Co-Dx

Logix Smart™ Coronavirus Disease 2019 (COVID-19) kit - IVD

Innovating Molecular Diagnostic Solutions

The Logix Smart™ Coronavirus Disease 2019 (COVID-19) kit is a real-time RT-PCR test intended for the in vitro qualitative detection of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in lower respiratory samples (e.g. bronchoalveolar lavage, sputum, tracheal aspirate), and upper respiratory samples (e.g. nasopharyngeal and oropharyngeal swabs) from individuals suspected of COVID-19 by their healthcare provider.

Results are for the identification of SARS-CoV-2 RNA during the acute phase of infection. The Logix Smart Coronavirus Disease 2019 (COVID-19) is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The test kit has been tested with the QIAamp® Viral RNA Mini Extraction Kit (Qiagen) on the CoDx Box thermocycler (Bio Molecular Systems).

Logix Smart™ COVID-19

- **Regulatory Status: FDA (EUA), European (CE-IVD), and Mexican (InDRE Emergency Use) Contains a simple and streamlined workflow**
- **Includes internal control to verify sample quality**
- **Includes a positive control to verify master mix quality**
- **Produces results that are easy to interpret**
- **For use with lower and upper respiratory tract specimen**

For use under the Emergency use Authorization (EUA) only
For in vitro diagnostic use
For prescription use only

CE IVD

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About Logix Smart™ COVID-19 PCR Test · Product Performance Characteristics

Intended Use	Qualitative real time RT-PCR test for detection of RdRp of SARS-CoV-2 from individuals suspected of COVID-19 by their healthcare provider.
Sample Type	Lower respiratory tract fluids (bronchoalveolar lavage - BAL, tracheal aspirate, and sputum), and upper respiratory tract fluids (Nasopharyngeal and oropharyngeal swabs).
User	Qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures
COVID-19	
Limit of Detection (copies/µl)	4.29
Sensitivity†	99.52%
Specificity†	100.00%
Clinical Matrix used for analytical verification	Lower respiratory tract fluid (bronchoalveolar Lavage (BAL), tracheal aspirate, and sputum), upper respiratory tract fluid (Nasopharyngeal and oropharyngeal swabs)
Analytical Specificity (in silico analysis)	No microorganism in the in silico analysis has revealed ≥ 80% homology between the cross-reactivity microorganisms, including the ones of relevance listed below. **IT DOES NOT cross-react with the following microorganisms:** SARS-CoV, MERS-CoV, Human coronaviruses (HCoV-229E, HCoV-OC43, HCoV-NL63, HCoV-HKU1), Adenovirus, Influenza A H3N2, Novel Influenza A H1N1, Influenza B, Influenza C, Metapneumovirus (hMPV), Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, Respiratory syncytial virus (subtype A), Respiratory syncytial virus (subtype B), Parechovirus, Candida albicans, Corynebacterium diphtheriae, Legionella non-pneumophila, Bacillus anthracis, Moraxella catarrhalis, Neisseria elongata, Neisseria meningitides, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus salivarius, Leptospirosis, Chlamydia psittaci, Coxiella burnetii (Q-Fever), Staphylococcus epidermidis, Enterovirus, Rhinovirus, Haemophilus Influenzae, Mycobacterium tuberculosis, Bordetella parapertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, and Legionella pneumophila
Time to detection	63-90 minutes, depending on the machine used
Extraction System	QIAamp Viral RNA Mini kit (QIAGEN)
Thermal cycler compatibility	CoDx Box (Bio Molecular Systems)

†Calculations are based on 631 replicates of contrived samples using synthetic SARS-CoV-2 RNA template or The following reagent was deposited by the Centers for Disease Control and Prevention and obtained through BEI Resources, NIAID, NIH: Genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WA1/2020, NR-52285

Each Logix Smart™ Coronavirus Disease 2019 (COVID-19) kit includes:

Cap color	Component	Description	Amount
Brown	Logix Smart COVID-19 Master Mix	Proprietary blend of SARS-CoV-2 CoPrimers™ and PCR reagents	1x500 µL (100 reactions) or 1x1,250 µL (250 reactions) or 1x25,000 µL (5,000 reactions)
Red	Logix Smart COVID-19 Positive Control	Proprietary blend of SARS-CoV-2 synthetic templates	1x500 µL (100 reactions) or 1x1,250 µL (250 reactions) or 1x25,000 µL (5,000 reactions)
Clear	Nuclease Free Water	Water free of DNase/RNase activity	1x500 µL (100 reactions) or 1x1,250 µL (250 reactions) or 1x25,000 µL (5,000 reactions)

Ordering Information:

Product Name	Product ID
Co-Dx Box™ Thermocycler	Request Quote
Logix Smart™ Coronavirus Disease 2019 (COVID-19) CE-IVD kit 100 rxns	COVID-K-001-100-I
Logix Smart™ Coronavirus Disease 2019 (COVID-19) CE-IVD kit 250 rxns	COVID-K-001-250-I
Logix Smart™ Coronavirus Disease 2019 (COVID-19) CE-IVD kit 5000 rxns	COVID-K-001-5000-I

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