Co-Dx

Co-Dx Logix Smart™ ABC (Influenza A/B, SARS-CoV-2)

Innovating Molecular Diagnostic Solutions

The Logix Smart™ ABC (Influenza A/B, SARS-CoV-2) is a real-time, RT-PCR multi-analyte test using proprietary Co-Primers™ technology, intended for the qualitative simultaneous detection and differentiation of nucleic acid from Influenza A, Influenza B, and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), targeting conserved regions of the viral genomes 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 Influenza A, Influenza B, or coronavirus disease COVID-19 and its related conditions as determined by their healthcare provider.

Results are for the identification of Influenza A (gene M, Influenza B, and SARS-CoV-2 RNA). The Logix Smart ABC 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 the QIAamp Viral RNA Mini kit (Qiagen) on the Co-Dx Box™ Cycler (Co- Diagnostics, Inc.), Mic qPCR Cycler (Bio Molecular Systems [BMS]), PCRmax Eco 48 Real-Time qPCR System (PCRmax Limited), and CFX 96 Touch Real-Time PCR Detection System (Bio-Rad).

For in vitro diagnostic use. For professional use only.

Co-Dx Logix Smart™ ABC

- 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 multi-analyte test, for detection of Influenza A, Influenza B, and 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., nasopharyngeal 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	Influenza: A 571.3 $CEID^{50}$/mL
	Influenza: B 60.0 $CEID^{50}$/mL
	SARS-CoV-2: 411.2 copies/mL
Sensitivity*	Influenza A: 96.78%
	Influenza B: 100%
	SARS-CoV2: 96.78%
Specificity*	100% specificity for Influenza A, B, and SARS-CoV2
Clinical Matrix used for Analytical Verification	Lower respiratory tract samples (e.g., bronchoalveolar lavage, sputum, tracheal aspirate), upper respiratory tract samples (e.g., nasopharyngeal and oropharyngeal swabs), and saliva from patients who are suspected of Influenza A, Infuenza B, or coronavirus disease 2019 (COVID-19).
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)
Thermal cycler compatibility	• Co-Dx Box™ Cycler (Co-Diagnostics, Inc.) • Mic qPCR Cycler (BMS, Biomolecular Systems) • ECO48 (PCR Max) • 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) • Quasar 670 (Cy5)

*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™ ABC (Influenza A/B, SARS-CoV-2) kit includes:

Cap Color	Component	Description	Amount
Brown	Logix Smart™ ABC Master Mix	Proprietary blend of Co-Primers™ and PCR reagents	1×1000 µL (100 reactions) or 1×25000 µL (2,500 reactions)
Red	Logix Smart™ ABC Positive Control	Proprietary blend of Influenza A/B, 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™ ABC (Influenza A/B, SARS-CoV-2) Kit	ABC-K-001

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