



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

Innovating Molecular Diagnostic Solutions

The Logix Smart™ Coronavirus Disease 2019

(COVID-19) test kit is an *in vitro* diagnostic test that uses our patented CoPrimer™ technology for the qualitative detection of RNA from SARS-CoV-2 coronavirus (COVID-19) from lower respiratory tract specimens (e.g. bronchoalveolar lavage, sputum, tracheal aspirate), upper respiratory tract specimens (e.g. nasopharyngeal fluids, nasal swab), and serum from patients who meet the clinical criteria (e.g. signs and symptoms) for coronavirus disease 2019 (COVID-19) as established by WHO (WHO, 2020) and the US CDC (CDC, 2020) (e.g. fever, cough, shortness of breath, travel history to China).

The test kit has been tested with QIAamp® Viral RNA Mini Extraction Kit (Qiagen) on CoDx Box thermocycler (Bio Molecular Systems), and Eco 48 Real Time PCR (PCRmax).

CDC. (2020, Feb 13). Coronavirus Disease 2019 (COVID-19): Evaluating and Reporting Persons Under Investigation (PUI). Retrieved Feb 19, 2020, from Centers for Disease Prevention and Control: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>

WHO. (2020). Coronavirus disease (COVID-19) technical guidance: Surveillance and case definitions. Retrieved Feb 19, 2020, from World Health organization: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/surveillance-and-case-definitions>



Logix Smart™ COVID-19

Compatible with multiple sample types

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

Compatible with multiple platforms & sample extraction techniques



About Logix Smart™ COVID-19 PCR Test

Product Performance Characteristics

Intended Use	Qualitative real time RT-PCR test for detection of gene <i>RdRp</i> of SARS-CoV-2 (COVID-19).
Sample Type	Lower respiratory tract fluids (bronchoalveolar lavage - BAL, tracheal aspirate, and sputum), and upper respiratory tract fluids (Nasopharyngeal and oropharyngeal swabs).
User	Laboratory technician trained in molecular diagnostics procedures
COVID-19	
Limit of Detection (copies/ml)	1,349.38
Sensitivity†	99.17%
Specificity†	100.00%
Clinical Matrix used for analytical verification	Lower respiratory tract fluid (Bronchoalveolar Lavage (BAL) and sputum), upper respiratory tract fluid (Nasopharyngeal fluid), and serum
Analytical Specificity (wet-test or in silico analysis)	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, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Respiratory syncytial virus (subtype A), Respiratory syncytial virus (subtype B), Parechovirus, <i>Candida albicans</i> , <i>Corynebacterium diphtheriae</i> , Legionella non-pneumophila, <i>Bacillus anthracis</i> , <i>Moraxella catarrhalis</i> , <i>Neisseria elongata</i> , <i>Neisseria meningitidis</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Streptococcus salivarius</i> , Leptospirosis, <i>Chlamydia psittaci</i> , <i>Coxiella burnetii</i> (Q-Fever), <i>Staphylococcus epidermidis</i> , Enterovirus, Rhinovirus , <i>Haemophilus Influenzae</i> , <i>Mycobacterium tuberculosis</i> , <i>Bordetella parapertussis</i> , <i>Mycoplasma pneumoniae</i> , <i>Chlamydia pneumoniae</i> , and <i>Legionella pneumophila</i>
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) Eco 48 (PCRmax) 2 channels: FAM and CF610 (ROX)

†Calculations are based on 360 replicates of contrived samples using synthetic SARS-CoV-2 RNA template.

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

- 1x500 µl (100rxns) or 1x1250 µl (250rxns) Logix Smart™ COVID-19 Master Mix
- 1x500 µl (100rxns) or 1x1250 µl (250rxns) Logix Smart™ COVID-19 Positive Control
- 1x500 µl (100rxns) or 1x1250 µl (250rxns) Nuclease Free Water

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-001-100I
Logix Smart™ Coronavirus Disease 2019 (COVID-19) CE-IVD kit 250 rxns	COVID-K-001 250I

