DiaLog

DiaSys International Newsletter

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Dear customers, dear friends,

This DiaLog edition has a clear focus: 30 years of innovation!
All topics emphasize DiaSys commitment to new initiatives: Release of Procalcitonin FS and HDL-c direct FS in 2020; launch of SARS CoV-2 UTAB FS antibody test, LDL-c direct FS, and CE marking of our rapid assays for SARS CoV-2 testing in 2021.

DiaSys memberships in IFCC working groups and task forces is featured - last but not least the innovation prize for developing a particle enhanced PTC assay accentuates DiaSys focus on innovation. Let us cooperate to bring the benefit of all these state-of-the- art products to our customers and finally to the patients for improved lab results!

In addition, the implementation of the new European IVDR in May 2022 needs the bundling of many resources and asks for your support, too. The rules become much tighter and comprehensive and the cooperation between you, our customers and DiaSys might need revised agreements and closer collaboration for which we ask for your understanding.

DiaSys, like most other manufacturers, have solicited the support of parliamentarians of all levels (state, federal and European) for a moratorium, i.e. to prolong the implementation for a whole year and we anticipate a positive outcome.

Our hope is as well that defeating COVID-19 will be a fast progress. We provide diagnostic tools in this context – please use them!

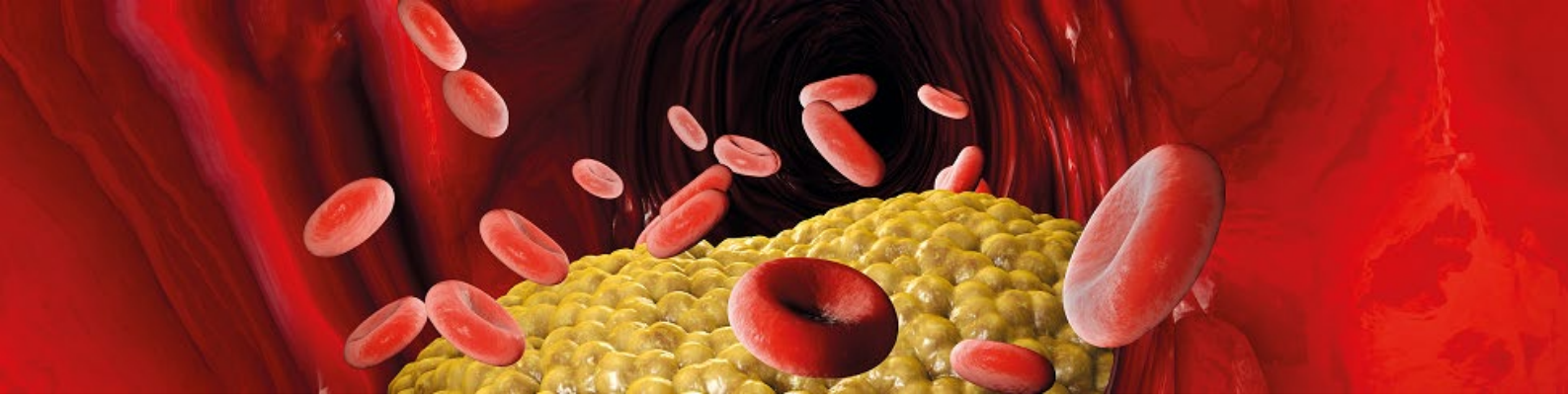
Thank you for your confidence throughout all these years – please stay healthy!

Sincerely yours,
Dr. Guenther Gorka

Author

Dr. Guenther Gorka
Managing Director and CEO

DiaSys Diagnostic Systems



New reagent for direct determination of LDL-cholesterol

DiaSys is pleased to announce the availability of LDL-c direct FS, a new homogenous assay for direct determination of LDL-cholesterol (LDL-C). LDL C is used as lipid panel parameter to estimate the risk of developing heart disease and to guide and monitor lipid-lowering therapies. Atherosclerotic cardiovascular disease (ASCVD) starts early in life, often during childhood. Studies revealed that 71% and 43% of middle-aged men and women, respectively, show evidence of subclinical atherosclerosis. Evidence from epidemiologic, genetic, and clinical intervention studies have clearly demonstrated that low-density lipoprotein (LDL) is causal in this process.

LDL-C is often not measured directly but is instead estimated by using the Friedewald equation, which estimates LDL-C from measurements of total cholesterol (TC), triglycerides (TG), and high density lipoprotein cholesterol (HDL-C) but the method only approximates LDL-C and is subject to well-established limitations.
Since the introduction of homogeneous methods at the end of the last century, these new methods have become the standard in clinical laboratories.

The new DiaSys assay LDL-c direct FS is characterized by a wide measuring range and shows good overall precision at clinical decision limits. The ready-to-use reagent offers a long stability on board combined with low calibration frequency. The new test may be applied on all automated clinical chemical analyzers and shows good comparability with commercially available methods for the determination of LDL-cholesterol.

The new test is available in different kit concepts. For further information, please follow the link: www.diasys-diagnostics.com/en/products/reagents/clinical-chemistry/reagent-details/240-ldl-c-direct-fs/reagent.show

Author

Irene Delseith-Hermsdorf
Global Marketing - Head of Marketing

Rapid antigen testing in COVID-19: Results within minutes

The rapidly progressing COVID-19 pandemic and limited laboratory based PCR test capacities require the availability of fast and easy-to-use tools. Rapid tests for professional user have been introduced to allow COVID-19 diagnostics in near-patient settings thus increasing the limited testing capacities/possibilities. In this respect, DiaSys already has been offering a rapid lateral flow immunochromatographic test since some time for professionals. The Product Management is pleased to announce that the rapid test Sugentech SGTi-flex COVID-19 Ag is now CE marked for self-use, approved by TÜV Süd, Germany as notified body.

This signifies that this qualitative antigen test is no longer restricted to professional use but may now reliably be used by non-professionals (laypersons), too; testing opportunities thus expand again enormously.
The cartridge based rapid test kit contains all necessary items for one testing of a nasal sample collected in the anterior nasal region (at a depth of 1-2 cm). This test is characterized by a high sensitivity and specificity, so that reliable results are available after just 15 minutes.

Kit size	1 test
Kit content	Nasal swab, prefilled extraction buffer, dropper cap, test cartridge, IFU
Sensitivity	95.06%
Specificity	97.02%
Time to result	15 minutes

Find out more on easy to handle rapid testing and order details:
www.diasys-diagnostics.com/products/rapid-tests/

Author

David Ehlers
Product Manager Systems

30 years anniversary

When a company celebrates its 30th anniversary, it is not necessarily granted that people have been working with the company since the first day. On April 1, 2021 Dr. Günther Gorka, main shareholder and one of the founders of DiaSys, celebrated his 30 years anniversary as employee. Beside a virtual celebration, which gave every staff member the opportunity to send congratulations, Dr. Gorka received two presents, representing his interest and commitment to sustainable activities. One is a slice of a tree with the most significant and important DiaSys milestones marking the year rings of the tree. The second present is a sponsorship of a Riesling grapevine; Dr. Gorka will annually receive the corresponding amount of wine output of this famous German grape. To work and to grow a company, for more than 30 years, is an extraordinary achievement. Dr. Gorka still drives DiaSys forward, despite his advanced age, with enormous “herd blood” and engagement.

Happy birthday to 30 years in DiaSys!

Dr. Günther Gorka showing the gifts.

Author

Dr. Jan Gorka
Managing Director and CEO

Innovation prize for DiaSys and Fresenius University of Applied Sciences

The state Rhineland-Palatinate awards the 2021 Innovation Prize in the category “cooperation“ to DiaSys Diagnostic Systems GmbH along with Hochschule Fresenius, University of Applied Sciences, for developing a new procalcition (PCT) test using PETIA technology.

In 2021, the prize, which is endowed with money, is awarded for the 33rd time. Due to the pandemic, the prize is virtually conferred by the Ministry of Economics, Transport, Agriculture and Viticulture together with the state working groups of the states chambers of industry, commerce and crafts on May 11, 2021.

For years, DiaSys and Hochschule Fresenius – University of Applied Sciences have closely cooperated in the areas of research, development and education. Both were honored by their appointment as core members of the IFCC PCT working group. The IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) is an association for the global advancement of clinical chemistry and laboratory medicine. The PCT Working Group has established a reference procedure for quality assurance of worldwide standardized sepsis diagnostics by procalcitonin.

The innovative reagent Procalcitonin FS, developed in cooperation with Hochschule Fresenius, is based on a further development of the PETIA technology (particle-enhanced turbidimetric immunoassay). In contrast to conventionally complex determination methods in laboratory, no special equipment is needed for handling. The PETIA method may be applied to almost all available clinical chemistry analyzers worldwide.

Author

Anette Weber
Assistant to the Head of Marketing

Innovation prize for DiaSys and Fresenius University of Applied Sciences

The test guarantees precise procalcitonin results while saving both cost and time and allows early diagnosis and immediate therapeutic measures. The excellent performance characteristics of Procalcitonin FS have been confirmed in renowned medical publications since its introduction; a patent has been filed for the innovative manufacturing process of Procalcitonin FS.

DiaSys is proud to belong to the most innovative companies in Rhineland-Palatinate.

Dr. Günther Gorka, C.E.O. of DiaSys thanks all those involved in making this award and the success of Procalcitonin FS possible.
See joint press release with Hochschule Fresenius on our website in the news sector or follow the links below for more details:
www.hs-fresenius.de
www.youtube.com/watch?v=YvNAAtJEfW8

Teams of DiaSys R&D and Fresenius - University of Applied Sciences

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Anette Weber
Assistant to the Head of Marketing

Member of the IFCC Task Force to manage the COVID-19 pandemic

In their August 2020 DiaLog newsletter, DiaSys reported that it has become a corresponding member of the IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) Task Force on COVID-19 since June 2020. The task force consists of 12 members in total, among them six from the diagnostic industry sector (Abbott, Beckman, DiaSys, Siemens, Sentinel, Ortho).

The task force has set up guidelines and recommendations to provide regular updates on epidemiology, pathogenesis, and lab diagnostics to manage SARS-CoV-2. It is integral part of their mission to practically harmonize the use of diagnostic tests and biosafety measures in managing specimens. Moreover, the IFCC Task Force organizes international studies to improve knowledge on pathogenesis, diagnostics and therapeutical management of COVID-19. Especially during the actual pandemic, it is essential to guarantee global reliability of all commercially available processes and testing tools. Manufacturers and laboratories may now align their work to the guidelines and recommendations of the IFCC task force on COVID-19 to improve overall routine testing consistency.

DiaSys is honored and will contribute with great commitment to the standardization and optimization of such tests; Professor Dr. Matthias Grimmler, Head of Research & Development who represents DiaSys in the committee states, “We are very proud to collaborate intensively with the IFCC and to demonstrate the innovative and progressive role of DiaSys in global diagnostics.”

Go to IFCC Task Force on COVID-19 for more info or directly to guidelines:

1) IFCC Interim Guidelines on Molecular Testing of SARS-CoV-2 Infection.
2) IFCC Interim Guidelines on Serological Testing of Antibodies against SARS-CoV-2.
3) IFCC Interim Guidelines on Biochemical/Hematological Monitoring of COVID-19 Patients.
4) IFCC interim guidelines on rapid point-of-care antigen testing for SARS-CoV-2 detection in asymptomatic and symptomatic individuals.

Author

Prof. Dr. Matthias Grimmler
Head of Research & Development

Implementation of IVDR (In Vitro Diagnostic Regulation) scheduled for 2022

Since project start, DiaSys has kept its customers up to date with regard to the implementation steps and requirements. It is becoming apparent that the continued incomplete provision of the necessary infrastructure from the authorities as well as the immense bottleneck with the necessary “Notified Bodies” (Supervising authorities) will lead to problems in implementing the IVDR for the majority of all manufacturers.

For this reason, DiaSys has recently submitted a written petition to twelve local politicians to support a postponement of the effective date (May 2022) of the IVDR by at least one year. As the timely and stringent implementation of the remaining infrastructure is predictably at risk, an urgent need for action has emerged to prevent real bottlenecks in diagnostic testing in order to protect patients, public health and the continuity of health care. As part of their general approach to companies and employers in their own constituency, the two state MPs Jörg Denninghoff and Dr. Tanja Machalet paid a visit to the company DiaSys in May 2021. During a two-hour meeting, DiaSys not only introduced the company's business field, but also their concern regarding a moratorium on the IVDR. Mr. Denninghoff and Dr. Machalet are very interested in the topic and understand the resulting precarious situation for DiaSys as an IVD manufacturer. They left with the promise to pass on the matter to the relevant bodies.

Picture (right to left):
J. Denninghoff, Dr. Machalet as well as DiaSys staff: Dr. Günther Gorka (C.E.O.), Dr. Jan Gorka (C.E.O.), Melanie Schönbach (Works council), Stefanie Giesener (Head of Regulatory Affairs and Quality Management), Stefan Gehm (Head of Production), Ulrich Sander (Head Accounting), Alexander Schwarz Head of IT) during visit at DiaSys on May 17, 2021

Author

Stefanie Giesener
Head of Quality Management & Regulatory Affairs

Implementation of IVDR (In Vitro Diagnostic Regulation) scheduled for 2022

IVDR moratorium follow-up meeting

Because of the above-mentioned note to politicians, the deputy chairman of CDU/CSU (German political party) in the European Parliament, Ralf Seekatz, Member of the European Parliament, has reacted. On 18 May 2021, a virtual meeting took place with him, Dr. Jan Gorka and Stefanie Giesener from DiaSys; both presented the precarious situation of the industry. Mr. Seekatz encouraged DiaSys in its request for a moratorium and has named contact persons to extend the dialogue with politics on a national level.

On the same day, DiaSys approached the State Secretary Dr. Thomas Gebhart (Member of the German Bundestag) and Erwin Rüddel (Member of Bundestag and Chairman of the Health Committee of the Bundestag) - with the successful outcome, that the issue was directly forwarded the Federal Ministry of Health (BGM).

At the same time, the VDGH (Verband der Diagnostika Industrie e.V.) has reported that the topic will be part of the agenda of the EPSCO (Employment, Social Policy, Health and Consumer Affairs Council) meeting on 14-15 June. After the VDGH, too, had made use of their political contacts to bring the issue to the attention of the European Parliament from the national side, it now seems that things might finally be moving. The EU Council for Employment, Social Policy, Health and Consumer Affairs meets in the EPSCO Meeting. Now it will be necessary to wait and see what will be decided and which additional measures might be taken.

Author

Stefanie Giesener
Head of Quality Management & Regulatory Affairs

30 Years DiaSys

In 2021, DiaSys celebrates its 30th company anniversary. An 'Inside DiaSys blog' has been established on the website, featuring ongoing articles from staff editors on 'the early days' and global growth: https://www.diasys-diagnostics.com/de/blog/inside-diasys/

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