



NEWS RELEASE

Bruker Launches FluoroType® SARS-CoV-2/Flu/RSV PCR Panel in Europe with CE-IVD Mark

12/18/2020

- Winter four-plex panel detects clinically most important respiratory viruses SARS-CoV-2, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV)
- Validation with nasopharyngeal swabs and oropharyngeal swabs for highest sensitivity
- Saliva sampling option convenient for patients, while also achieving high PCR sensitivity; saliva samples do not require extraction and enable a faster, resource-effective workflow

NEHREN, Germany--(BUSINESS WIRE)-- **Bruker Corporation** (Nasdaq: BRKR) today announced the launch of the **FluoroType SARS-CoV-2/Flu/RSV** winter four-plex PCR panel, which enables the sensitive and simultaneous detection of the SARS-CoV-2 virus, of both influenza A and B viruses, as well as of the respiratory syncytial virus (RSV). In the winter season, multiple viruses need to be differentiated in one assay to facilitate diagnosis and patient management.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20201218005104/en/>

Figure 1: FluoroType SARS-CoV-2/Flu/RSV Test Kit (Photo: Business Wire)

The **FluoroType SARS-CoV-2/Flu/RSV** panel is CE-IVD labelled according to European IVD Directive (98/79/EC). It has been validated for nasopharyngeal swabs, oropharyngeal swabs and saliva samples. The kit includes all reagents to generate up to 96 PCR result panels in under two hours after nucleic acid extraction. In evaluations, the sensitivity and specificity from 112 nasopharyngeal or oropharyngeal swabs have achieved 100% for all four viruses with very low limits of detection. In addition, the winter four-plex panel has also been validated with an RNA extraction-free protocol on 60 saliva samples with 100% sensitivity and 97.5% specificity. In large scale patient sampling and diagnostic use, sensitivity

and specificity near 100% may not always be achievable, but swab and saliva PCR protocols remain the most sensitive assays.

Saliva samples are convenient for patients, e.g. during repeat surveillance or longitudinal testing. Saliva PCR testing is also resource-effective for clinical laboratories in case of extraction kit shortages, and time-to-result is shortened. For optimal performance from saliva, it is recommended not to eat, drink, brush teeth or rinse prior to sampling.

The **FluoroType SARS-CoV-2/Flu/RSV** panel can be used with Bruker's high-precision **FluoroCycler® XT** real-time PCR system, or with other common real-time thermocyclers. It is validated for use on Bruker's **GenoXtract® (GXT)** automated nucleic acid extraction devices with associated Bruker RNA extraction kits, and for Qiagen extraction chemistry, as well as for the saliva workflow without RNA extraction

Dr. Steffi Czieschnek, the Head of PCR Diagnostics at the Medical Healthcare Center (MVZ) for Clinical Chemistry and Microbiology in Suhl, Germany, explained: "For many months, Bruker's high-quality **FluoroType SARS-CoV-2 plus** assay was our standard for COVID-19 testing. For the winter season, with an increased incidence of influenza infections, we also needed differentiation of multiple respiratory viruses in one test to avoid additional workload or costs. In an early access program, we have internally validated the **FluoroType SARS-CoV-2/Flu/RSV** panel, and we are very pleased with the performance of this winter four-plex panel, which we now use broadly for our respiratory disease samples."

Dr. Wolfgang Pusch, Executive Vice President Microbiology & Diagnostics at Bruker Daltonics, commented: "We appreciate the positive customer feedback on the performance of our new **FluoroType SARS-CoV-2/Flu/RSV** panel. Compared to PCR assays that detect only the SARS-CoV-2 virus, our winter four-plex panel offers added value in a cost-effective workflow. Our clinical laboratory customers now also have the option of offering the saliva workflow for patient convenience, faster time-to-result, and reduced resource requirements without RNA extraction."

About Bruker-Hain Diagnostics

Bruker-Hain Diagnostics is focused on Molecular Diagnostics (MDx) products within Bruker's Microbiology & Diagnostics business. Hain Lifescience GmbH is also the 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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