

Media & Investor Release

Research Use Only

Flu SC2 Multiplex RT-PCR Assay

- ❖ **BioGenex launches Flu SC2 Multiplex RT-PCR Assay that aids in the detection and differentiation of RNA from influenza A virus, influenza B virus or/and SARS-CoV-2 and is based on widely used nucleic acid amplification technology.**
- ❖ **Designed intended for the qualitative detection of RNA from influenza A, influenza B, and SARS-CoV-2 in nasopharyngeal swabs collected in commercially available Viral Transport Media (VTM) from individuals suspected of respiratory viral infection consistent with COVID-19.**
- ❖ **The product contains oligonucleotide primers and dual-labeled hydrolysis probes, and control material used in RT-PCR for the *in vitro* qualitative detection and differentiation of RNA of influenza A virus, influenza B virus or SARS-CoV-2 in upper and lower respiratory specimens such as nasopharyngeal (NP) swabs.**
- ❖ **Periodic assessments against emerging respiratory diseases with multiple infection have shown that BioGenex current diagnostic tests for detecting influenza A virus, influenza B virus or/and SARS-CoV-2 infections remain accurate and effective. Three results from one test means less discomfort for patients and conserves resources all around.**
- ❖ **The test runs on widely used RT-PCR systems and is for research use only and not for the diagnostic purposes.**

**BioGenex** is announcing the launch of the Flu SC2 Multiplex RT-PCR Assay to detect differentiate of RNA from influenza A virus, influenza B virus or/and SARS-CoV-2 and is based on widely used nucleic acid amplification technology. This research use only laboratory test can be used to help scientists track disease prevalence and to assess any potential impact on diagnostics, therapeutics, providing crucial insight (e.g. hospital beds, oxygen ventilators and multiple medications) for healthcare systems in making appropriate measures to combat COVID-19 and Influenza.

Respiratory symptoms of flu and COVID-19 are similar, it may be hard to articulate the difference between them based on symptoms alone, and testing may be needed to help confirm a diagnosis. Detection of viral RNA not only aids in the diagnosis of illness but also provides epidemiological and surveillance information said Krishan Kalra, CEO BioGenex. “Sustained surveillance is essential for public health. Our latest tests provide definite result for differentiation of RNA of influenza A virus, influenza B virus or SARS-CoV-2 in upper and lower respiratory specimens such as nasopharyngeal

(NP) swabs.

### **About Flu and COVID 19**

Respiratory symptoms of flu and COVID-19 are similar. Flu and COVID-19 share many characteristics, but there are some key differences between the two. Symptoms shared between the two infections include fever, chills, cough, difficulty breathing, fatigue, body aches, headache, sore throat, runny nose, nausea, vomiting, and diarrhea. COVID-19 spreads more readily and is often more severe. It may be hard to articulate the difference between them based on symptoms alone, and only testing can tell the difference between the two.

### **About Flu SC2 Multiplex RT-PCR Assay**

Flu SC2 Multiplex RT-PCR Assay is nucleic Acid test for use with the available RT-PCR Systems is an automated, multiplex, real-time reverse transcription polymerase chain reaction (RT-PCR) assay for the rapid in vitro qualitative detection and discrimination of RNA of influenza A virus, influenza B virus or SARS-CoV-2 in upper and lower respiratory specimens such as nasopharyngeal (NP) swabs.

BioGenex is committed to providing additional diagnostic tests as needed based on regular assessments of the infectious disease landscape.

### **About BioGenex's response to the COVID-19 pandemic and**

As a leading diagnostic and molecular pathology company we are doing all we can to support countries in minimizing the impact of COVID-19. We have developed a growing number of diagnostic solutions that help to detect and diagnose the infection in patients. We continue to identify, develop and support potential diagnostics which can play a role in detecting the disease.

We understand the health complexities of COVID-19 infection and its impact on patients emotional wellbeing, which is why we are working with healthcare providers, laboratories, authorities and organizations to help make sure that patients continue to receive the tests, treatment and care they need during these challenging times. As we learn from the pandemic, we are partnering with concerned organizations to understand and strengthen our diagnostic portfolio to develop-deliver reliable and sustainable diagnostic solutions in the future.

Besides helping to pinpoint those who have the virus and stop the spread of COVID-19, getting three results from one test means less discomfort for patients and conserves resources all around—a big deal during a time when everything from cotton swabs to PPE has been in short supply.

### **Our diagnostics solutions:**

- ❖ **COVID-19 RT-PCR direct** - Molecular test to detect SARS-cov-2, the virus that causes COVID-19 in direct VTM containing nasopharyngeal or oropharyngeal swab sample, without need of RNA extraction,
- ❖ **B117 RT-PCR** - Assay is rapid in vitro qualitative detection test and discrimination of select SARS-CoV-2 wild type and UK variant in nasal swab from individuals suspected of COVID-19.
- ❖ **COVID-19 Antigen Rapid** - is an in vitro diagnostic test based on an immunochromatographic assay. Designed for qualitative detection of Spike antigen and Nucleocapsid antigen of the novel Coronavirus (COVID-19) in human serum, saliva, nasopharyngeal or oropharyngeal specimens.
- ❖ **CRISPR-COVID-19 Test** - is an in vitro molecular diagnostic test for the detection of COVID-19 within 1 hour. Using synthetic COVID-19 virus RNA fragments able to detect COVID-19 target sequences (ORF1 ab and E gene) from the samples. Test kit carried out starting with RNA purified from patient samples as is used for qRT-PCR assays.

### **About BioGenex:**

BioGenex a premium diagnostic solutions company manufacturing diagnostic products like VTM, RT-PCR, CRISPR, Rapid antigen & antibody diagnostic tests and automated pathology instrumentations. The facilities, equipment's and processes have been designed in accordance with current GMP regulations as specified in Schedule M-III (for the manufacturing of Medical Devices). BioGenex is at the forefront of the emerging discipline of molecular pathology, the study and diagnosis of disease through the examination of molecules within organs, tissues or bodily fluids. The company designs, develops and commercializes systems for Tumor diagnosis, prognosis, precision medicine and life science research. BioGenex's industry-leading next-generation cytogenetic FISH, IHC, ISH workflow solution and miRNA system for characterization of Cancer of Unknown Primary (CUP) and undifferentiated tumors are revolutionizing pathology. Proprietary fully-automated molecular pathology workstations from BioGenex are the most advanced systems available globally. BioGenex was founded in 1981 in San Ramon, California. The mission was clear, become a global molecular medicine company providing affordable biomedical reagent systems.

Today, BioGenex is a global market leader in molecular pathology providing customer-centric solutions for complete automation of cell & tissue staining and COVID-19 diagnostics. Through proprietary cutting-edge technologies, the company has transformed the practice of slide-based staining

performed in modern molecular pathology laboratories and RT-PCR mediated amplification performed in Molecular biology laboratories. Early, affordable and accurate diagnosis at the molecular level has resulted in a higher quality of life for cancer patients and COVID patients. BioGenex takes pride in making a difference through its innovative products and superior customer service.

Please visit [www.biogenex.com](http://www.biogenex.com).

### **References**

1. Center for Disease Control and Prevention. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health HHS Publication No. (CDC) 21-1112, revised December 2009.
2. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from occupationally acquired infections.
3. <https://www.fda.gov/media/135659/download>