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Co-Dx

Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO

REF **COVID-R-001**

Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO
CO-DIAGNOSTICS, INC.

RUO

CO-DIAGNOSTICS, INC. | 2401 Foothill Dr., Ste D, Salt Lake City, UT 84109 USA

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1 MANUFACTURER

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RUO

2 INTENDED USE

The **Logix Smart™ Coronavirus Disease 2019 (COVID-19)** product is a research use only (RUO) test, based on real-time PCR (qPCR) technology, for the qualitative detection of the Coronavirus Disease 2019 (COVID-19).

For research use only. Not for use in diagnostics procedures.

3 PRODUCT DESCRIPTION

The **Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO** tests for the presence or absence of ribonucleic acid (RNA) of the Coronavirus Disease 2019 (COVID-19) microorganism.

The **Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO** includes an internal control to identify possible qPCR inhibition, confirm the integrity of the reagents, and verify the quality of sample extraction. The **Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO** also includes a positive control (PC) with a synthetic RNA molecule carrying sequences that are homologous to Coronavirus Disease (COVID-19) microorganism that this assay targets. PCs represent a source of amplicon contamination. Take precautions to prevent or minimize the risk.

CoPrimers™ included in the **Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO** are the following:

- CoPrimers™ that target COVID-19 and are labelled with the FAM™ fluorophore.
- CoPrimers™ that target the Internal Positive Control (IPC) deoxyribonucleic acid (DNA) are labelled with CAL Fluor® Red 610 fluorophore.

4 RUO COMPONENTS

See Table 1 for the components found in the **Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO**.

Table 1

RUO Components

Lid Color	Component	Symbol	Catalog Number	Description	Amount
Brown	Logix Smart™ COVID Master Mix	MM	COVID-MM- 001	Proprietary blend of CoPrimers™ and PCR reagents	1×500 µL (100 reactions)
Red	Logix Smart™ COVID Positive Control	PC	COVID-PC- 001	Proprietary blend of target templates	1×500 µL (100 reactions)
Clear	Nuclease-Free Water	NTC	GEN-NF-001	DNase/RNase-free water	1×500 µL (100 reactions)

The **Smart™ Coronavirus Disease 2019 (COVID-19) RUO** Catalog Number is COVID-R-001. Contact Sales at (801) 438-1036 ext. 01 or at www.co-dx.com/contact/ to order.

5 STORAGE

The following list includes important storage and handling information:

- The **Logix Smart™ COVID-19** RUO is shipped on dry ice. The components of the RUO should arrive frozen. If one or more of the components are not frozen upon receipt or are compromised during shipment, contact your distributor for assistance.
- All components should be stored immediately at a temperature between -40°C and -16°C to prevent degradation of reagents.
- Always work with each **Logix Smart™ COVID-19** component on ice. Make aliquots, if necessary, to avoid 10 or more freeze/thaw cycles.
- If you work in an area prone to power outages, ensure you have a back-up generator for your freezer and a temperature data log to ensure that the **Logix Smart™ COVID-19** RUO remains frozen.
- With proper storage and handling, the **Logix Smart™ COVID-19** RUO reagents are stable for up to 12 months from the date of manufacture.

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6 MATERIALS REQUIRED (NOT INCLUDED)

Materials and devices required but not provided include the following:

- An appropriate 2-channel real-time PCR instrument, compatible with the fluorophores used in this test
- An appropriate nucleic acid extraction system or kit
- Several micropipettes capable of pipetting volumes from 5 µL to 1,000 µL
- A cold block or ice
- A vortex and centrifuge
- A PCR workstation, for master mix (MM) plating and setup

7 BACKGROUND INFORMATION

Coronavirus (2019-nCoV) was initially reported to the World Health Organization (WHO) on December 31, 2019, as an outbreak in Wuhan City, Hubei Province, China of pneumonia of unknown etiology. Thousands of human infections were confirmed in that region, resulting in exported cases worldwide. Cases involved severe illness to death. Based on this worldwide spread of the contagion, countries and the WHO called for diagnostic testing to identify, detect and diagnose coronavirus (2019-nCoV) and its emerging variants.

8 ACCESSORIES (NOT INCLUDED)

8.1 Thermocycler

Co-Diagnostics, Inc. can either directly or through reagent rental programs, provide the CoDx Box™ thermocycler machines (manufactured for Co-Diagnostics, Inc. by Bio Molecular Systems). **Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO** can also be used in other real-time PCR systems if the parameters to run the test are set as established in the **Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO**.

The CoDx Box thermocycler is recommended due to its ease of use, small size, durability, and fast report generation. The CoDx Box thermocycler software was developed by Bio Molecular Systems solely for Co-Diagnostics, Inc., and it has been verified for use with Co-Diagnostics, Inc. real-time PCR products, simplifying result interpretation.

The CoDx Box thermocycler reads fluorescence in real-time, generated from the PCR reagents loaded into CoDx Box PCR reaction tubes, amplifies the virus RNA by thermal cycling using magnetic induction, and displays output data through the integrated software. The CoDx Box thermocycler is available with 48 reaction wells and 4 channels. Other Co-Diagnostics, Inc. real-time PCR products also utilize this CoDx Box thermocycler. The Microsoft Surface™ Pro 4 System (MSPRO-4) is

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available for use with CoDx Box software in a windows-based operation system. The output device used with the CoDx Box thermocycler can be a printer or external computer. Alternately, the results can be manually recorded. The method of reporting is left to the discretion of the user.

8.2 Extraction Kit

The quality of the extraction of the RNA from the samples is essential for the performance of Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO. The extraction protocol to be followed should be performed following manufacturer's instructions or an internally validated protocol. The extraction method suggested with Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO is the QIAamp Viral RNA Mini Kit, Qiagen, cat No. 52904 (50 preps) and cat No. 52906 (250 preps), and the QIAcube instrument.

Other kit options include: MagMax™ Viral/Pathogen Nucleic Acid Isolation kit, MagMax™ Viral/Pathogen II Nucleic Acid Isolation Kit, and QuickGene Tissue II RNA kit, along with KingFisher Flex and Myra instruments, even though no test Co-Diagnostics performance studies have been performed with the current iteration of the Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO. Please, always use the most recent version of this document as more information as added with future studies. For the most recent version go to http://codiagnostics.com/resources/instructions-for-use/ for free download of this manual

9 WARNINGS AND PRECAUTIONS

WARNING!
Before performing any testing or running any sample, verify that all instruments have been properly installed, calibrated, and are well maintained. Do **not** use instruments with an outdated calibration.

Read and follow this Instructions for Use document carefully before using the product. Before first use, check the components for the following:

- Integrity
- Frozenness upon arrival

Users should adhere to the following guidelines:

- Limit the use of this product to personnel instructed and trained in the techniques of real-time PCR.
- Always treat samples as infectious and/or biohazardous. Use standard precautions.

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- Wear protective gloves, lab coat, and eye protection when handling samples. Always wear gloves when handling RUO components.
- Always use DNase/RNase-free disposable pipette tips with filters.
- Use segregated working areas for sample preparation, reaction setup, and amplification/detection activities. The workflow in the laboratory should proceed in a unidirectional workflow. To prevent contamination, change Personal Protective Equipment (PPE) between areas.
- Store and extract positive materials (specimen, controls, and amplicons) separately from other reagents. Dedicate supplies and equipment to separate working areas and do not move them from one area to another.
- Consult appropriate SDS for safety. The SDS for the **Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO** is provided with the shipment. If not provided with shipment the SDS can be retrieved from Co-Diagnostics website at the link: Safety Data Sheets | Co-Diagnostics, Inc. (co-dx.com)
- Do not open the reaction tubes/plates post amplification.
- Do not autoclave reaction tubes/plates after the PCR, because this will not degrade the amplified nucleic acid and will pose a risk to the laboratory area to contamination.
- Do not use components of the RUO that have passed expiration date.
- Discard sample and assay waste according to your local safety regulations.

10 SAMPLE INFORMATION

Sample selection, collection, storage, and handling play an essential part in the performance of nucleic acid assays. This document includes valuable information to help laboratories develop better procedures for the analysis of results and for troubleshooting other issues.

For more information, visit the Centers for Disease Control (CDC) and the WHO websites at the following addresses:

- CDC - https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
- WHO - https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance

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10.1 Sample Storage

Store specimens at 2-8°C for up to 72 hours after collection. If you expect a delay in testing or shipping, store specimens at -70°C or below. Avoid repeated freezing and thawing of a specimen. If you keep a specimen for retesting, aliquot the specimen in different tubes to avoid repeated freezing and thawing cycles. Monitor and record the temperature in the storage areas regularly to identify potential fluctuations. Domestic refrigerators/freezers with wide temperature fluctuations are not suitable for the storage of frozen specimens (CDC, 2020).

10.2 Sample Handling

Laboratory workers should wear appropriate PPE, which includes disposable gloves, laboratory coat/gown, and eye protection when handling potentially infectious specimens.

If you suspect or confirm that a sample is infected with COVID-19, work under a certified Class II cabinet in a BSL-2 containment facility. More details are provided in the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* (CDC, 2009) or the *WHO Laboratory Biosafety Manual* (WHO, 2004).

For specific instructions on the handling of specimens associated with coronavirus disease 2019, see the CDC's webpage for the *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019* (COVID-19) (CDC, 2020).

11 PROCEDURE

Warning!

If your sample preparation system uses washing buffers that contain ethanol, eliminate any traces of ethanol prior to elution of the nucleic acid. Ethanol is a strong inhibitor of real-time PCR.

The use of carrier RNA can be crucial for extraction efficiency and the stability of extracted nucleic acid.

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11.1 Real Time RT-PCR Setup

11.1.1 Set up the Reagent

Perform the following steps to set up the reagent:

11.1.1.1 Clean all working surfaces with a fresh 10% bleach solution followed by a molecular-grade alcohol or another equivalent method of cleaning that disinfects and degrades nucleic acids.

11.1.1.2 Vortex all **Logix Smart™ COVID-19** MM, PC, nuclease-free water (used as a no template control [NTC]), and all sample tubes for 3 seconds.

11.1.1.3 Briefly spin the MM, PC, NTC down before using to ensure reagents are properly mixed and to ensure removal of any condensation or residue from the lids.

11.1.1.4 Thaw all reagents and samples on ice, or a cold block, before starting the setup.

11.1.2 Set Up the Reaction

11.1.2.1 Collect enough reaction wells for each of the following:

- One for NTC,
- One for each unknown sample you want to test, and
- One (or more) for each PC

Note: The example below shows the number of wells needed for 5 unknown samples.

PC	1
NTC	1
Unknown samples	5
Total wells needed	7

Important:
Pipette on ice, if possible.
Perform PC pipetting and sample extraction in a separate area, or at a separate time, from the MM and NTC.
Change pipette tips between unknown sample elution and change pipette tips after pipetting each component.
Pipette the PC last, if possible, to avoid contamination events.

11.1.2.2 Pipet 5 µL of MM into each well collected.

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11.1.2.3 Pipet 5 µL of the unknown sample (elution from nucleic acid extraction) or 5 µL of NTC control to the appropriate wells (in addition to the 5 µL of MM already in the well).

Note: Include at least one NTC control in each run and that enough space remains for at least one PC.

11.1.2.4 Pipet 5 µL of PC into the appropriate well.

11.1.2.5 Seal the reaction plate with an optical adhesive film or seal each reaction tube with its appropriate lid.

11.1.2.6 Place the plate or tubes into the real-time PCR instrument in the correct orientation and start the run.

11.2 PCR Instrument Setup

11.2.1 For basic information regarding setup and programming of the different real-time PCR instruments, refer to the user manual of the respective instrument. For programming instructions questions regarding the use of other real-time PCR instruments please contact the Laboratory at (801) 438-1036 ext.03 or at www.co-dx.com/contact/.

11.2.2 If using a Co-Diagnostics Inc. CoDx Box, contact the Laboratory at (801) 438-1036 ext. 03 or at www.co-dx.com/contact/ for the template file for download. The template file comes pre-programmed with the PCR instrument setup described in this section. When not using a template, or when using another device, use the settings outlined below to program the PCR instrument.

11.2.2.1 To achieve optimal performance from the test, it is important to ensure that the instrument is compatible with the conditions outlined below.

11.2.3 Define the settings displayed in Table 2.

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Table 2

Settings for PCR Instruments

Item	Setting
Reaction Volume	10 µL
Ramp Rate	Default
Passive Reference	None

11.2.4 Program PCR instrument with the cycling conditions displayed in Table 3.

Table 3

PCR Instrument Cycling Conditions

Item	Stage	Cycles	Temperature	Time
Reverse Transcription	Activation	1	45˚C	15 minutes
Initial Denaturation	Hold	1	95˚C	2 minutes
Amplification	Cycling	50	95˚C	3 seconds
			55˚C	32 seconds

11.2.5 Always use the PCR instrument compatible with the fluorophores listed in Table 4. Some devices may not have options for the quencher. If you need assistance or have questions, contact Co-Diagnostics Inc. Technical Support at (801) 438-1036 ext. 02 or at support@co-dx.com.

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11.2.6 Define the fluorescence detectors (dyes) as outlined in Table 4.

Table 4

Fluorescence Detectors (Dyes) Definitions

Target	Detector Name	Reporter	Quencher
13BCOVID-19 specific RNA	12B13BCOVID-19	FAM™	BHQ® - 1
RNaseP specific DNA (IPC)	RNaseP	CAL Fluor® Red 610	BHQ® - 2

11.2.7 When you finish the run, save the run file.

12 DATA ANALYSIS

For basic information regarding data analysis on specific real-time PCR instruments please refer to the user manual of the respective instrument.

12.1 Validity of Test Runs

12.1.1 Valid Test Run

Ensure that both the PC and NTC pass and that the control conditions displayed in Table 5 are met.

Table 5

Control Conditions

Control Type	Control Name	Purpose of Control	12B13BCOVID-19 FAM channel	Internal Control (RNaseP) CF610 channel
COVID Positive Control	COVID-19 (FAM™) RNaseP (CF®610)	Verifies the performance of the master mix	+	+
No Template Control	Master Mix + Water	Verifies the reagents are free of contamination	-	-

12.1.2 If controls pass, interpret the sample results.

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12.1.3 Invalid Test Run

12.1.3.1 If any of the controls fail, the run is invalid. Document the run and initiate troubleshooting.

12.2 Interpretation of Results

Once the controls have passed, the unknown samples can be interpreted based on one of the following three outcomes:

- Positive
- Negative
- Inconclusive

A **positive** result displays an amplification curve or cycle threshold value for COVID-19. The cut-off value should be determined by in house validation testing. However, internal studies have shown rare primer-dimer formation or other non-specific amplification at 45 cycles. This fact can be attributed to the nature of the CoPrimers™ (Satterfield, 2014) (Poritz & Ririe, 2014). The amplification of the RNaseP (IPC) shows that the extraction was successful.

A **negative** result displays no amplification for COVID-19; The absence of a curve for COVID-19 strain indicates a negative result ONLY when the RNaseP (IPC) marker is positive.

An **inconclusive** result will occur if any of the controls fail. See the Troubleshooting section.

The interpretation of results can be translated to Table 6 (version KM).

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Table 6

Results Interpretation

	Sample Result		Logix Smart™ COVID-19 Positive Control	No Template Control (NTC) (Master Mix + Water)	Interpretation
	COVID-19 FAM channel	Internal Positive Control (RNaseP) CF610 channel			
Instrument Reading	+	+	+	-	COVID-19 +
	-	+	+	-	COVID-19 -
	Any Result (+/-)	-	+	-	Invalid: See Troubleshooting
		+	-	-	
		+	+	+	

The cut off value will determine what results are to be considered positive or negative. It should be determined by the assay development.

An analyte result will be considered as positive (+) if a **Cq value of ≤45 is determined, while any analyte values ≥45 should be considered as negative (-).**

13 TROUBLESHOOTING

Co-Diagnostics Inc. values customer feedback and we hope you inform us of any issues you have with the **Logix Smart™ Coronavirus Disease 2019 (COVID-19) RUO**, even if the recommended steps for troubleshooting solve the issue. To give feedback please fill out the Customer Feedback Form by visiting www.co-dx.com/contact/feedback/

13.1 Stability

Real-time and accelerated shelf-life and in-use stability studies are currently under testing. Presently, we establish the expiration date of this product to be 12 months. We do not recommend the use of expired RUO reagents because doing so may lead to inaccurate results.

Always use the most recent version of this document because we add more stability information when studies are completed.

13.2 User Errors

Good Laboratory Practices for Molecular Biology Diagnostics (Viana & Wallis, 2011) are necessary when using this product. Only trained personnel should use this product.

It is essential for the user to have some molecular biology experience and be familiar with proper pipetting technique to prevent errors, such as splashes, crossover

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contamination, and errors on volume selection. Always replace pipette tips after every pipetting and replace gloves often. Calibrate equipment such as pipettes and real-time PCR instruments when applicable.

A 90-minute training course for Good Laboratory Practices for Molecular Genetics Testing (Centers for Disease Control and Prevention, 2017) is available at the CDC website at the following link https://www.cdc.gov/labtraining/training-courses/good-lab-practices-molecular-genetics-testing.html

13.3 Invalid Results

13.3.1 **Logix Smart™ COVID-19** Positive Control (PC) not Amplifying

13.3.2 No amplification from the PC could be the result of one or multiple factors, including one or more of the following:

- Pipetting errors (pipetting control into the wrong well, missing a well, pipetting inadequate amount of reagent)
- Incorrect placement of plates or tubes into the real-time PCR instrument
- **Logix Smart™ COVID-19** MM or **Logix Smart™ COVID-19** PC degradation (the result of reagents being at temperatures above -16°C for an extended period)
- Use of expired reagents
- Use of wrong reagents

Without further evidence, it is best to disregard the results from the samples and re-test by re-amplification. If the PC fails again, investigate to identify probable causes for error, and reprocess the test from extraction, depending on the investigation results and risks identified in the process. If failure of the PC occurs a third time after re-extraction and re-amplification, open a new **Logix Smart™ COVID-19** PC or MM, and retest. If the PC fails a fourth time, contact Co-Diagnostics Inc. Technical Support by calling (801) 438-1036 ext. 02 visiting support@co-dx.com.

13.3.3 Internal Positive Control (IPC) Not Amplifying in Samples

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13.3.4 A no amplification result from the RNaseP channel could be due to one or multiple factors, such as the following:

- Not enough nuclear material was in the sample.
- PCR inhibitors were present, such as ethanol and/or heparin.
- The person performing extraction, did it incorrectly.
- The extraction used is not compatible or has a step that eliminates a crucial element for extraction.

The sample origin is not compatible to the test's intended use.

Note: Positive amplification in the COVID-19 channel indicates a positive result despite the lack of concurrent amplification in the IPC channel. The IPC in Co-Diagnostics test RUOs may vary due to the test application. In most cases, amplification is dependent on the presence of human genomic DNA (gDNA) in the extracted sample, the amount of which is governed by the type of the sample and the extraction procedure used. Samples obtained from culture or sterile/pure sites (e.g., CSF, urine, cell lysates) may not contain the human RNaseP gene. In such cases, the two negative markers indicate a true negative result for Coronavirus Disease 2019 (COVID-19).

In some instances, negative results will require retesting by reamplification to ensure integrity and quality of results. If the IPC fails again, samples should be re-extracted and re-amplified. If it fails after a third time an investigation should be conducted to identify possible causes for error. If the cause for the error is clear, the test can either be called as inconclusive due to either PCR inhibitors being present or not enough nuclear material being present. If the cause for error is unclear, contact Co-Diagnostics Inc. Technical Support by calling (801) 438-1036 ext. 02 or by visiting support@co-dx.com.

13.3.5 No Template Control (NTC) Showing Amplification

Amplification of COVID-19 in an NTC indicates contamination in one or more of the reagents, incorrect placement of a plate or tubes into the real-time PCR instrument, or pipetting errors.

In this case, do not trust the results. Instead, re-test by re-amplifying. If the NTC fails again, then an investigation should be conducted to identify probable causes for error and the test must be either reprocessed from extraction or not, depending on the investigation results and risks identified in the process. If failure of the NTC, after re-extraction and re-amplification, happens a third time, open a new nuclease-free water and retest. If it fails a fourth time, contact Co-Diagnostics Inc. Technical Support by calling (801) 438-1036 ext. 02 or by visiting mailto:support@co-dx.com.

14 REFERENCES

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15 LEGEND OF PACKAGE SYMBOLS

Table 7 displays the legend for the package symbols used.

Table 7

Legend of Package Symbols

Icon	Description
	Catalog number
	Batch Code
	Cap color
	Component
	Content/Volume
	Number
	Use-by-date
	Contains sufficient for 25 tests/reactions
	Protect from light
	Temperature limit
	Consult Instructions for Use
	Non-sterile product - Do not sterilize.
	Manufacturer
	Research Use Only

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