

AT THE CORE of QUALITY



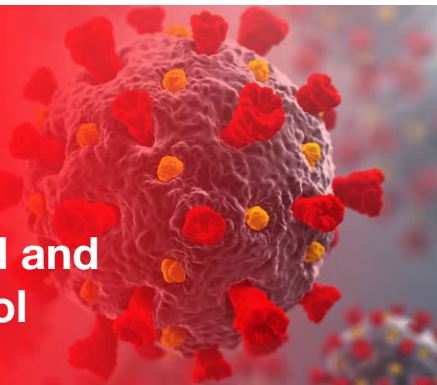
REDx™ FLOQ® REDx™ controls



Quality Assessment Products (QAPs)

**REDx™ SARS-CoV-2 Positive Control and
REDx™ SARS-CoV-2 Negative Control**

**REDx™ FLOQ® SARS-CoV-2 Swab Positive Control and
REDx™ FLOQ® SARS-CoV-2 Swab Negative Control**



REDx™ Positive Controls are designed to meet the full needs of the modern clinical molecular diagnostic industry

ADVANTAGES

- Contain SARS-CoV-2 whole genome (cDNA) and human cells
- Available as liquid in alcohol-based STM or on swabs (Copan FLOQ®)
- Inactivated to meet Clinical Lab Biosafety requirements
- Designed to meet the instrument/device Sample Adequacy requirements if needed
- Industry first whole genome control, allowing cross-platform compatibility and commutability
- Dedicated SARS-CoV-2 Negative Control

PERFORMANCE

- REDx™ SARS-CoV-2 products are designed to be compatible with the most RT-PCR based NATs
- Suitable for verification/validation on SARS-CoV-2 nucleic acid tests (NATs)

INTENDED USE

- REDx™ SARS-CoV-2 products are a whole genome (cDNA) unassayed controls intended to evaluate laboratory testing performance, procedures, and workflow with nucleic acid tests (NATs) that detect SARS-CoV-2 in human nasopharyngeal (NP) or oropharyngeal (OP) specimens.
- REDx™ SARS-CoV-2 products are used for controlling the elution, extraction, amplification, and detection steps of NATs.



OVERVIEW

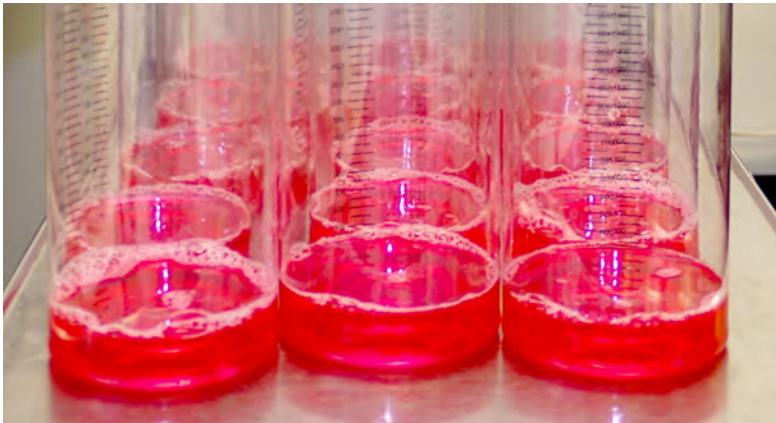
- Enveloped positive-stranded RNA virus with genome size of approximately 30 kb. Approximately 60-140 nm in diameter.
- Target Viral Genes for testing; E, N, and RdRP.
- Responsible for the COVID-19 outbreak. Infection can be asymptomatic or with symptoms ranging from mild illness to severe pneumonia.

CLASSIFICATION

- Member of family Coronaviridae, Genus Betacoronavirus, which includes MERS-CoV, and SARS-CoV. Shares 96% nucleotide sequence identity with SARS-CoV.

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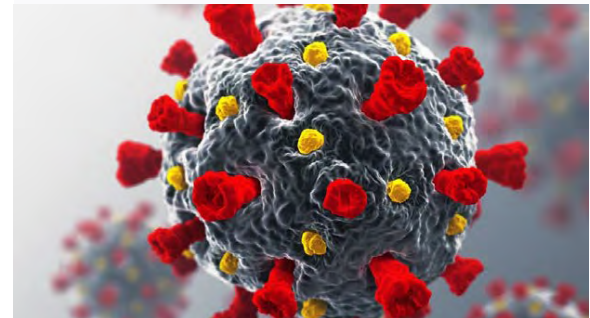
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Product Name	Product #
REDx™ SARS-CoV-2 Positive Control	RED-19-01
REDx™ FLOQ SARS-CoV-2 Swab Positive Control	RED-S-19-01
REDx™ SARS-CoV-2 Negative Control	RED-99-M3
REDx™ FLOQ SARS-CoV-2 Swab Negative Control	RED-S-99-M4



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