Corona Virus (COVID-19)

1. 2019-NOVEL CORONAVIRUS INFORMATION

Coronavirus are a group of enveloped viruses with a positive-sense, single-stranded RNA genome.

There are six human Coronavirus that cause illness ranging from common cold to more severe disease such as Middle East Respiratory Syndrome (|MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV).

SARS-CoV-2 in the Wuhan region of China in December 2019 and as spread worldwide within 2 months. The virus was initially termed as 2019-nCoV (novel Coronavirus) and renamed as SARS-CoV-2 by the "International Committee on Taxonomy of Viruses", on 11.02.2020. At the same time the WHO named the disease, caused by SARS-CoV-2 COVID-19.

Considering the rapid escalation and propagation of COVID -19 worldwide, the WHO characterized the outbreak as a pandemic on 12.03.2020.

SARS-CoV-2 is highly contagious and transmitted via aerosols and droplets and causes acute respiratory infection with flu-like symptoms. Mainly, but not exclusively, in elderly people and persons with pre-existing illness, infection with SARS-CoV-2 can lead to severe and life-threatening disease. Cases of asymptomatic infection, mild illness, severe illness, and deaths have been reported.

2. WARNING AND PRECAUTIONS

- This is for in vitro diagnostic use under the FDA Emergency Use Authorization only.
- Use of this product is limited to personnel specially instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.
- Use of this product is limited to specified laboratories and clinical laboratory personnel who have been trained on authorized instruments.
- Laboratories are required to report all positive results to the appropriate public health authorities.
- Results need to be interpreted in conjunction with clinical signs and symptoms of thee patient or contact information.
- Do not use reagents from other manufacturers with this assay.
- Please ensure that all instruments used have been installed, calibrated, checked and maintained according to the manufacturer's instructions and recommendations.
- Specimens should always be treated as if infectious and/or biohazardous in accordance with safe laboratory procedures.

- Follow necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines.
- Good laboratory practice is essential for proper performance of this assay. Extreme care should be taken to preserve the purity of the components of the kit and reaction setups.
  All reagents should be closely monitored for impurity and contamination. Any suspicious reagents should be discarded. False positive results may occur from cross-contamination by target organism, their nucleic acids or amplified product.
- Avoid microbial and nuclease (DNase/RNase) contamination of the specimen and the components of the kit.
- Always use DNase/RNase –free disposable pipette tips with aerosol barriers.
- Always wear protective disposable powder-free gloves when handling kit components.
- Use separated and segregated working areas for (i) specimen preparation, (ii) reaction set-up and (iii) amplification/detection activities. Workflow in the laboratory should proceed in unidirectional manner. Always wear disposable gloves in each area and change them before entering different areas.
- Dedicate supplies and equipment to the separate working areas and do not move them from one area to another.
- Store positive and/or potentially positive material separated from all other components of the kit.
- Do not open the reaction tubes/\plates post amplification to avoid contamination with amplicons.
- Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations.
- Do not use components of the kit that have passed their expiration date.
- Dispose sample and assay waste according to your local safety regulations.
- Due to the relatively fast molecular evolution of RNA viruses, there is an inherent risk for any RT-PCR based test system that accumulation of mutations over time may lead to false negative results.
- Perform all manipulations of live virus sample within a Class II (or higher) biological safety cabinet (BSC).