NEWS RELEASE

Bruker Launches CE-IVD Quantitative Coronavirus Mid-Plex PCR Assay with Mutation Detection for Routine Variant Differentiation

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- FluoroType® SARS-CoV-2 varID Q is a novel LiquidArray® mid-plex PCR panel
- Detection of selected SARS-CoV-2 mutations enables differentiation of major viral variants, or strains, without the costs and delays of selective NGS for variant epidemiology
- Quantification of viral load provides indication of infectivity and of stage of COVID infection
- Validated with nasopharyngeal swabs and oropharyngeal swabs for highest sensitivity

NEHREN, Germany--(BUSINESS WIRE)-- **Bruker Corporation** (Nasdaq: BRKR) today announced the launch of the FluoroTypeSARS-CoV-2 varID Q assay – a quantitative LiquidArray®mid-plexPCR panel. This novel assay panel also detects several important mutations to enable laboratories and hospitals to differentiate many major viral variants routinely on all positive samples. The very sensitive FluoroTypeSARS-CoV-2 varID Q diagnostic test detects the SARS-CoV-2 virus using three independent gene targets for high assay robustness, even in case of future additional mutations. The assay achieved a sensitivity of 98% and a specificity of 100% during its clinical performance evaluation study.

This press release features multimedia. View the full release here:
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FluoroType SARS-CoV-2 varID Q test kit (Photo: Business Wire)

The CE-IVD marked FluoroTypeSARS-CoV-2 varID Q assay simultaneously detects and differentiates four major virus mutations. Their combinations determine multiple major variants, such as the original Wuhan strain, as well as variants that have emerged in the UK (B.1.1.7), in Nigeria (B.1.525), in South Africa (B.1.351), in Brazil (P.1), and in Denmark (B.1.1.298). While this test does not differentiate the new Indian strains (e.g., B.1.617), they are reported reliably as SARS-CoV-2.

Moreover, the FluoroTypeSARS-CoV-2 varID Q assay now also offers quantification of the viral load in the sample in standardized International Units per milliliter (IU/ml), in accordance with WHO standards1. Quantitative PCR results may provide insights into whether the COVID patient is likely to be infectious, or whether she/he may already be in a later COVID stage with low viral loads.

Sensitive and robust detection, mutation differentiation and quantification of viral load are all done simultaneously in a single PCR tube and a single assay run. This permits efficient laboratory workflows without the need for a second PCR test, or for RNA sequencing for strain detection. As major variants can be differentiated in all positive samples, this novel test strategy provides improved statistics for epidemiology with shorter (overnight) time-to-result (TTR) and lower costs than NGS, which typically can be done only on a fraction of positive samples with much longer TTRs.

The novel FluoroTypeSARS-CoV-2 varID Q mid-plex assay is enabled by Bruker´s proprietary LiquidArray® assay format, which supports a higher degree of PCR multiplexing on Bruker´s high-performance Fluorocycler XT system.The assay is validated for nasopharyngeal and oropharyngeal swabs, and for automation of nucleic acid extraction and PCR setup it is validated on Bruker's new CE-IVD marked GenoXtract fleXT system for 96 samples.

Dr. Katharina Madlener, the Director of the Department of Laboratory Medicine and Hospital Hygiene in the Kerckhoff-Klinik Bad Nauheim in Germany, explained: "During the very dynamic situation of the SARS-CoV-2 pandemic, we need molecular diagnostics solutions that reflect the changing requirements. The added value from the differentiation of major virus variants, without the need to send samples for sequencing, is a major benefit to keep track of the local spread and prevalence."

Dr. Miguel Ángel Benítez Merelo, the Technical Director & Head of Microbiology at CLILAB Diagnostics in Barcelona, Spain, added: "The quantification of the SARS-CoV-2 viral load is a further plus of the assay. It is important to get the virus detected in a sensitive assay, but we also want to get further indications whether the patient is currently highly infectious or not. This information may be used to adjust healthcare measures appropriately."

Dr. Wolfgang Pusch, Executive Vice President Microbiology & Diagnostics at Bruker Daltonics, commented: "With the FluoroType SARS-CoV-2 varID Q we can now provide the public healthcare systems in Europe with a LiquidArray assay that detects, differentiates and quantifies the SARS-CoV-2 virus rapidly and inexpensively in just one PCR test. This avoids the workload, cost and time for a second PCR test or for sequencing. Accordingly, this novel CE-IVD assay offers major benefits for patients, physicians, testing laboratories and healthcare systems at the same time."

About Bruker-Hain Diagnostics

Bruker-Hain Diagnostics is focused on Molecular Diagnostics (MDx) products within Bruker´s Microbiology & Diagnostics business. Its subsidiary Hain Lifescience GmbH is the legal manufacturer of the FluoroType SARS-CoV 2 varID Q assay, as well as of the FluoroCycler® XT, MTBDR 2.0 assay, GXT nucleic acid preparation kits and of the FluoroType SARS-CoV-2 plus assays. For more information, please visit, **www.bruker.com/en/products-and-solutions/microbiology-and-diagnostics/covid-19-testing** or **www.hain-lifescience.de**.

About Bruker Corporation (Nasdaq: BRKR)

Bruker is enabling scientists to make breakthrough discoveries and develop new applications that improve the quality of human life. Bruker's high performance scientific instruments and high value analytical and diagnostic solutions enable scientists to explore life and materials at molecular, cellular and microscopic levels. In close cooperation with our customers, Bruker is enabling innovation, improved productivity and customer success in life science molecular and cell biology research, in applied and pharma applications, in microscopy and nanoanalysis, as well as in industrial applications. Bruker offers differentiated, high-value life science and diagnostics systems and solutions in preclinical imaging, clinical phenomics research, proteomics and multiomics, spatial and single-cell biology, functional structural and condensate biology, as well as in clinical microbiology and molecular diagnostics. For more information, please visit: **www.bruker.com**.

1 Bentley et al., Collaborative Study for the Establishment of a WHO International Standard for SARS-CoV-2 RNA. 2020, WHO Expert Committee on Biological Standardization. WHO/BS/2020.2402.

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