



NEWS RELEASE

Bruker Launches Second-Generation FluoroType® SARS-CoV-2 plus PCR Test for Detection of SARS-CoV-2 Viral Infections in Europe

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- Detects two independent SARS-CoV-2 viral RNA targets from respiratory samples for increased confidence
- Differentiates SARS-CoV-2 from four other endemic human coronaviruses for specificity
- Validated with Bruker-Hain GenoXtract® NA and GenoXtract® 96 X3 nucleic acid extraction system and kits
- Validated with novel Bruker-Hain FluoroCycler® XT real-time PCR thermocycler

NEHREN, Germany--(BUSINESS WIRE)-- **Bruker Corporation** (Nasdaq: BRKR) today announced the launch of the **FluoroType® SARS-CoV-2 plus** next-generation 6-plex PCR assay for the highly specific detection of the SARS-CoV-2 virus, which causes the respiratory and systemic disease COVID-19 (CV19).

The **FluoroType® SARS-CoV-2 plus** assay is CE-IVD labelled according to the European IVD Directive (98/79/EC). In two clinical trials involving approximately ninety CV19 positive patients and over 100 CV19 negative individuals, this advanced CV19 infection assay showed 100% sensitivity and 100% specificity. Actual clinical results may be lower, as all PCR tests depend on properly timed and executed nasopharyngeal or oropharyngeal sampling.

The **FluoroType® SARS-CoV-2 plus** assay has been validated for respiratory samples (nasopharyngeal swabs and oropharyngeal swabs in viral transport medium) using commonly available laboratory real-time PCR thermocyclers. The kit includes all necessary reagents to produce up to 96 results in under two hours. It is validated for use on Bruker's **GenoXtract® (GXT)** automated nucleic acid extraction devices with associated extraction kits. The **FluoroType® SARS-CoV-2 plus** assay can also be used with Bruker's novel, high-precision **FluoroCycler® XT** real-time PCR system or alternatively with other commonly available real-time thermocyclers. The assay targets two independent genes of the SARS-CoV-2 genome, while simultaneously allowing for the



differentiation of non-SARS-CoV-2 patients by detecting four endemic human coronaviruses (HCoVs) using four different HCoV gene locations.

Dr. Steffi Czieschnek, the Head of PCR Diagnostics at Medical Health Care Center (MVZ) for Clinical Chemistry and Microbiology in Suhl, Germany, explained: “We have implemented Bruker’s **FluoroType® SARS-CoV-2 plus** assay since several weeks now as our standard routine approach for COVID-19 testing. We like the added value of a second gene target and of the discrimination of potential other human coronaviruses. We use this second generation COVID-19 assay on the **FluoroCycler® XT** and are impressed by the capabilities and performance of this new cutting-edge real-time PCR platform.”

Dr. Wolfgang Pusch, Executive Vice President Microbiology & Diagnostics at Bruker Daltonics, commented: “With the combination of our **GenoXtract® (GXT)** products for nucleic acid extraction, our latest **FluoroCycler® XT** real-time thermocycler and dedicated detection assays, Bruker offers a complete solution for the sample preparation and detection of the SARS-CoV-2 virus. With the **FluoroType® SARS-CoV-2 plus** assay we expand our portfolio by an assay with added value by detecting two gene targets. Additionally, the differentiation from other human coronaviruses, which for example can cause a common cold, reduces the risk of false positive results due to potential cross-reactivity. We expect that these analytical features enable a very robust second-generation PCR assay with highest sensitivity and specificity.”

In a pilot phase and in collaboration with several partners, Bruker has recently also begun to offer CE-IVD marked serology antibody tests to detect previous COVID-19 infection in selected European countries, as well as a CE-IVD point-of-care (POC) antigen tests to screen for active CV19 infections in under two hours.

About Bruker-Hain Diagnostics

Bruker-Hain Diagnostics is focused on Molecular Diagnostics (MDx) products within Bruker’s Microbiology & Diagnostics business. Hain Lifescience GmbH is the legal manufacturer 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.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 research, in applied and pharma applications, in microscopy and nanoanalysis, and in industrial

applications, as well as in cell biology, preclinical imaging, clinical phenomics and proteomics research and clinical microbiology. For more information, please visit: www.bruker.com.

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