



Dialog

DiaSys International Newsletter

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Dear customers, dear friends,

The second year under pandemic conditions draws to its end.

We all had high hopes when the vaccination campaign started in early 2021. Unfortunately the virus has still more arrows in its quiver than anybody expected - and we may have to face the fact that the Greek alphabet will not be enough to name all the mutants that are likely to come in the future!

Thanks to the great progress, we have made in developing adapted vaccines and the fact that vaccination against the wild-type also provides quite good protection against all known corona virus mutants, we will finally celebrate our victory over it - perhaps later than expected - but for sure!

2021 was a very special year for DiaSys: We celebrated our 30th company anniversary! What a pity that we could not do it with all our friends around the world! But the time will come when we all will meet again!

To celebrate our anniversary with you anyway, we have come up with some nice sales campaigns that will help your business and, in the best case, generate some success stories! We look forward to hearing them!

You may remember the introduction of our own Procalcitonin assay last year. We had great success with this, especially in Germany. We are confident that this will be possible in your countries as well!

Of course, our developments are still ongoing: A major milestone of our R&D team this year was the development of our SARS-CoV-2 UTAB FS test for the detection of total antibodies against the SARS-CoV-2 virus. This test has recently become available in WHO standardized units. We hope this test will find its way to many of your customers!

Authors



Dr. Jan Gorka, Dr. Günther Gorka, Peter Zöller
Executive Board



Another highlight was the launch of our new homogeneous tests HDL-c direct FS and LDL-c direct FS for the determination of HDL and LDL cholesterol. The respons[®]940 has also gained a lot of momentum - by itself and even more by the 30th anniversary campaign!

In the last few months, we all worked hard to pass our triple audit, which we had at the same time as our exhibition presence at MEDICA: DIN EN 13485:2016, MDSAP and IVDR audit - all at once! We are pleased that we passed them all so well. However, there is still a lot of work to do to complete all the documents required for the IVDR now and in the future - so the year 2022 will still be very busy with all that activities!

But now that this year is about to end, we would like to wish you all, your families and friends a peaceful and quiet time. Hopefully you can relax a bit and get new power for the coming year.

We would like to close with a modified motto of DiaSys:
Choosing Quality - Choosing Vaccination!

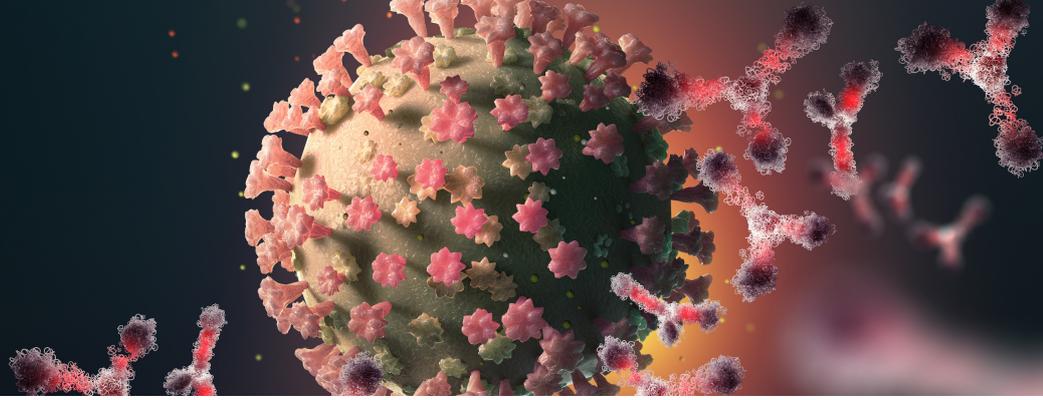
All the best, Merry Christmas and a happy and successful New Year 2022!

The staff and management board of DiaSys Diagnostic Systems GmbH

Authors



Dr. Jan Gorka, Dr. Günther Gorka, Peter Zöller
Executive Board



Quantitative anti-SARS-CoV-2 total antibody determination in WHO standardized units (BAU/mL)

DiaSys is particularly pleased to announce the standardization of the SARS-CoV-2 UTAB FS (UTAB = Universal Total AntiBody) assay.

The quantitative SARS-CoV-2 UTAB FS assay had been developed before an international standard for anti-SARS-CoV-2 immunoglobulins was available. Therefore, the manufacturer specific unit AU/mL had to be initially assigned. Since the first WHO International Standard for anti-SARS-CoV-2 immunoglobulin (human) NIBSC code 20/136* is now available, DiaSys has correlated the calibrator of the test SARS-CoV-2-UTAB FS in a linear regression comparison.

The WHO International Standard correlates well with the current standardization of the DiaSys SARS-CoV-2 UTAB FS assay. Since the manufacturer-specific unit AU/mL is essentially equivalent to the BAU/mL unit of the first WHO international standard for anti-SARS-CoV-2 immunoglobulin (human) NIBSC code 20/136, results will be reported in BAU/mL in the future.

Due to the standardization and the resulting adaptation of the calibrators, the measuring range could be extended to 250 BAU/mL. More information about the quantitative anti-SARS-CoV-2 total antibody assay in WHO standardized units can be found [here](#).

Author

Irene Delseith-Hermsdorf
Global Marketing - Head of Marketing



DiaSys Japan celebrates its 15th anniversary

2021 is not only a special anniversary year for DiaSys Diagnostic Systems, but also for our subsidiary DiaSys Japan, which proudly celebrates its 15th anniversary this year! CEO Yoshihiko Akagi gives us a glimpse into the history of DiaSys Japan.

Before I talk about DiaSys Japan, I would like to introduce myself. My name is Yoshihiko Akagi. I have been working for DiaSys for more than 25 years, since 1995. The first 10 years I worked for DiaSys as a consultant and window to Japan. DiaSys Japan was established on January 23, 2006, and initially had two functions: one was to operate an R&D laboratory, and the other was marketing and sales promotion. When I started to promote DiaSys' fluid stable reagents, many Japanese in-vitro diagnostic companies were still selling lyophilized reagents. All of them said: "We will develop and launch liquid type clinical chemistry reagents soon." However, they did not succeed the way DiaSys did. We had the confidence to enter the Japanese market.

Why did we base DiaSys Japan in Kobe?

Hyogo Prefecture and the city of Kobe offer a special incentive for foreign-affiliated companies. Kobe city had a plan to establish a medical industrial city on an artificial island. Good population: not as busy as Tokyo, Osaka and Kyoto Good atmosphere: Kobe has both mountains and a harbor by the sea Good food and drink: Famous Kobe beef & Kobe wine, sake and Kobe water. + My hometown :-)

The history of DiaSys Japan

1992: Establishment of Akagi Trading Co., Ltd.

Yoshihiko Akagi started his company for IVD R&D and sales support service.

Author



Yoshihiko Akagi
President & CEO of DiaSys Japan K.K.



1995 July: AACC in Anaheim: The first contact between DiaSys and Akagi Trading

Mr. Akagi attended Japan Tectron's booth at AACC in Anaheim, USA, in 1995 as a consultant. Japan Tectron was a manufacturer of clinical chemistry analyzers. At this exhibition, Mr. Akagi and Mr. Guenther Jans from DiaSys met for the first time.

1995 September: JSCLA (Japan Society for Clinical Laboratory Automation) in Kobe

Mr. Jans came to JSCLA congress in Kobe to visit Akagi Trading. DiaSys Diagnostic Systems GmbH and Akagi Trading signed a consultancy agreement.

2001: Start of the import

The first DiaSys products were imported to Japan as OEM.

2006: Establishment of DiaSys Japan K.K. (DJ) in Kobe

DiaSys Japan's focus was on R&D laboratory, marketing and sales promotion. DJ had a booth at JSCLA in Kobe for the first time.

2008: Cooperation with JEOL Ltd. of Tokyo

A cooperation contract was signed with JEOL Ltd. of Tokyo for the BioMajesty and associated reagents.

2010: JSCLA congress in Kobe

DiaSys Japan had a booth at JSCLA in Kobe for the second time. Our booth was set nearby JEOL Ltd. of Tokyo.

2021: 15th anniversary of DiaSys Japan

DiaSys celebrates its 30th anniversary and DiaSys Japan turns 15 at the same time. When I visited DiaSys in Holzheim for the first time, the facility was exceedingly small. I did not expect the company would grow into such a big global company in the IVD field. Congratulations for the 30th anniversary!

Author



Yoshihiko Akagi
President & CEO of DiaSys Japan K.K.



Digital professional education: DiaSys hosted virtual training for South-East Asian customers

As the virtual training for South American partners in August turned out to be a great success, we hosted a further trans-regional customer training in October 2021, this time for our partners in South-East Asia.

More than 80 people from Singapore, Thailand, Indonesia, Malaysia, Vietnam and the Philippines took part in the 3-day training.

Besides a general introduction to the product lines and the concept of DiaSys by Area Business Director Mr. Teo Chee Kian, the main topics of this event were:

- Diabetes (Focus on HbA1c net FS)
- Evaluation of rheumatoid arthritis
- Iron metabolism
- Inflammatory markers (Focus on CRP and CRP U-hs)
- Procalcitonin in sepsis
- Cystatin C
- Lipids diagnostics (Focus on HDL-c direct FS and LDL-c direct FS)
- Apolipoproteins A1 and B
- Thromboembolic events (Focus on D-Dimer)

Together with our colleagues Mrs. Irene Delseith-Hermsdorf, Head of Global Marketing and Product Management, Mrs. Isabella Wieland, Strategic Product Manager Reagents and Mr. Malte Hilsch, Strategic Product Manager Reagents, we provided our customers with a lot of valuable product information. In addition, we convinced them not only of the quality of our reagents, but also of the DiaSys philosophy.

We are very pleased that this training was so well attended by our customers and that we received a lot of positive feedback.

Author



Chee Kian, Teo
Area Business Director



Ministry of Economics Rhineland-Palatinate visits DiaSys at MEDICA

After MEDICA had to be organized as a virtual trade fair in 2020 due to the pandemic, exhibitors and visitors were looking forward to the presence event in the Düsseldorf exhibition halls again this year.

46.000 trade visitors (73% international visitors) from 150 nations took advantage of the opportunity to exchange information in person about the latest developments in the medical technology sector. The figures show that personal encounters and conversations are still the basis of a good partnership.

DiaSys enjoyed numerous visits from new and long-standing partners at the booth. Special attention was paid to the newly developed immunoturbidimetric SARS-CoV-2 antibody test - SARS-CoV-2 UTAB FS, which is now available in WHO standardized units (BAU/mL).

Another highlight was the visit of Dr. Martin Hummrich and Mrs. Daniela Arnold from the Ministry of Economy, Transport, Agriculture and Viticulture Rhineland-Palatinate.

Dr. Hummrich and Mrs. Arnold learned about the product portfolio of the family-owned, medium-sized but globally active diagnostics specialist.

The focus of their visit was on special offers in the field of COVID diagnostics as well as accompanying parameters for the management of COVID diseases. However, not only the currently all-overshadowing topic of the corona pandemic was discussed, but also topics such as the upcoming change in legislation within the framework of the IVDR, employee recruitment and securing the company's location in rural Rhineland-Palatinate, where DiaSys has now been located for 30 years and has written a local success story.

We feel strongly anchored in Rhineland-Palatinate and it was an honor to welcome Dr. Martin Hummrich and Mrs. Arnold at our booth at MEDICA.

Picture: MWVLW Rheinland-Pfalz, Foto: CONZENTRAT Düsseldorf, Jörg Pruß

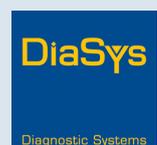
Author



Dr. Jan Gorka
Managing Director
and CEO



Julia Herrmann
Marketing
Communication Manager





First training in new DiaSys Lounge in Egypt

Although it is not officially inaugurated yet, a first instrument training took place in our new DiaSys Lounge in Cairo.

Seven engineers of our distributors from Libya, Albania, Djibouti and Chad received a comprehensive training for the respons®920 from our technical support team (connected online) and employees of our local partner. During 5 days, the participants learned about general installation as well as technical know-how by disassembling and assembling the analyzer. Special attention was paid to the topic of trouble shooting.

The training was a complete success and we hope that the participants now feel well prepared for all tasks their customers may face.



About the DiaSys Lounge

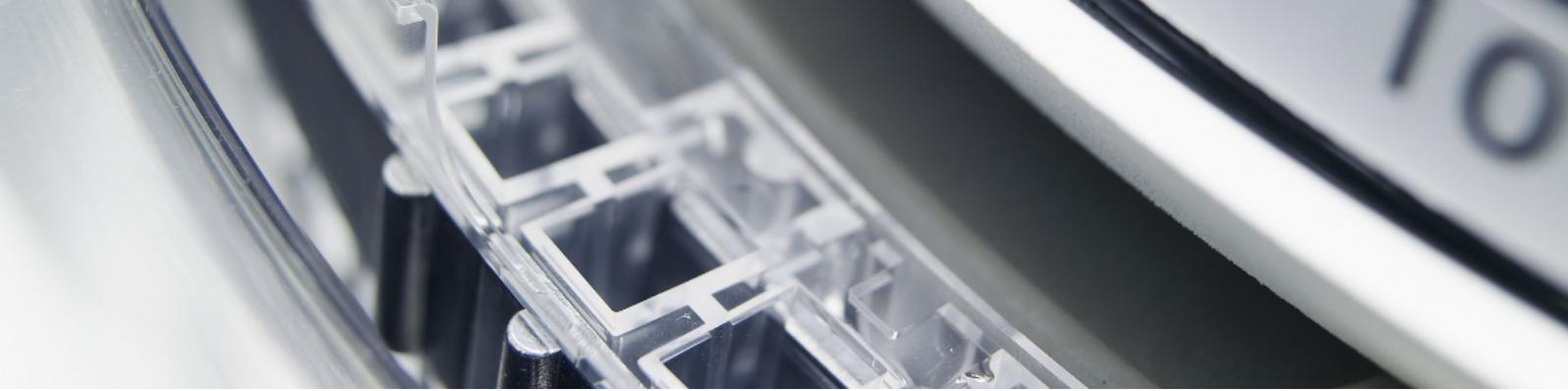
In 2021, we opened the training center "DiaSys Lounge" in the building of our long-standing partner in Egypt, Lab Top. The aim is to provide easier access to personally supervised trainings outside Europe, especially for our partners from MEA and Asia. All DiaSys analyzers are installed in the lounge. Thus, there is the possibility to use the premises also as a showroom and for sales meetings. The DiaSys Lounge is a new step to provide excellent support to our distributors around the world.

Author



Christophe Bayet
General Manager Global Business / Head of Sales





"Choosing quality" becomes a matter of the heart

Mr. Shakeel Baig from Ruwi Advanced Medical Equipment LLC in Oman has been our partner since 2018. During this time, he has successfully introduced the DiaSys respons[®]910 and respons[®]920 systems to a highly price-sensitive market.

He is passionate about customer support, as all his uploaded videos, including the recent publication on the DiaSys respons[®]910 analyzer, show.

<https://www.youtube.com/watch?v=DBbk-p8Fj70&t=6s>

Moreover, Mr. Baig is committed to quality. "Choosing Quality" is not just a phrase for him, as it is for DiaSys, but the vision to improve laboratory diagnostic services in all markets - from the first drop of water to reliable results in diagnostic laboratories. He promotes the DiaSys system concept to his customers by emphasizing that the high-quality reagents from DiaSys, in combination with the analyzers, provide results that medical professionals can rely on.

Thank you Mr. Baig! We look forward to the coming years to celebrate the success of the new respons[®] family member, the respons[®]940, at its launch in Oman!



Author



Péter Aradi
Area Business Director (Greater EMEA)



DiaSys presentations at SEPTIMET and EURAMET

DiaSys' immunoassay developer Thomas Masetto was invited to speak at the Stakeholder Event of the EU-funded (EMPIR) project SEPTIMET and at a EURAMET workshop.

SEPTIMET Stakeholder Event - September 14, 2021

The SEPTIMET project is dedicated to improve the time to result, accuracy and reproducibility of diagnostic tests for the detection and treatment of sepsis.

The aims of this clinically oriented project are:

- Improve the accuracy of established biomarkers used to identify sepsis patients
- Develop a metrological framework for current methods used to guide treatment of sepsis
- Reference methods for rapid near patient (Point of care) testing for sepsis
- Describe performance and measurement needs of new methods for early sepsis diagnosis
- Facilitate measurement infrastructure uptake by hospitals, industry and standard providers

Mr. Masetto's presentation highlighted challenges an IVD manufacturer faces when developing IVD kits for sepsis marker measurement. He also explained the advantages and disadvantages of CLIA and PETIA technology, the impact of antibodies on the performance of various Procalcitonin assays, and the standardization of calibrators.

Those interested in learning more about the SEPTIMET project and expanding their knowledge of sepsis have the opportunity to view the full recording of the event on YouTube.

The DiaSys presentation starts at 1:06:03: <https://www.youtube.com/watch?v=kjD8GnRyElk>

Author



Julia Herrmann
Marketing Communication Manager



EURAMET Workshop - November 10, 2021

The EUROPEAN ASSOCIATION OF NATIONAL METROLOGY INSTITUTES (EURAMET) aims to develop and disseminate an integrated, cost-effective and internationally competitive metrology infrastructure for Europe. The highest priority for the association and its members is to increase the benefits of metrology for society.

The workshop on November 10 focused on the challenges of (bio)chemical measurement techniques in the context of diagnostic measurements, therapeutics and new techniques.

As part of this workshop, immunoassay developer Thomas Masetto gave a presentation on the topic of challenges in the development of IVD tests for innovative biomarkers entitled: "What an IVD manufacturer needs for accurate measurements". Using some of DiaSys' new clinical chemistry and immunoassay parameters as examples, he described the challenges faced during the design phase and development process.

Information on EURAMET and upcoming workshops can be found here: www.euramet.org

Author



Julia Herrmann
Marketing Communication Manager



Successful completion of another milestone for IVDR implementation!

As every year, an audit by TÜV Rheinland took place at DiaSys in November. Everything was different this time, as the audit had an extended objective.

From November 15 to November 24, 2021, TÜV Rheinland audited DiaSys and its subsidiaries DiaSys Deutschland GmbH, DiaSys Technologies Sarl and pes diagnosesysteme GmbH. In addition to the re-certification audit for DIN EN 13485:2016, the auditing according to IVDR, the new European In-vitro Diagnostics Regulation and the MDSAP audit for the countries Brazil, Japan and USA were also scheduled. With this objective, the Quality Management and Regulatory Affairs (QM/RA) department faced a particular challenge, especially since it was necessary to obtain all three certificates within the scope of a single audit.

Compared to previous audits, this time the scope differed in particular in the preparations. Already weeks before, a comprehensive documentation audit was carried out by TÜV Rheinland.

Not only the QM/RA department was greatly challenged. All DiaSys employees had to focus on this audit for many weeks and transfer process descriptions into our new QM software Consense. In addition, technical documents for the conformity assessment of the first products under the IVDR were already provided to the TÜV. These were also created in new software in order to be able to transmit them digitally to the notified body in the future and to maintain their life cycle more easily.

All these efforts were followed by a great success of which we are very proud. We have successfully achieved the certification for DIN EN 13485:2016, the certificate according to MDSAP for the countries Brazil, Japan, and USA as well as the QMS audit regarding the IVDR requirements.

Now we can continue the lengthy process of bringing all our products under the new IVDR: We will keep you, dear customers and partners, informed.

Author



Stefanie Giesener
Head of Quality Management & Regulatory Affairs



30 years of committed sustainability and practiced environmental compatibility

The success story of the owner-managed company DiaSys Diagnostic Systems GmbH, which began in 1991, not only internalizes "choosing quality" as a guiding principle, but also goes hand in hand with the concept of offering products that are not only extremely reliable, but as well produced in an environmentally friendly and sustainable manner.

Located in a rural setting and directly adjacent to a bird sanctuary, DiaSys is consistently committed to the use of reusable energy. In addition to a cistern that collects up to 7,500 liters of rainwater for flushing the toilets (service water), the sight of a pond in the courtyard is a delight. It serves as a fire-fighting pond if required (30,000 liters); of course WITHOUT its inhabitants: six grass carps (which have felt at home here for more than 18 years by now), a mirror carp as well as many moderlieschen (a freshwater fish species).

A block heating plant powered by natural gas supports the building's heating with 17 kW in winter and hot water in summer. This combination of heat and power generation provides maximum thermal efficiency and minimizes the production of exhaust gases that normally contribute to the greenhouse effect.

Since 1999, the production, storage, disinfection and distribution of the precious raw material water has been carried out in the company's own ultra-pure water system. So-called "purified water" is used for a wide variety of applications: In addition to cleaning purposes in production and lab facilities, it is primarily used in reagent production. The water treatment plant is continuously modernized and today offers graphic visualization and convenient control via a human-machine interface (HMI) from any office computer.

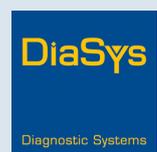
Authors



Yvonne von Gruchalla
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Mostly electronic filing systems and package inserts, provided to customers for download on the website, help avoiding paper. DiaSys only uses two primary packaging materials: Reagent containers, vials, lids and labels are made of polyethylene (PE), all outer packaging is made of paper and cardboard, which can be recycled. Brochures are printed climate neutrally on FSC-certified paper. For some years now, DiaSys has been operating an e-car plus its electric charging station; a second electric charging station is made available for visitors.

Employees benefit from this environmental attitude in terms of a pleasant working environment; fruit trees are planted on the spacious grounds (harvesting is expressly permitted), and the roof of the building is partly planted, so that the view during a meeting is actually 'into the green', which stimulates concentration.

By showing responsibility for high-quality laboratory systems and environmentally friendly production in Germany, DiaSys, as a reliable cooperation partner, sets a benchmark for sustainability.



<https://www.diasys-diagnostics.com/company/philosophy/>

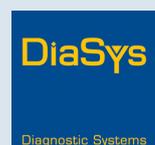
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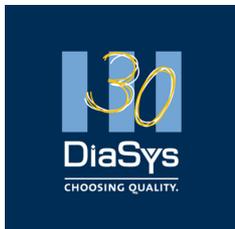




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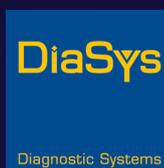
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30 years of DiaSys

This year we celebrate our 30th anniversary.
For this reason, we regularly publish articles that give you an insight
into the early days and development of DiaSys. [Enjoy reading!](#)



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