



Co-Dx Logix Smart™ SARS-CoV-2 DS

Innovating Molecular Diagnostic Solutions

The Logix Smart™ SARS-CoV-2 DS is a real-time multiplex RT-PCR test, using a proprietary primer Co-Primers™ technology, intended for the in vitro qualitative detection of nucleic acid from SARS-CoV-2, targeting the RdRp and E genes, in saliva from individuals suspected of COVID-19, as determined by their healthcare provider.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in saliva during the acute phase of infection. The Logix Smart™ SARS-CoV-2 DS test 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 Co-Dx Box™ (Co-Diagnostics, Inc.), Mic qPCR Cycler (BMS, BioMolecular Systems), QuantStudio 5 (Thermo Fisher Scientific), CFX96 Touch (Bio-Rad), and ABI 7500 Fast (Thermo Fisher Scientific).

For in vitro diagnostic use. For professional use only.

Co-Dx Logix Smart™ SARS-CoV-2 DS

- Regulatory Status: European Union (IVD)
- Includes internal control to verify sample quality
- Includes a positive control to verify master mix performance
- Produces results that are easy to interpret
- For use with saliva specimen



Intended Use	Qualitative detection of nucleic acid from SARS-CoV-2, targeting the RdRp and E genes, in saliva, from individuals suspected of COVID-19.
Sample Type	Saliva
User	Testing is limited to clinical laboratory environments and operations.
Limit of Detection	Co-Dx Box™ Cyclers 3.0 copies/μL
	MIC qPCR Cyclers 1.7 copies/μL
	QuantStudio 5 3.5 copies/μL
	CFX 96 5.0 copies/μL
	7500 Fast Dx 2.0 copies/μL
	7500 Fast Dx 1.0 copies/μL
Sensitivity*	96.7%
Specificity*	100.0%
Clinical Matrix used for analytical verification	Saliva
Analytical Specificity (in silico analysis)	<p>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:</p> <p>Human coronavirus OC43, Human coronavirus HKU1, Human coronavirus NL63, MERS-coronavirus, Human (hMPV), Parainfluenza virus 3, Enterovirus (e.g., EV68), Respiratory syncytial virus, Rhinovirus, Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Pneumocystis jirovecii (PJP), microbial flora in the human respiratory tract, Candida albicans, Pseudomonas aeruginosa, Staphylococcus epidermidis, Streptococcus salivarius.</p> <p>It may cross-react poorly with SARS-coronavirus (1) (2003).</p>
Time to detection	Approximately 90 minutes, depending on the instrument used.
Extraction System	No sample extraction, only a brief sample processing procedure.
Thermal cycler compatibility	<ul style="list-style-type: none"> • Co-Dx Box™ Cyclers (Co-Diagnostics, Inc.) • MIC qPCR Cyclers (BMS, BioMolecular Systems) • QuantStudio 5 (Thermo Fisher Scientific) • CFX96 Touch (Bio-Rad) • ABI 7500 Fast (Thermo Fisher Scientific)

*Results obtained from clinical evaluation with 30 remnant positive saliva samples, and 30 negative paired saliva and anterior nasal swabs.

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

Cap Color	Component	Description	Amount
Brown	Co-Dx Logix Smart™ SARS-CoV-2 DS Master Mix	Proprietary blend of SARS-CoV-2 Co-Primers™ and PCR reagents	1×1000 μL (100 reactions) or 1×25000 μL (2,500 reactions)
Red	Co-Dx Logix Smart™ SARS-CoV-2 DS Positive Control	Proprietary blend of SARS-CoV-2 synthetic templates	1×1000 μL (100 reactions) or 1×25000 μL (2,500 reactions)
Clear	Nuclease Free Water	Water free of DNase/RNase activity	1×1000 μL (100 reactions) or 1×25000 μL (2,500 reactions)

Ordering Information:

Product Name	Product ID
Co-Dx Box™ Thermocycler	Request quote
Co-Dx Logix Smart™ SARS-CoV-2 DS Kit	COVDS-K-003 (Protease K sold separately)

