Co-Dx

Co-Dx Logix Smart™ SARS-CoV-2 (genes RdRp/E)

Innovating Molecular Diagnostic Solutions

The Logix Smart™ SARS-CoV-2 (genes RdRp/E) test is a real-time RT-PCR multiplex test intended for the in vitro qualitative detection of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), targeting the genes RdRp in the polygene Orf1ab region and gene E of the virus genome, in lower respiratory tract samples (e.g., bronchoalveolar lavage, sputum, tracheal aspirate), upper respiratory tract samples (e.g., nasopharyngeal and oropharyngeal swabs), and saliva from individuals suspected of COVID-19, as determined by their healthcare provider.

Results are used for the identification of SARS-CoV-2 RNA during the acute phase of infection. The Logix Smart™ SARS- CoV-2 (genes RdRp/E) 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 Kit (Qiagen), Sbeadex Viral RNA Purification kit (Biosearch Technologies), Viral DNA/ RNA kit (CW Bio), and HighPrep Viral DNA/RNA kit (MagBio) extraction systems on the Co-Dx Box™ (Co-Diagnostics, Inc.) Mic qPCR Cycler (BMS, Biomolecular Systems), QuantStudio 5 (Thermo Fisher Scientific), CFX96 (Bio-Rad).

For in vitro diagnostic use. For professional use only.

Co-Dx Logix Smart™ SARS-CoV-2

- Regulatory Status: European Union (IVD)
- 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 as well as saliva samples

CE IVD

2401 South Foothill Drive, Ste D., Salt Lake City, Utah 84109 (801) 438-1036 www.co-dx.com info@co-dx.com

Intended Use	Qualitative real-time RT-PCR multiplex test for in vitro detection of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
Sample Type	Lower respiratory samples (e.g., bronchoalveolar lavage, sputum, tracheal aspirate), upper respiratory samples (e.g., naso-pharyngeal and oropharyngeal swabs), and saliva.
User	Qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.
Limit of Detection	The Limit of Detection (LoD) for Logix Smart™ SARS-CoV-2 utilizing QIAamp RNA Viral Mini Kit (cat. no. 52904/ 52906, Qiagen) was confirmed to be 0.8 copies/µL. For the HighPrep Viral DNA/RNA Kit (MagBio, CAT#HPV-DR96) the LoD was confirmed to be 1.0 copies/µL. For the Viral DNA/RNA Kit (CW Bio, CAT#CW3126M) the LoD was confirmed to be 2.0 copies/µL. For the sbeadex Viral RNA Purification Kit was run on the oKtopure (Biosearch Technologies, CAT#NAP-40-026-04) the LoD was confirmed to be 6.0 copies/µL.
Sensitivity*	99.448%
Specificity*	98.908%
Clinical Matrix used for analytical verification	Lower respiratory samples (e.g., bronchoalveolar lavage, sputum, tracheal aspirate), upper respiratory samples (e.g., naso-pharyngeal and oropharyngeal swabs), and saliva.
Analytical Specificity (in silico analysis)	No microorganism in the in silico analysis has revealed significant homology between the cross-reactivity microorganisms, including the ones of relevance listed below. IT DOES NOT cross-react with the following microorganisms: Human coronavirus 229E, Adenovirus, Influenza C, Human coronavirus OC43, Human Metapneumovirus (hMPV), Parechovirus, Human coronavirus HKU1, Parainfluenza virus 1-4, Corynebacterium diphtheriae, Human coronavirus NL63, Influenza A & B, Legionella non-pneumophila, SARS-coronavirus, Enterovirus, Bacillus anthracis (Anthrax), MERS- coronavirus, Respiratory syncytial virus, Moraxella catarrhalis, Rhinovirus, Neisseria elongata, Chlamydia pneumoniae, Neisseria meningitides, Haemophilus Influenza, Leptospirosis, Legionella pneumophila, Chlamydia psittaci, Mycobacterium tuberculosis, Coxiella burnetii (Q-Fever), Streptococcus pneumoniae, Staphylococcus aureus, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Pneumocystis jirovecii (PJP), Pooled human nasal wash – to represent diverse microbial flora in the human respiratory tract, Candida albicans, Pseudomonas aeruginosa, Staphylococcus epidermidis, and Staphylococcus salivarius.
Time to detection	Approximately 90 minutes, depending on the instrument used.
Extraction System	• QIAamp Viral RNA Mini Kit (Qiagen) • Sbeadex Viral RNA Purification kit (Biosearch Technologies) • Viral DNA/RNA kit (CW Bio) • HighPrep Viral DNA/RNA kit (MagBio)
Thermal cycler compatibility	• Co-Dx Box™ Cycle (Co-Diagnostics, Inc.) • Mic qPCR Cycler (BMS, Biomolecular Systems) • QuantStudio 5 (Thermo Fisher Scientific) • CFX96 (Bio-Rad) Each thermal cycler validated with the test and listed above is compatible with the following detection channels: • FAM • CF560 (VIC) • CF610 (ROX)

* Sensitivity based on clinical study of 30 clinical remnant positive samples, 15 contrived Influenza A, and 15 contrived Influenza B, and 30 negative clinical samples.

Each Co-Dx Logix Smart™ SARS-CoV-2 kit includes:

Cap Color	Component	Description	Amount
Brown	Co-Dx Logix Smart™ SARS-CoV-2 Master Mix	Proprietary blend of SARS-CoV-2 Co-Primers™ and PCR reagents	1×500 µL (100 reactions) or 1×1250 µL (250 reactions) or 1×25000 µL (5,000 reactions)
Red	Co-Dx Logix Smart™ SARS-CoV-2 Positive Control	Proprietary blend of SARS-CoV-2 synthetic templates	1×500 µL (100 reactions) or 1×1250 µL (250 reactions) or 1×25000 µL (5,000 reactions)
Clear	Nuclease Free Water	Water free of DNase/RNase activity	1×500 µL (100 reactions) or 1×1250 µL (250 reactions) or 1×25000 µL (5,000 reactions)

Ordering Information:

Product Name	Product ID
Co-Dx Box™ Thermocycler	Request quote
Co-Dx Logix Smart™ Coronavirus Disease 2019 (COVID-19) CE-IVD Kit	COVID-K-002

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