NeuMoDx Announces US FDA Emergency Use Authorization (EUA) for SARS-CoV2 Test

- High throughput system provides STAT results in about 80 minutes -

March 31, 2020 (Ann Arbor, Michigan) NeuMoDx™ Molecular, a sample-to-result molecular diagnostic company focused on providing high throughput testing solutions to hospital and commercial reference laboratories, announced that the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the NeuMoDx™ SARS-CoV-2 Assay implemented on the NeuMoDx™ Molecular Systems.

The NeuMoDx™ SARS-CoV-2 Assay is a rapid, automated *in vitro* real-time RT-PCR diagnostic test for the direct detection of SARS-CoV-2 Coronavirus RNA from nasopharyngeal, oropharyngeal and nasal swab specimens in transport medium from individuals with signs and symptoms of infection of COVID-19. This multiplexed assay detects highly conserved regions of two SARS-Cov-2 genes, the Nsp2 gene and N gene, and uses different fluorophores for reporting each target. The assay is available to CLIA certified hospitals and reference laboratories with experience performing high complexity tests.

The high throughput, fully automated NeuMoDx 288 and 96 Molecular Systems can provide the first test results in as little as 80 minutes from primary collection or daughter tubes. "Our proprietary NeuDry™ technology enables efficient automation of the NeuMoDx SARS-CoV-2 Assay, as all reagents and consumables do not require refrigeration and are provided in a "ready to use" format for immediate processing," said Sundu Brahmasandra, PhD., President and Chief Operating Officer of NeuMoDx.

With the NeuMoDx™ SARS-CoV-2 Assay, the NeuMoDx Systems integrate the entire process of testing for SARS-CoV-2 - from specimen lysis through detection or 'sample to result" - and provide operators with the ability to load up to 288 patient samples in a continuous, random-access workflow resulting in on-demand, high throughput testing. Additionally, the NeuMoDx Systems allow laboratories to efficiently validate their own SARS-Cov-2 Laboratory Developed Tests, including those provided by WHO and the CDC, in order to immediately improve throughput and increase the volume of testing. "NeuMoDx is committed to employing its technology and resources to the global effort to limit the continued spread of Coronavirus," said Jeff Williams, Chairman and CEO of NeuMoDx. "We believe our easy-to-use, high throughput systems allow laboratory clinicians to rapidly increase the volume of SARS-CoV-2 testing conducted by their lab."

About NeuMoDx™

NeuMoDx™ Molecular designs and develops revolutionary molecular diagnostic solutions for hospital and clinical reference laboratories. Our patented, 'sample-to-result' platform offers market-leading ease of use, true continuous random-access, and rapid turnaround time while achieving optimal operational and clinical performance for our customers and the patients they serve. For more information visit www.neumodx.com.