



PRESS RELEASE

NEW! Complete range of products enabling rRT-PCR testing for SARS-CoV-2. Products now available from CellMade™ and its distributors!

June, 2020

Severe Acute Respiratory Syndrome 2 (SARS-Cov-2) is the novel betacoronavirus that causes the COVID-19 respiratory disease. The COVID-19 respiratory disease is transmitted amongst infected human within populations via respiratory droplets that spread during talking, coughing and sneezing. Symptoms of COVID-19 range from mild illness (dry cough, fatigue, fever and shortness of breath) to severe illness and death.

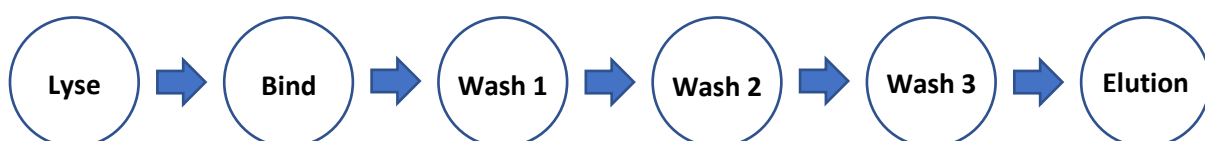
The current pandemic of SARS-CoV2 infection, with >4 million confirmed cases reported globally to date, has resulted in the need for the rapid implementation of diagnostic testing for the detection of SARS-CoV2 RNA using real-time RT-PCR.

➤ **CellInsight™ SARS-Cov-2 detection kit (REF#9001) – CE IVD**

The CellInsight™ SARS-Cov-2 detection kit (REF#CM9001) is a multiplex real-time reverse transcriptase polymerase chain reaction (PCR) assay for use on the Agilent AriaMX Real-time PCR System for the qualitative detection of RNA from the nucleocapsid phosphoprotein gene (N-gene) of the SARS-Cov-2 virus and the human RNase P gene. The primer and probe sets are based on the United States Centers for Disease Control and Prevention (US CDC) assay for the detection of SARS-Cov-2 by amplifying two unique regions of the N Gene (i.e., N1 and N2). Detection of the human RNase P serves as an endogenous Sample Processing Control (SPC) and allows to verify the nucleic acid extraction procedures and serves as an internal amplification control. No external addition of SPC is required.

➤ **CellInsight™ Total Nucleic Acid Extraction Kit – Pathogens (Ref#CM9100) – RUO**

CellInsight™ Total Nucleic Acid Extraction Kit – Pathogens (Ref#CM9100) is intended for manual and automated extraction of total nucleic acids (DNA and RNA) from a wide range of biological samples. Processing time for the preparation of 96 samples is *about* 40 minutes. The kit requires no phenol/chloroform extraction, no alcohol precipitation and eliminates the need for centrifugation, vacuum filtration or column separation. **The obtained total nucleic acids can be used directly as template for downstream applications such as PCR, real-time PCR and real-time RT-PCR.**



CellInsight™ Total Nucleic Acid Extraction Procedure



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CellInsight™ Total Nucleic Acid Extraction Kit – Pathogens (Ref#CM9100) is suitable for use with blood samples, liquid samples (e.g. *plasma, serum, urine, sputum, swab washes*), tissue samples, faeces. This User Manual contains further details on the individual procedures for sample pre-treatment.

- Extraction of total nucleic acid from *nasopharyngeal swabs and/or oropharyngeal swabs* using V = 200µL sample
 - Water-based Wash Buffers reduce solvent carry-over and results in the absence of PCR inhibitors in the final elution of Total Nucleic Acid
 - Total Nucleic Acid is obtained in V = 100 µL elution buffer
 - Automatable
- **CellInsight™ Synthetic RNA Control Template Kit – N1, N2 and RNase P (REF#CM9201) – RUO**

The CellInsight™ Synthetic RNA Control Template Kit – N1, N2 and RNaseP (Ref#CM9100) is intended for rRT-PCR control procedures and troubleshooting. The kit contains *in vitro* transcribed RNA for N1, N2 and RNaseP targets that are calibrated to exact copies / µL using BioRad Droplet PCR technology. **These control RNA samples can be used directly as template in real-time RT-PCR.**

- **CellInsight™ Process Control Kit (REF#CM9202) – RUO**

The positive controls included in the CellInsight™ Process Control Kit (REF#CM9202) enable to control the pre-analytical (lysis, TNA extraction) and analytical (rRT-PCR) procedures of the SARS-Cov-2 test for the N1 and N2 targets as well as for the RNase P endogenous control **These process control samples must be used starting from the lysis and extraction procedure!**

About CellMade™: A Biopharmaceutical developing biomarkers and diagnostic tools for widespread diseases such as *obesity, non-alcoholic fatty liver disease, type II diabetes, cardiovascular and respiratory diseases*. The Company established joint laboratory facilities with the University Savoie Mont Blanc and is located within the University laboratories at the scientific development campus of Le Bourget-du-Lac (France).

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