

**Media & Investor Release****Research Use Only****B117 RT-PCR Assay**

- ❖ **BioGenex launches SARS-CoV-2 variant test to help monitor emerging coronavirus mutations.**
- ❖ **The B117 RT-PCR Test is designed to detect Nucleocapsid gene (N gene) mutation (specific) in virus variants associated with increased human-to-human transmission.**
- ❖ **Accurate detection and differentiation of SARS-CoV-2 mutations can help assess the spread of circulating variant and monitor their potential impact on therapeutics, vaccines and public health interventions (e.g. hospital beds, oxygen ventilators and multiple medications).**
- ❖ **Periodic assessments against emerging variants have shown that BioGenex current diagnostic tests for detecting active SARS-CoV-2 infections remain accurate and effective.**
- ❖ **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 B117 RT-PCR Test to detect and differentiate mutation found in variant that originated in the UK (B.1.1.7). This research use only laboratory test can be used to help scientists track mutation 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.

Variant of B117 lineage gained prominence in late 2020, with each carrying a number of genomic mutations. Among them, mutations N501Y and del 69-70 are located in the spike protein, the region that enables the virus to attach to and enter the human cell. Apart from that B.1.1.7 variant has unique mutation D3L in Nucleocapsid gene which South Africa (B.1.317) and Brazil variant (P.1) does not possess. Studies have suggested that these mutations may be linked to increased disease transmissibility, possibly decreased therapeutic, vaccine efficacy and as well increase hospital causality.

In concern to the present scenario, India is currently experiencing a massive COVID-19 surge. The daily case count has crossed the 400,000 plus-mark, and the country has already reported the highest number of daily new cases in the world for the last two days – and all this despite limited testing. The reported positive rate is around 8% for the whole country and nearly 30% in Maharashtra. The growth in the number of new daily cases has been exponential and there is no doubt that the second wave is

going to be more severe than it was last year, at least if the steep rise is any indication. In fact, since February 15, the number of cases has increased to more than 10-fold.

India's health ministry recently released data on genome-sequencing of 10,787 samples from 18 states, which showed 771bcases of known variants: 736 of B.1.1.7 (UK). There were 336 samples from Punjab that tested positive for the B.1.1.7 variant. Officials also reported this strain in samples from Telangana (87), Delhi (65) and Andhra Pradesh.<sup>3</sup>

This developed kit identifies and differentiates both wild type and UK variant virus through newly designed primer and probe of mutated N (D3L) gene of RT-PCR” said Krishan Kalra, CEO BioGenex. “Sustained surveillance is essential for public health. Our latest tests provide definite result for SARS CoV2 wild type and UK variant and at the same time. Therefore, no need for expensive process like NGS is needed which is not widely available to diagnose UK and other variants. The B117 RT-PCR test runs on the widely available RT-PCR Systems.

It is important to note that BioGenex has confirmed its existing diagnostic tests to detect SARS-CoV-2 are not affected by known mutations and remain accurate and effective in detecting active infections. The company is conducting assessments on a regular basis and will continue to monitor as new variants arise.

#### **About SARS-CoV-2 Variants B.1.1.7**

First reported in the UK in December 2020, B.1.1.7 variant has quickly become the dominant circulating variant and has since been found in countries worldwide. B.1.1.7 carries a large number of mutations, eight of which are accumulated in the spike region. Preliminary studies have suggested that two such spike mutations, N501Y and del 69-70, are associated with increased transmissibility of the disease. Apart from that B.1.1.7 variant has unique mutation D3L in N gene which may cause severity of lung infection.

#### **About B 117 RT-PCR Test**

B117 RT-PCR 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 select SARS-CoV-2 wild type and UK variant. BioGenex designed unique primer and probe targeting D3L mutation of N gene which other variant of concern does not possess. This test can identify only UK variant.

BioGenex is committed to providing additional variant tests as needed based on regular assessments of

the infectious disease landscape.

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

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.

#### **Our diagnostics solutions:**

- ❖ **COVID-19 RT-PCR direct** - Molecular test to detect SARS-cov-2, the virus that causes COVID-19,
- ❖ **FLU-SC<sub>2</sub> Multiplex-PCR** - Molecular test to simultaneously detect and differentiate between SARS-CoV-2 and influenza A/B, as the symptoms are similar for both.
- ❖ **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:**

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