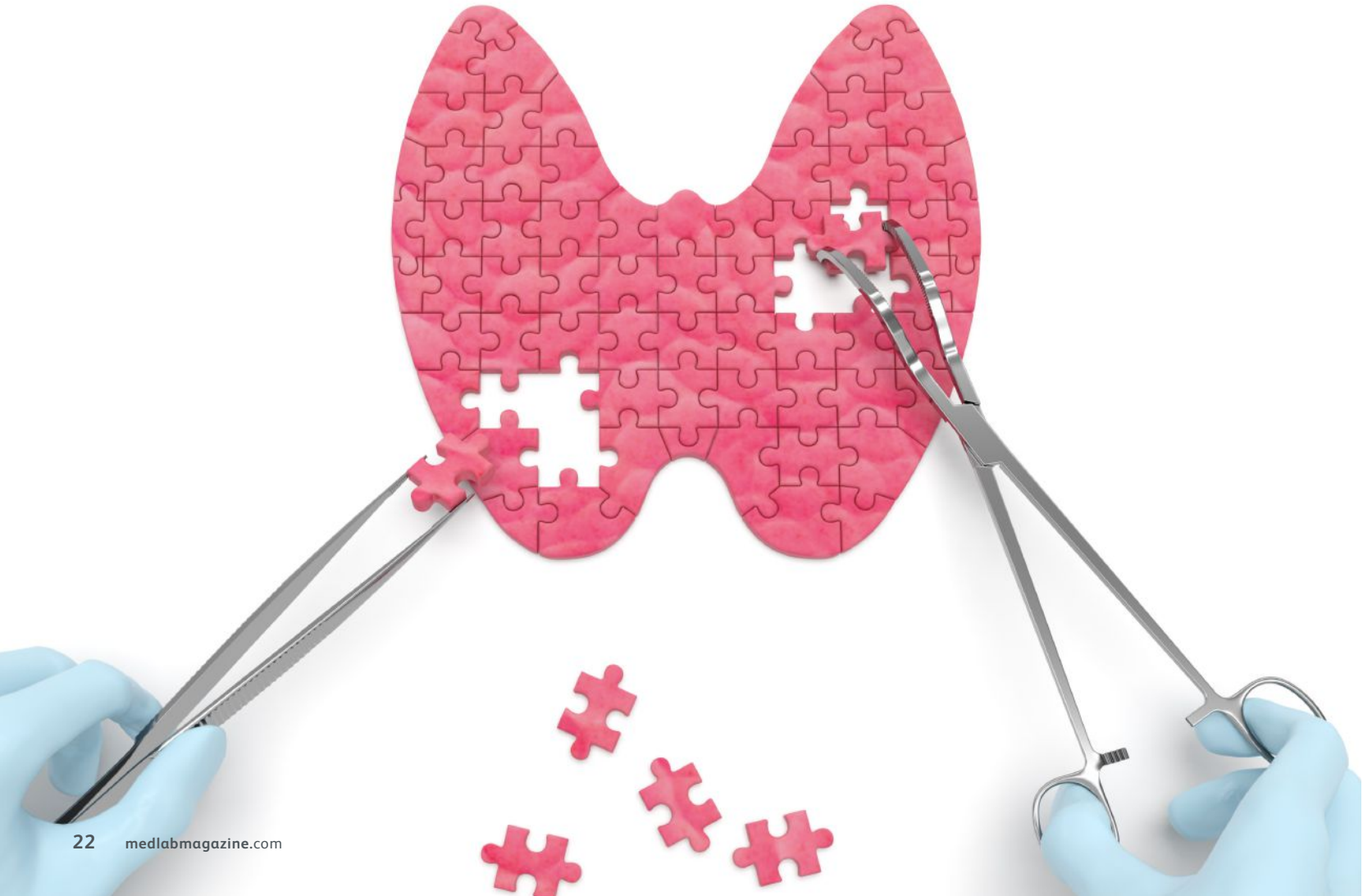
Non-invasive follicular thyroid neoplasm with papillary like nuclear features

By Luvo Fatman and Pamela Michelow, Cytology Unit, National Health Laboratory Service, and Department of Anatomical Pathology, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

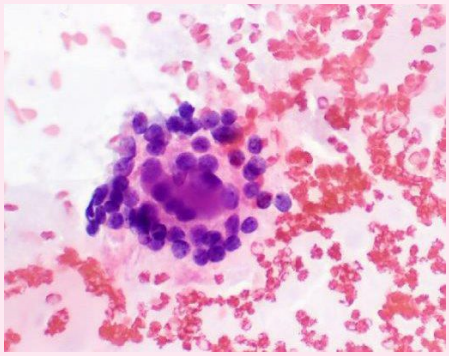
The molecular profile of NIFTP is similar to follicular adenoma and carcinoma.

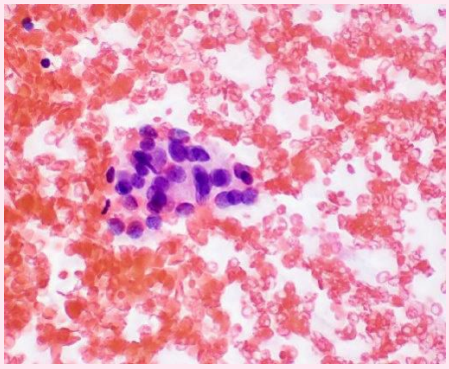
Non-invasive follicular variant of papillary thyroid carcinoma (FVPTC) has recently been reclassified as "invasive follicular thyroid neoplasm with papillary like nuclear features" (NIFTP). This is an indolent, low risk tumour that likely represents the preinvasive stage of invasive FVPTC. The implication of NIFTP not being classified as a malignant entity is important as it spares patients the burden of a cancer diagnosis.

A diagnosis of NIFTP promotes much more conservative surgical management of these patients and helps to avoid radioactive treatment postoperatively. The traditional management of PTC includes total thyroidectomy, central neck dissection as well radioactive iodine therapy. Surgery is extensive and may include complications such as hypothyroidism, which is especially important in our population where patients often show poor compliance with medical treatment in general. Other postoperative complications include injury to the recurrent laryngeal nerve and inadvertent excision of the parathyroid glands. Radioactive iodine may be associated with

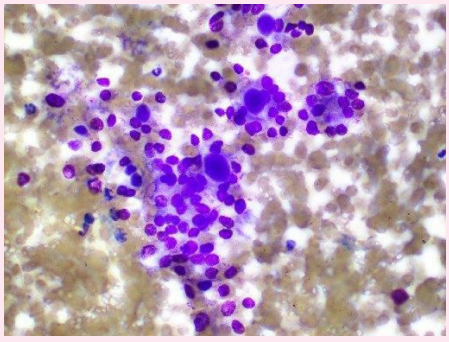


▼**Figure 1 and 2 :** Microfollicles with central inspissated colloid. The cells show round to oval pale nuclei with small nucleoli. Very infrequent longitudinal nuclear grooves. Pap stain x40.

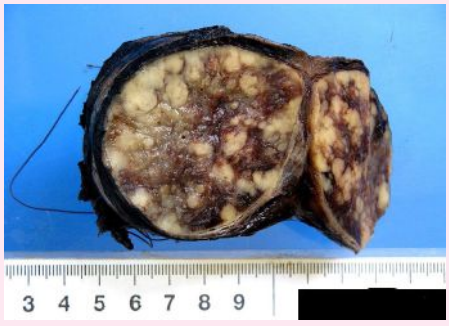




▼**Figure 3**: Diff Quik stain showing similar cytologic features. Note colloid within follicles.



▼**Figure 4:** Thyroid lobe with a solitary encapsulated nodule. The capsule varies from thin to thick in areas.



salivary gland dysfunction and the development of secondary malignancies.

Molecular studies show that NIFPT has more frequent RAS mutations. They also demonstrate PAX8/PPARß; THADA fusions as well as BRAF k601E mutations. NIFTP molecular alterations are in contrast to conventional PTC, which tends to be associated with BRAF v600E and RET fusions. The molecular profile of NIFTP is similar to follicular adenoma and carcinoma. Sonographic features of NIFTP include a benign appearing, round to oval well circumscribed nodule with a hypoechoic rim.

In this report, a case that was recently diagnosed as NIFTP in our institution is discussed. A 49-year-old female who presented with a 5cm right thyroid mass of six months' duration. She is HIV positive with a CD4 count of 391. Cytologic examination revealed a microfollicular and dispersed pattern throughout; microfollicles with inspissated intraluminal colloid.

The cells showed a high nucleocytoplasmic ratio, round nuclei, focal contour irregularities, finely granular chromatin with small distinct nucleoli; nuclear pallor and infrequent longitudinal grooves, which were focal. Distinct intranuclear cytoplasmic invaginations (INCIs) were absent. The cytologic diagnosis rendered was "follicular neoplasm" and lobectomy was recommended as per the Bethesda system for reporting thyroid cytopathology (TBSRTC) (Figure 1-3).

Surgical excision (right lobectomy) revealed a solitary encapsulated nodule. The tumour measured 75X60X60mm; showed a homogenous cream coloured surface with areas of haemorrhage. Extensive examination of the capsule revealed no evidence of capsular and/or lymphovascular space invasion. The architecture was entirely follicular with no papillae and/or psammomatous calcification. A diagnosis of NIFTP was made. (Figure 4-7).

NFTP is a surgical diagnosis i.e. the diagnosis is made with certainty only on excision specimens. There are several studies that have been conducted to determine whether a NIFTP diagnosis can be made prospectively on cytologic samples. Result outcomes are poor thus far with some series showing preoperative accuracy rate of 21 per cent.

Strict criteria must be adhered to for a final diagnosis of NIFTP. The following histologic and molecular features must be met:

- The tumour must be well circumscribed; completely or partially encapsulated
- Where there is partial encapsulation, there must be a distinct interphase between tumour and surrounding normal thyroid parenchyma with no

NFTP is a surgical diagnosis i.e. the diagnosis is made with certainty only on excision specimens.

Using stricter criteria for a diagnosis of PTC did not change the sensitivity of thyroid FNA and helps to minimise placing NIFTP in an unequivocal malignant category.

tongues of tumour infiltrating normal thyroid

- The predominant architectural pattern should be follicular with no papillary structures. If papillae are present, they should comprise less than 1 per cent of the tumour volume
- Unequivocal nuclear features of PTC must be present i.e nuclear pallor, INCIs, longitudinal nuclear grooves; nuclear crowding, overlap and elongation; small nucleoli
- If concomitant thyroid carcinoma types are present – solid, trabecular, insular – these should not exceed 30 per cent of tumour mass
- No psammoma bodies
- No tumour necrosis or increased mitoses
- No BRAF v600E mutations
- Absence of extrathyroidal extension and/or distant metastases

NIFTP Cytologic diagnostic criteria

- Hypercellular smears; microfollicles dispersed and in syncytia
- Sheets with branched irregular contours may be seen
- Colloid may be present – thick and within follicles
- Subtle nuclear features of PTC

The following should be absent or inconspicuous: papillae true with a fibrovascular core and papillary configuration; multinucleated giant cells, INCIs, psammoma bodies and marked cystic change.

When cytopathologists are faced with the above findings, a reporting option includes: "Although the architecture suggests a follicular neoplasm (or another diagnostic category), some nuclear features raise the possibility of FVPTC (invasive) or its indolent counterpart NIFTP; definitive diagnosis is not possible on cytology".

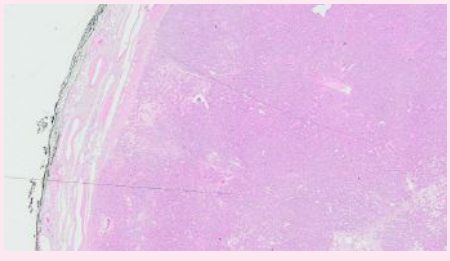
Cytologically, most cases of NIFTP fall under TBSRT categories: atypia of undetermined significance/follicular lesion of undetermined significance (AUS/FLUS), suspicious for follicular neoplasm/follicular neoplasm (SFN/FN) and suspicious for malignancy (SUS).

Maletta et al showed that a blind review of histologically proven cases of NIFTP were retrospectively reclassified on cytology as follicular neoplasm (56 per cent), suspicious for malignancy (27 per cent), AUS/FLUS (15 per cent) and malignant (2 per cent). Mitto et al made criteria for diagnosing PTC more stringent: nuclear features of PTC and at least one of the following features: - frequent INCIs (>3), presence of papillae and psammoma bodies. They examined the effectiveness of more stringent criteria after one year of implementation. Their results showed that there was no significant reduction of the malignant category; most PTCs were diagnosed as malignant. There was minimal change in the proportions of TBSRT categories. Most NIFTPs were diagnosed as abnormal and placed in one of TBSRTC indeterminate categories. Only 21 per cent of NIFTPs were prospectively identified. Their conclusion was that using stricter criteria for a diagnosis of PTC did not change the sensitivity of thyroid FNA and helps to minimise placing NIFTP in an unequivocal malignant category.

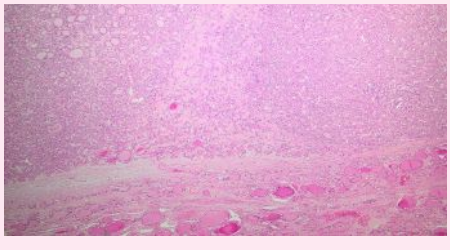
Li et al and others have demonstrated that removing NIFTP as a malignant diagnosis alters the risk of malignancy (ROM) of TBSRT categories (Table 1).

Li et al demonstrated that implementing NIFTP may potentially impact the risk of malignancy for

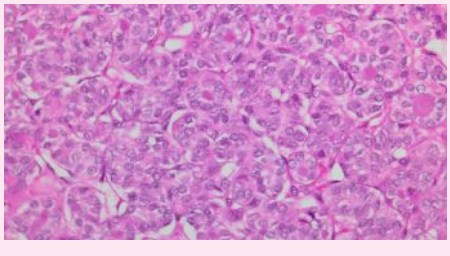
▼**Figure 5:** There is a lack of capsular invasion or lymphovascular invasion. The tumour capsule was processed in its entirety. H&E X20.



▼**Figure 6:** Higher power view demonstrating the neoplasm (top) with a follicular architecture. The capsule with the adjacent normal thyroid parenchyma is evident at the bottom of the field. H&E X40.



▼**Figure 7:** High power view demonstrating follicles lined by cells showing crowding and nuclear overlapping. Nuclear grooves are present. Focally, chromatin clearing, and margination is also present.



▼**Table 1.** Comparison of risk of malignancy (ROM) before and after excluding NIFTP from malignant categorization.

TBSRT category	ROM before (%)	ROM after (%)	Absolute ROM decrease (%)	Relative ROM decrease (%)
Non diagnostic	9.8	9.8	0	0
Benign	5.6	4.4	1.2	21.4
FLUS	12.8	9.5	3.3	25.8
SFN	26.5	20.6	5.9	22.3
SUS	81.4	79.1	2.3	2.8
Malignant	97.7	97.1	0.6	0.6

▼**Table 2.** Relative risk of ROM decrease in different studies in the literature.

Studies	Cases with surgical follow up	PTC – histologically proven	Cases classified as NIFTP	ND %	Benign %	FLUS %	SFN %	SFM %	Malignant %
Strickland	**655**	**304 (46.4)**	**72 (23.7)**	**10**	**59**	**45**	**18**	**48**	**5**
Fanquin	**1827**	**756 (41.4)**	**173 (22.8)**	**5.5**	**37.6**	**43.6**	**45.5**	**28.3**	**3.3**
Canberk	**1886**	**341 (18.1)**	**94 (27.5)**	**50**	**14**	**33**	**66**	**33**	**11.2**
Layfield	**315**	**-**	**-**	**0**	**33.6**	**13.2**	**11.3**	**20.5**	**12.8**
Li	**908**	**252 (27.8)**	**17 (16.7)**	**0**	**21.4**	**26.8**	**22.3**	**2.8**	**0.6**

thyroid nodules categorised as AUS/FLUS and FN/SFN. The most significant relative reduction in the risk of malignancy was in the FLUS and SFN categories, which showed 25.8 and 22.3 per cent respectively. A meta-analysis of different series also showed significant relative risk of malignancy reduction in the indeterminate categories viz FLUS, suspicious for follicular neoplasm and suspicious for malignancy categories (range 2.8-66 per cent) (Table 2).

The management of NIFTP is surgical lobectomy with no postoperative radiation. Long-term follow up studies show no risk of recurrence and/or metastatic disease in different series.

NIFTP experience in our institution

An audit of all thyroid FNAs in or institution between January 2014 and December 2017 showed a total of 2737 thyroid FNAs. Of these, a total of five cases of NIFTP were diagnosed. One histologically confirmed NIFTP had no prior FNA. Two cases that were originally diagnosed as NIFTP on histology behaved in an aggressive manner clinically and demonstrated metastatic disease. These were subsequently reviewed, and the original diagnoses changed to invasive FVPTC. One case showed extensive papillary morphology on cytology. And one case (discussed above) met inclusion criteria for both cyto and histology.

Unpublished data from our institution show that FVPTC is the most common PTC variant diagnosed. 70 per cent of PTC cases are classified as FVPTC; 30 per cent as classic variant. The other variants are rare. Our patient demographics include large thyroid nodules at presentation with an average nodule size of 4cm but presenting goitres can exceed 20cm in diameter.

A frequent indication for surgery is compressive symptoms due to size rather than a primary diagnosis of malignancy. We generally have fewer cases of incidental thyroid nodules as a result of liberal imaging studies. Literature notes that institutions with a high rate of FVPTC should theoretically have a higher incidence of NIFTP. This is not the case in our circuit. Our histopathologists are familiar with the change in terminology and reclassification of NIFTP as a non-malignant entity. Possible hypotheses for the low incidence of NIFTP in our institution includes advanced stage at presentation and potentially different molecular profile in our patient population.

Unfortunately, due to limited financial resources, we have no access to molecular testing, which is a serious impediment on studying, treating and monitoring thyroid pathology in our setting. The incidence of FVPTC is increasing; reported as high as 30 per cent in some studies. However, a high incidence of 70 per cent such as in our setting is unusual. Future studies should include the molecular profiling of our patient population to better understand the spectrum of thyroid disease in South Africa. In conclusion, the reclassification of non-invasive FVPTC to NIFTP helps to avoid unnecessary extensive surgery and avoid debilitating complications in a subset of patients. Clinicians and pathologists need to be aware of this diagnosis as it has significant clinical implications.

A frequent indication for surgery is compressive symptoms due to size rather than a primary diagnosis of malignancy.

Genetic testing for primary lactose intolerance

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

In total, around 35 per cent of the population worldwide is lactase persistent.

Many adults have a genetically caused deficiency of the enzyme lactase (LCT gene) which results in intestinal disorders on consumption of milk or milk products. Molecular diagnostic testing is useful for confirming or excluding primary lactose intolerance as a cause of digestive complaints. The two main polymorphisms associated with lactose intolerance, LCT -13910$_{C/T}$ and LCT -22018$_{G/A}$, can be determined in parallel using PCR-based microarray analysis. The use of whole blood samples streamlines the analysis by circumventing the need for DNA isolation. Fully automated data evaluation ensures standardised and objective results.

Primary lactose intolerance

Primary lactose intolerance is a genetically caused deficiency of lactase, the digestive enzyme responsible for breaking down the disaccharide lactose into its sugar monomers glucose and galactose. Unsplit lactose is fermented in the ileum and the large intestine, resulting in unwanted by-products such as short-chain fatty acids, methane and hydrogen. These lead to digestive disorders and the typical symptoms of lactose intolerance, such as abdominal pain, nausea, meteorism and diarrhoea. Secondary manifestations include deficiencies, for example of vitamins, and as a result unspecific symptom such as fatigue, chronic tiredness and depression.

Lactose intolerance represents the natural state in mammals. Lactase activity decreases after weaning, and in adulthood is often only a fraction of the activity in infancy. Some humans, however, retain the ability to metabolise lactose into adulthood due to specific genetic variants.

Lactase persistence polymorphisms

In total, around 35 per cent of the population worldwide is lactase persistent. However, frequencies vary immensely between different population groups. Lactase persistence is prevalent in regions with a long tradition of pastoralism and dairy farming. It is particularly common in Europe and in populations of European descent. Higher frequencies are found in the northwest of the continent, with a decreasing cline towards the southeast. In these populations, lactase persistence is predominantly linked to the polymorphisms LCT -13910$_{C/T}$ and LCT -22018$_{G/A}$, which are located in the regulatory region of the lactase gene. The LCT -13910$_{C/T}$ and LCT -22018$_{G/A}$ alleles are also found in lactase persistent populations in the Indian subcontinent. In pastoralist populations in eastern Africa and the Arabian Peninsula, lactase persistence is associated with various other polymorphisms, such as LCT -13915$_{T/G}$, LCT -14010$_{G/C}$, LCT -13907$_{C/G}$. In large parts of eastern Asia, almost 100 per cent of the population is lactose intolerant. According to current knowledge, homozygous carriers of the wild type variants LCT -13910$_{C/C}$ and LCT -22018$_{G/G}$ develop lactose intolerance, while heterozygous carriers of the polymorphisms LCT -13910$_{C/T}$ and LCT -22018$_{G/A}$ only show corresponding symptoms in stress situations or with intestinal infections. Homozygous carriers of the mutant variants LCT -13910$_{T/T}$ and LCT -22018$_{A/A}$ are lactose tolerant as adults. These two polymorphisms are strongly coupled.

Primary versus secondary lactose intolerance

As well as the genetically caused primary form, lactose intolerance can also occur as a secondary, acquired form. This develops as a result of damage to the intestine, for example, from other gastrointestinal diseases, and can often be resolved within a few months. Coeliac disease, Crohn's disease, infectious enteritis and injury from abdominal surgery are among the conditions that can lead to lactose maldigestion.

Secondary lactose intolerance needs to be distinguished diagnostically from the primary form due to different treatment regimes. Individuals with primary lactose intolerance must adhere to a lactose-free or low-lactose diet for life, or alternatively take lactase supplements. These patients, moreover, need to ensure adequate intake of calcium from other sources to prevent secondary bone disease due to the milk-restricted diet. Patients with secondary lactose intolerance only need to restrict their dairy intake until the intestinal epithelium has regenerated through treatment of the underlying cause.

Molecular genetic diagnostics

Molecular genetic testing enables verification or exclusion of primary lactose intolerance with high probability. It represents an important supplement to the hydrogen breath test and blood glucose test. These classic tests generally have a low specificity and sensitivity and are influenced by individual factors such as the composition of intestinal flora, colonic pH, gastrointestinal motility, and sensitivity to lactose fermentation products. Furthermore, classic tests cannot distinguish between primary and secondary lactose intolerance. In contrast, molecular diagnostic tests enable differentiation of the two forms. Genetic testing is, moreover, a non-invasive and more comfortable examination, which does not carry the risk of provoking symptoms of lactose intolerance in non-persistent individuals.

Simple microarray analysis

The two polymorphisms LCT -13910$_{C/T}$ and LCT -22018$_{G/A}$ can be determined simultaneously using molecular genetic tests such as the EUROArray Lactose Intolerance Direct. This test is performed on whole blood samples, eliminating the need for costly and time-consuming DNA isolation. In the test procedure (Figure 1), the sections of DNA containing the alleles are first amplified by multiplex polymerase chain reaction (PCR) using highly specific primers. During this process the PCR products are labelled with a fluorescent dye. The PCR mixture is then incubated with a microarray slide containing immobilised DNA probes.

The PCR products hybridise with their complementary probes and are subsequently detected via the emission of fluorescence signals. The data is evaluated fully automatically using EUROArrayScan software (Figure 2), and in the case of positive results, homozygous and heterozygous states are differentiated. Numerous integrated controls ensure high reliability of results, for example, by verifying that there are no other rare mutations in direct proximity to the tested positions, which could interfere with the analysis. All EUROArray processes from sample arrival to report release are IVD validated and CE registered.

Studies on blood donors

The performance of the EUROArray was investigated using samples from blood donors from northern Germany. In 85 pre-characterised samples, the EUROArray revealed a sensitivity of 100 per cent and a specificity of 100 per cent with respect to the reference molecular genetic method.

In a cohort of 152 randomly selected blood donor samples, the microarray analysis revealed allele prevalences as expected in the studied population group. For the allele LCT -13910$_{C/T}$, these amounted

Genetic testing is a non-invasive and more comfortable examination, which does not carry the risk of provoking symptoms of lactose intolerance in non-persistent individuals.

Genetic testing is particularly useful for differentiating primary from secondary lactose intolerance, enabling more targeted patient management.

to 20.4 per cent for C/C (homozygous C), 48.0 per cent for C/T (heterozygous) and 31.6 per cent for T/T (homozygous T). For the allele LCT -22018$_{G/A}$ the prevalences were 19.7 per cent for G/G (homozygous G), 40.0 per cent for G/A (heterozygous) and 32.2 per cent for A/A (homozygous A). Around 20 per cent of the tested subjects were thus lactose intolerant.

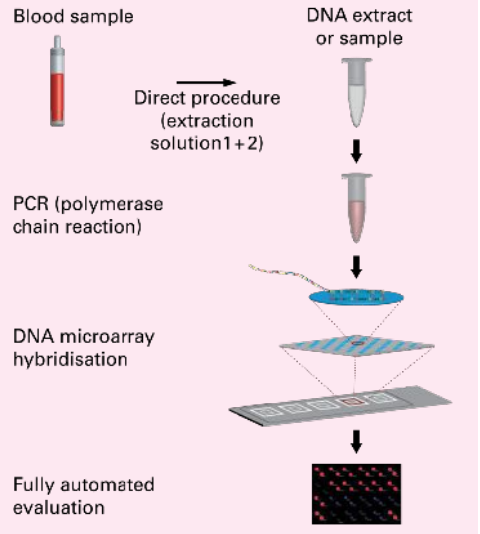
Milk allergy

Digestive complaints on ingestion of milk or milk products may also be caused by an allergic reaction to specific proteins in milk. This should also be taken into account in differential diagnostics. Milk allergy is common in children and manifests with gastrointestinal disorders, atopic dermatitis, urticaria, asthma and anaphylaxis. Diagnosis of milk allergy is supported by the detection of specific IgE antibodies against milk proteins such as casein, lactoferrin, α- and β-lactoglobulin and serum albumin. Multiplex analysis based on defined partial allergens (DPA-Dx) is especially suitable for establishing a detailed patient sensitisation profile. In particular, the differentiation of reactions to heat-stabile and heat-labile components helps to establish, which milk products may be tolerated by the patient (e.g. cheese, yogurt) and which must be strictly avoided.

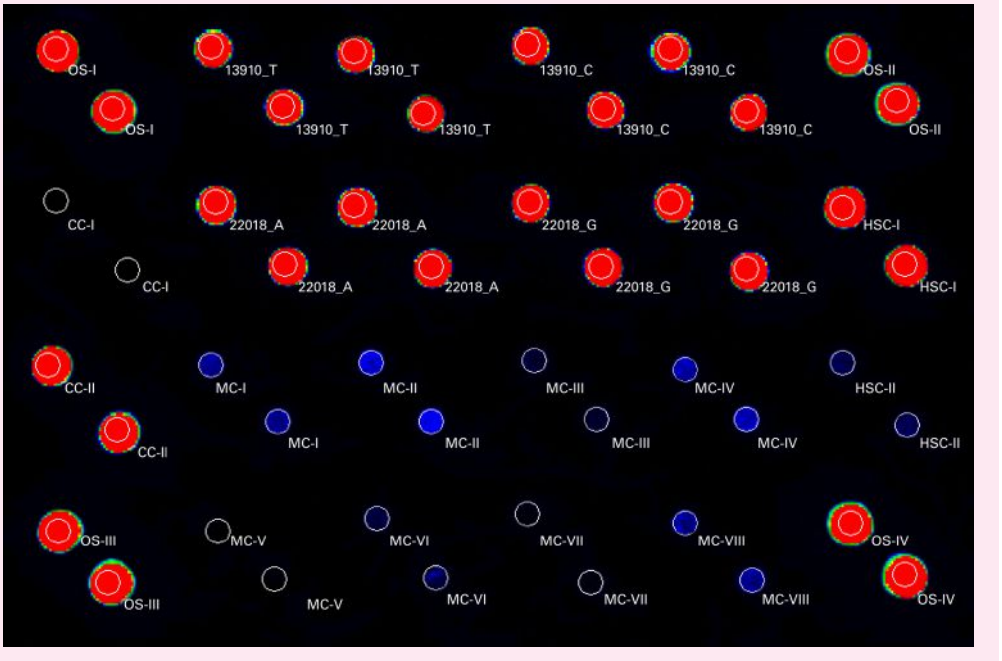
Perspectives

The advent of simple molecular genetic tests to detect the major polymorphisms associated with primary lactose intolerance has significantly enhanced the diagnosis of this common condition. Genetic testing is particularly useful for differentiating primary from secondary lactose intolerance, enabling more targeted patient management. Exclusion of the primary form helps to direct attention to searching for another cause of gastrointestinal complaints and may save patients from unnecessarily restricting their diet and potentially their calcium intake in the long-term. DNA testing is quick, easy and highly specific and thus a valuable initial test for patients presenting with sensitivity to dairy products.

▼**Figure 1.** EUROArray procedure



▼**Figure 2.** Evaluation of EUROArray Lactose Intolerance Direct



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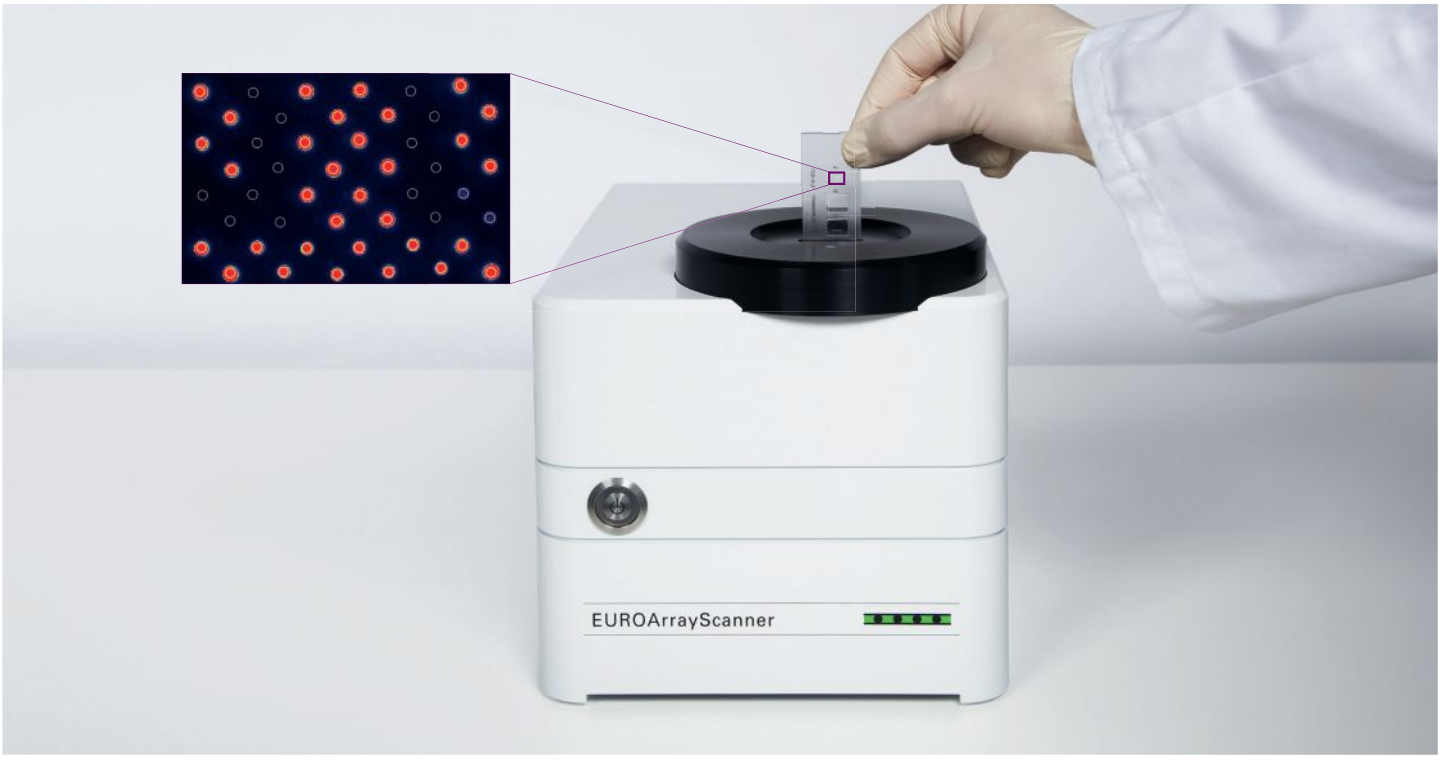
EUROArrays for infection diagnostics

Multiplex direct detection of HPV, STI and dermatophytes



- **Comprehensive detection of different infectious agents in a single reaction**
- **Simple test performance with ready-to-use reagents**
- **High result security due to various integrated controls**
- **Fully automated standardised evaluation and result documentation**
- **LIMS connection available**

Test system	Application
EUROArray HPV	Detection and typing of all 30 relevant high- and low-risk anogenital HPV for cervical cancer prevention
EUROArray STI	Detection of up to 11 relevant sexually transmitted pathogens (bacteria, viruses, protozoa)
EUROArray Dermatomycosis	Detection of 50 dermatophytes plus species identification for 23 dermatophytes and 6 yeasts/moulds

For further information contact Dr. Daniel Langenstroth-Röwer (mdx-pm@euroimmun.de, +49 173 167 7802)

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Lab networks join Malaffi

By Medlab Magazine Staff

Malaffi, the Abu Dhabi Health Information Exchange platform, recently announced the joining of the healthcare group VPS Healthcare and the first two clinical laboratory networks – National Reference Laboratory (NRL) and MENALabs, by signing the Participant Agreement. This comes after the recent announcement that two major UAE healthcare groups, Mediclinic Middle East and NMC Healthcare, have also joined Malaffi.

Malaffi is the region's first Health Information Exchange (HIE) platform, that will securely connect all public and private healthcare providers in the Emirate of Abu Dhabi to create a unified patient record and to improve healthcare quality, as well as patient outcomes.

Malaffi will house different types of patient medical information, collated from different Abu Dhabi healthcare providers, including allergies, diagnoses, medications, laboratory and radiology reports and clinical notes. Laboratory test results inform the majority of medical decisions and are among the main types of information centralised in Malaffi. Access to the longitudinal records of patients' laboratory results, collated from the different on-site and referral laboratories, presents vital information for physicians and will undoubtedly enhance reliable and timely diagnosis for patients in Abu Dhabi.

Mohamed Al Hameli, Undersecretary of Department of Health (DOH), commented: "At the DOH, we strive to remain a leader in patient experience and to continue enhancing healthcare quality standards while ensuring the sector's long-term sustainability. We are proud to welcome VPS Healthcare Group and the first two network of clinical laboratories to the Malaffi network. We are confident that the system will be a central platform for facilitating information exchange among health facilities in the Emirate, and will continue elevating the quality and efficiency of healthcare delivery in the Emirate."

"We are glad to welcome the new Malaffi participants – VPS Healthcare, National Reference Laboratory and MENALabs to the Malaffi network. The participation of these providers will increase the value of information available to healthcare professionals through Malaffi, affording improved patient outcomes," said Atif Al Braiki, the Chief Executive Officer of Abu Dhabi Health Data Services, the operator of Malaffi.

"We believe that the Malaffi platform will enable all healthcare providers to manage their data more efficiently," said Dr. Shamsheer Vayalil, Chairman and Managing Director of VPS Healthcare that operates Burjeel, Medeor, LLH and Lifecare hospitals and clinics in the UAE.

"These data sets will also be of great value for stratifying populations to achieve public health priorities and recommendations, while at the same time empowering patients and ensuring they are equal stakeholders for their health and well-being," he added.

"This will also allow us to produce actionable insights to improve patient outcomes. As healthcare delivery in the UAE evolves, we need data for everything from managing increasing medical costs to providing personalised medicines for complex conditions."

"NRL is proud to be one of the first laboratories to join Malaffi. We truly believe Malaffi will help elevate patient experiences and support the making of timely clinical decisions by reducing unnecessary duplication of laboratory tests. As a network of 10 laboratories across the UAE and the biggest laboratory network in the Middle East, accredited by the College of American Pathologists (CAP), NRL has been investing in advanced IT systems. Thanks to this we are in a great position to be among the first providers to implement Malaffi for our Abu Dhabi-based laboratories," says Abdul Hamid Oubeisi, Chief Executive Officer of NRL.

"In addition to centrally storing patients' clinical information and laboratory tests results, another great benefit of Malaffi is enabling the enhanced practice of precision medicine. At MENALabs we specialise in genetic tests, which are a very important prerequisite for precision medicine. This common goal brings us together and is why we are especially honoured to be among the first laboratories in Abu Dhabi to join Malaffi," said Zerela Henry, Chief Executive Officer of MENALabs.

As provided in the DOH Policy on ADHIE, the DOH seeks to ensure that all licensed healthcare facilities in the Emirate of Abu Dhabi participate in Malaffi. All Abu Dhabi healthcare facilities are expected to begin utilising Malaffi by the end of 2019.

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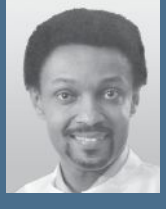

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Advances in Cardiology

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- Innovative biomarkers and risk indicators for cardiovascular diseases
- Small and Smart Diagnostics in Sports Medicine

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Advances in Oncology

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Accreditation of Biosystems' Prevecal EQAS According to ISO/IEC 17043:2010

Article provided by Biosystems

Following its policy of continuous improvement of Quality, BioSystems S.A. has obtained the accreditation according to ISO/IEC 17043:2010 "General requirements for Proficiency Testing" for programs PREVECAL BIOCHEMISTRY and PREVECAL BIOCHEMISTRY HUMAN.

ISO/IEC 17043:2010 specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes. These requirements are intended to be general for all types of proficiency testing schemes, and they can be used as a basis for specific technical requirements for particular fields of application.

We obtained this first accreditation in Spain on April 26 through ENAC (Entidad Nacional Española de Acreditación). ENAC is integrated in the global structure of accreditation, which operates through two organizations: International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF), which are supported in turn, by regional organizations (America, Asia/Pacific).

These organizations have set many international agreements, mainly based on mutual acknowledge of certificates and reports issued by accredited entities that facilitate the achievement of the ultimate aim: a report or certificate issued under ENAC accreditation will be acknowledged by the rest of signatories all over the world.

The accreditation of Prevecal programs brings to light a greater technical exigence beyond the important improvements in the performances, which benefit all users, among others:

- Robust statistical treatment (ISO 13528:2015)
- Elimination of outlier results by means of a standardized IUPAC protocol
- Specifications based on biological variability
- z-score
- Final assessment based on total error
- Technical Support on the reported performance

Prevecal program is on a level with other entities who organize inter-comparison programs. Furthermore, its main advantage is the international scope of participants, which allows obtaining a worldwide comparison that most of national programs can't offer.

This achievement and the continuous effort to attain new accreditations for the rest of Prevecal programs allow us to be the reference international accredited external program amongst clinical laboratories worldwide.

Prevecal programs consist of 12 monthly analysis from January to December with monthly and final reports based on z-score and % error assessment.

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Total bile acids 21 FS – reliable assessment of liver function

Article provided by DiaSys

Serum total bile acid (TBA) levels are a sensitive marker of liver function and may be used for diagnosis and monitoring of various liver diseases. Increased serum TBA levels are associated with diseases such as acute and chronic hepatitis, intrahepatic cholestasis of pregnancy (ICP), liver sclerosis, cirrhosis, and cancer; TBA may as well detect hepatic dysfunction. Conventional liver tests such as ALT and AST cannot provide this because they are indicators for hepatocellular integrity.

TBA measurement corresponds to the sum of more than 20 individual bile acids synthetized by the liver, modified by gut bacteria, and involved in complex enterohepatic circulation. Commercially available assays show limitations regarding the detection of individual primary and secondary bile acids. The new DiaSys reagent, total bile acids 21 FS, is an enzyme cycling assay, which enables assessment of all relevant bile acids in a sample and hence offers the possibility to precisely cover all stages of liver diseases.

The new liquid-stable, ready-to-use reagent provides a wide measuring range, outstanding precision and shows significantly reduced interferences compared to nitrotetrazolium blue (NBT) methods.

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Randox Laboratories: Enhancing Quality of Life

By Emma Callaghan, Marketing Executive, Martin Conway, Marketing Executive, and James Crilly, Marketing Team Leader, Randox

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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.

$sPLA_2$-IIA

$sPLA_2$-IIA, a prototypic member of the group II $sPLA_2$ subfamily has been found to be induced by pro-inflammatory stimuli in a variety of cells and tissues. Consequently, $sPLA_2$-IIA has been found to be associated with several inflammatory diseases including atherosclerotic coronary artery disease (ASCAD) and coronary heart disease (CHD). These factors contributed to its nickname "inflammatory $sPLA_2$".

$sPLA_2$-IIA is already expressed in the normal arterial wall and its expression is readily up-regulated by inflammatory stimuli. Its role in producing fatty acids and biologically active phospholipids is linked to platelet, monocyte, and endothelial activation, processes known to be critical steps in atherogenesis. Research indicates that serum $sPLA_2$-IIA levels are higher among ASCAD patients than normal subjects. The lipid mediators produced through $sPLA_2$-IIA and their related lipids in the arterial wall can stimulate T cells and macrophages to synthesize and release the pro-atherogenic and pro-inflammatory cytokines, which in turn induces $sPLA_2$-IIA production in the atherosclerotic walls. The Randox automated $sPLA_2$-IIA assay utilizes the enhanced immunoturbidimetric method, delivering high performance. Dedicated controls and calibrator are available offering a complete testing package. Applications are available detailing instrument-specific settings for the convenient use of the Randox $sPLA_2$-IIA assay on a wide range of clinical chemistry analyzers.

RX series NGSP certified direct HbA1c testing capabilities

The Randox RX series world leading test menu welcomes the addition of NGSP certified direct immunoturbidimetric HbA1c testing on the RX modena, RX imola and RX daytona+. The latex enhanced immunoturbidimetric method, which the RX series utilises makes the test simple and quick to perform. The removal of the pre-dilution step removes the risk of human error compromising your results. The RX series removes the need for a separate HbA1c analyser and allows laboratories to expand their testing capabilities onto one single platform, providing cost savings through consolidation.

The Randox automated immunoturbidmetric HbA1c test exhibits high accuracy and reproducibility with the added advantages of using liquid reagents with good stability, and on-board pre- treatment of samples; therefore, offering an improved method for the rapid direct measurement of HbA1c in human blood.

Randox HbA1c assay features:

- Sample type – suitable for use with whole blood samples
- Latex enhanced immunoassay method – the Randox assay utilises an immunoassay method making it simple and quick to perform
- Liquid ready to use reagents – for ease of use and convenience
- Excellent stability – all reagents are stable to expiry date when stored at +2 to +8˚C or 28 days on board the analyser at approximately 10˚C

Acusera Infectious Disease (Serology) Controls

Randox Acusera Infectious Disease (Serology) Controls are designed to deliver high quality solutions for analysis of infectious diseases whilst challenging clinically relevant ranges to ensure accurate and reliable instrument measurements, time and time again.

Our new Serology controls cover an extensive range of infectious disease testing including HIV, Hepatitis, EBV, ToRCH and Lyme Disease, all of which are compatible for use on most immunoassay systems including Roche, Abbott, Siemens, Beckman and Biomerieux.

These controls are available in a cost effective liquid ready-to-use format and are manufactured from human plasma, helping meet ISO 15189:2012 requirements and reducing the risk of pipetting error. The availability of multi-marker controls reduces the number of individual materials required, while maintaining a working stability of 60 days when stored between 2°C to 8°C. These features combined help reduce laboratory costs, minimise wastage and relieves the need for additional storage space.

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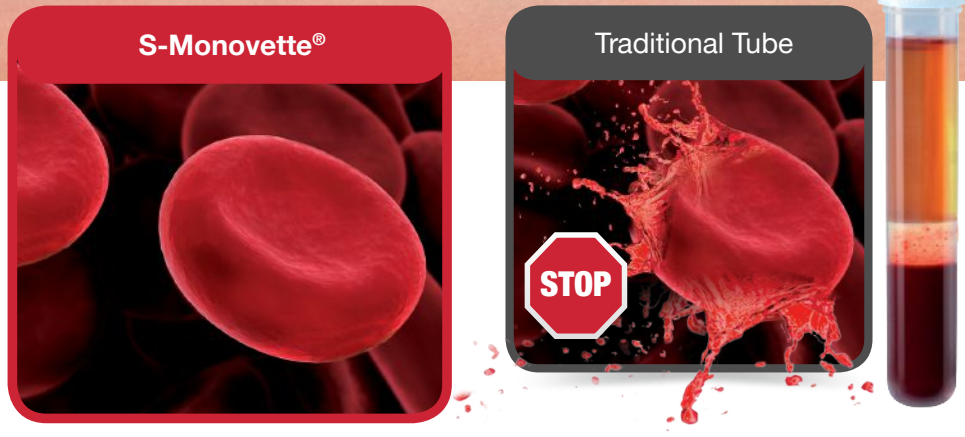

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