Anchor COVID19/Influenza/RSV Quality Control

NAME AND INTENDED USE

The Anchor COVID19/Influenza/RSV Quality Controls are intended for use by clinical labs and assay manufacturers to assess the performance of any molecular-based testing of SARS-COV-2, Influenza A, Influenza B, Respiratory syncytial virus (RSV) A or B and to validate the assay's performance.

PRODUCT DESCRIPTION

The Anchor COVID19/Influenza/RSV Quality Controls contain a non-pathogenic recombinant RNA virus. This allows for the monitoring of the entire testing process, from the extraction of viral RNA to the end result of the nucleic acid amplification. The virus carries the entire sequences of Wuhan-Hu-1, NC_045512.2, complete segments 7 and 8 of influenza A and B (M and NS genes), and the most conserved regions on RSV A and B. The target titer of the Quality Controls is 10,000 copies/ml. For the exact value of a specific lot, please refer to the Certificate of Analysis (CoA).

INSTRUCTION FOR USE

Make sure the sample is thawed and homogenous before use. For best result, the Anchor COVID19/Influenza/RSV Quality Control should be treated exactly the same way as a patient sample after its transfer to a virus transfer medium.

STORAGE AND HANDLING

For longer storage, the Anchor COVID19/Influenza/RSV Quality Control should be stored at -20°C or below. After thawing, they are stable for up to 60 days when stored between 2 - 8°C. Avoid repeated freeze-thaw cycles. Do not use the product beyond its expiration date.

LIMITATIONS

The Anchor COVID19/Influenza/RSV Quality Control should not be diluted without appropriate validation. For research use only.

SAFETY PRECAUTIONS

Use CDC's recommended universal precautions for handling reference materials and human specimens. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

Although in-house quantitation results were provided in the CoA, each laboratory must establish an assay-specific expected value. When the results for the product significantly deviate from values on the CoA, it may indicate an unsatisfactory test performance. Possible sources of error include: deviation from instruction for use, deterioration of test kit reagents, operator error, faulty performance of equipment, contamination of reagents, etc.

REFERENCES

CDC resources for labs: 2019-Novel Coronavirus (2019-nCoV) Real-time rRT-PCR Panel Primers and Probes. https://www.cdc.gov/coronavirus/2019-ncov/downloads/rt-pcr-panel-primer-probes.pdf.