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2022

Co-Dx

Logix Smart ABC (Influenza A/B, SARS-CoV-2) RUO

REF **ABC-R-001**

Logix Smart ABC (Influenza A/B, SARS-CoV-2) 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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2 INTENDED USE

The **Logix Smart™ Influenza A/B, SARS-CoV-2 (Logix Smart™ ABC) RUO** is for the simultaneous qualitative detection of the Influenza A (INFA), Influenza B (INFB), and SARS-CoV-2 (COVID-19) specific RNA.

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

3 PRODUCT DESCRIPTION

The **Logix Smart™ ABC RUO** is a research-use-only multiplex test, based on real-time polymerase chain reaction technology. It tests for the presence or absence of ribonucleic acid (RNA) of the Influenza A, Influenza B, and SARS-CoV-2 viruses.

The **Logix Smart™ ABC RUO** includes an internal control to identify possible quantitative polymerase chain reaction (qPCR) inhibition, confirm the integrity of the reagents, and verify the quality of the sample extraction. The **Logix Smart™ ABC RUO** also includes a positive control (PC) which includes three synthetic RNA molecules carrying sequences that are homologous to INFA, INFB, and COVID-19 viruses targeted by this multiplex assay. PCs represent a source of cross contamination. Take precautions to prevent and minimize the risk of cross contamination.

CoPrimers™ in the **Logix Smart™ ABC RUO** include the following:

- CoPrimers™ that target INFA are labelled with the Quasar® 670 fluorophore.
- CoPrimers™ that target INFB are labelled with the CAL Fluor® Orange 560 fluorophore.
- CoPrimers™ that target COVID-19 are labelled with the FAM™ fluorophore.
- CoPrimers™ that target the Internal Positive Control (IPC) DNA are labelled with CAL Fluor® Red 610 fluorophore.

4 RUO COMPONENTS

See Table 1 for components included in the **Logix Smart™ ABC RUO**.

Table 1

RUO Component Information

Lid Color	Component	Symbol	Catalog Number	Description	Amount
Brown	Logix Smart™ ABC Master Mix	MM	ABC-MM- 001	Proprietary blend of CoPrimers™ and PCR reagents	1×1000µL (100 reactions)
Red	Logix Smart™ ABC Positive Control	PC	ABC-PC- 001	Proprietary blend of target templates	1×1000µL (100 reactions)
Clear	Nuclease-Free Water	NTC	GEN-NF-001	DNase/RNase-free water	1×1000µL (100 reactions)

The catalog number for this product is ABC-R-001. Contact Sales at (801) 438-1036 ext. 01 or at www.co-dx.com/contact/ to order.

5 COLLECTION, HANDLING, STORAGE, AND SHIPPING

See the following information for **Logix Smart™ ABC RUO** collection, handling, storage, and shipping:

- The **Logix Smart™ ABC RUO** is shipped on dry ice and should arrive frozen. Contact your distributor if one or more of the RUO components are not frozen upon arrival or are compromised during shipment.
- Upon receipt of RUO, follow internal laboratory procedures for quality control.
- Upon arrival, store all components at a temperature between -40°C and -16°C to prevent degradation of reagents.
- Avoid excessive thawing and freezing of components, specifically the master mix (MM), as this might affect the performance of the assay. Freeze reagents in multiple aliquots if they are to be used intermittently to ensure that less than 10 freeze-thaws are performed.
- Avoid storing components for more than 4 hours at between +2°C and +8°C.
- If you work in an area prone to power outages, keep a back-up generator for your freezer as well as a temperature data log system to ensure that the **Logix Smart™ ABC RUO** remains frozen at a temperature between -40°C and -16°C.
- Protect the MM from light.
- Do not use expired products because the integrity of the components cannot be guaranteed.

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- The product is not a biological waste. The Safety Data Sheet (SDS) can be retrieved from Co-Diagnostics website at the following link: Safety Data Sheets | Co-Diagnostics, Inc. (co-dx.com). Disposal should be in accordance with applicable regional, national, and local laws and regulations.

6 MATERIALS REQUIRED (NOT INCLUDED)

The following materials and devices are required but are not provided with this RUO:

- Appropriate 4-channel real-time PCR instrument, compatible with the fluorophores used in this test.
- Appropriate nucleic acid extraction system or kit
- Vortex mixer
- Centrifuge with a rotor for 2 mL reaction tubes
- Adjustable pipettes
- Disposable pipette tips with filters
- Disposable powder-free gloves
- Ice
- Biosafety cabinet, ideally BSL-2 facility

Warning!

Install, calibrate, and maintain all instruments properly according to the manufacturer's instructions and recommendations. Do **not** use instruments with outdated calibration.

7 BACKGROUND INFORMATION

The outbreak of COVID-19 was first identified in December 2019 in Wuhan, Hubei province, China. COVID-19 is caused by the Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2), a novel virus in humans that is capable of person-to-person transmission. The notification was made on 31-Dec-2019. The World Health Organization declared the outbreak a Global Health Emergency on 30-Jan-2020. Shortly thereafter, Co-Diagnostics started preliminary design activities on Logix Smart COVID-19 diagnostic testing.

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8 ACCESSSORIES (NOT INCLUDED)

8.1 Thermocycler

Thermocyclers validated but not included with the test are displayed in Table 2.

Table 2

Thermocyclers Validated but Not Included with the Test

Thermocycler Machine	Catalog Number	Manufacturer
CoDx Box	MIC-4	Co-Diagnostics, Inc.
Mic qPCR Cycler	MIC-4	BMS, Bio Molecular Systems
PCRmax Eco 48 Real-Time qPCR System	EW-93947-00	PCRmax Limited
CFX 96 Touch Real-Time PCR Detection System	1855195	Bio-Rad

8.2 Extraction System

Extraction System required but not included with the test are displayed in Table 3.

Table 3

Extraction and Automation Systems Validated with the Test

Extraction Reagent		Automation Platform (If applicable)	Manufacturer	Sample Input Volume/Sample Elution Volume
Name	Cat. Number			
QIAamp Viral RNA Mini Kit (Qiagen)	52904 (50 extractions) 52906 (250 extractions)	N/A	Qiagen	200 µL/60 µL

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.

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Read 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 ensure the following:

- Limit 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.
- Wear protective gloves, lab coat, and eye protection when handling samples and 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 the appropriate SDS for safety. The SDS for the **Logix Smart™ ABC RUO** is provided with the shipment. If not provided with the shipment, the SDS can be retrieved from Co-Diagnostics website at the following 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, since this will not degrade the amplified nucleic acid and will pose a risk to the laboratory area to contamination.
- Do not use components that have passed expiration date.
- Discard sample and assay waste according to your local safety regulations.

10 SAMPLE INFORMATION

10.1 Sample Storage

Ensure the following when storing samples:

- Process all specimen types within 48 hours after collection, if storage is needed after 48 hours, store the samples frozen, preferably at -70°C (ECDC, 2020).

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- Avoid repeated freezing and thawing of any specimen. If you need to keep a specimen for retesting, aliquot the specimen in different tubes to avoid freezing and thawing cycles.
- Monitor the temperature in the storage areas and recorded temperatures regularly to identify potential fluctuations.
- Do not use domestic refrigerators/freezers with wide temperature fluctuations. Domestic refrigerators/freezers 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.

Conduct samples suspected to be or confirmed to be infected with influenza A, influenza B, and/or SARS-CoV-2 under a certified Class II biosafety 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 clinical specimens for coronavirus disease 2019, see also the CDC's webpage for the *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019* (COVID-19) (CDC, 2020).

The quality of the extraction of the RNA from the samples is essential for the performance of **Logix Smart™ ABC RUO**. Perform extraction by following manufacturer's instructions or an internally validated protocol. The suitability of the nucleic acid extraction procedure for use with **Logix Smart™ ABC RUO** must be validated by the user.

Warning!

If your sample preparation system uses washing buffers containing ethanol, make sure to 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 is crucial for extraction efficiency and stability of the extracted nucleic acid.

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11 PROCEDURE

11.1 Logix Smart™ ABC Setup

11.1.1 Set Up the Reagent

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

11.1.1.3 Vortex all **Logix Smart™ ABC RUO** MM, PC, nuclease-free water (used as an NTC), and all sample tubes for 3 seconds.

11.1.1.4 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.

11.1.2 Set Up the Reaction

Perform the steps below to set up the reaction.

11.1.2.1 Collect enough reaction wells for each of the following:

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

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

PC	1
NTC	1
Samples	5
Total wells needed	**7**

Important:

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

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11.1.2.2 Pipet 10 µL of MM into each well collected.

11.1.2.3 Pipet 10 µL of the sample or 10 µL of NTC control to the appropriate wells (in addition to the 10 µL of MM already in the well).

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

11.1.2.4 Pipet 10 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 and Thermocycler Setup

11.2.1 For basic information regarding setup and programming of the different real-time PCR instruments, please 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 (801) 438-1036 ext. 03 or at www.co-dx.com/contact/.

11.2.2 If using Co-Diagnostics Inc. CoDx Box, contact the Laboratory (see contact information in Section 7.4.2) 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 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 make sure that the instrument is compatible with the conditions outlined below.

11.2.3 Define the settings as displayed in Table 4.

Table 4

Recommended Instrument Settings

Item	Setting
Reaction Volume	20 µL
Ramp Rate	Default
Passive Reference	None

11.2.4 Program PCR instrument with the cycling conditions displayed in Table 5.

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Table 5

Recommended Cycling Condition Settings

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

11.2.5 Ensure that the PCR instrument being used is compatible with the fluorophores below. Some devices may not have options for the quencher. If you need help or have questions, contact Co-Diagnostics Inc. Technical Support at (801) 438-1036 ext. 02 or at: support@co-dx.com.

11.2.6 Define the fluorescence detectors (dyes) as displayed in Table 6.

Table 6

Fluorescence Detector Definitions

Target	Detector Name	Reporter	Quencher
INFA specific RNA	INFA	Quasar® 670	BHQ® - 2
INFB specific RNA	INFB	CAL Fluor® Orange 560	BHQ® - 1
COVID-19 specific RNA	COVID-19	FAM™	BHQ® - 1
RNaseP specific DNA (IPC)	RNaseP	CAL Fluor® Red 610	BHQ® - 2

11.2.7 When the run is finished, ensure that the run file is saved.

12 DATA ANALYSIS

For basic information regarding data analysis on specific qPCR instruments, please refer to the user manual of the respective instrument.

12.1 Positive and No-Template Controls

Validate the test run by checking to see that both the positive and no-template control have passed and that the control conditions displayed in Table 7 are met.

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Table 7

Required Control Conditions

Control Type	Control Name	Purpose of Control	INFA	INFB	COVID-19	Internal Control (RNaseP)
ABC Positive Control	INFA (Quasar®670)	Verifies the performance of the master mix	+	+	+	+
	INFB (CF®560)					
	COVID-19 (FAM™)					
	RNaseP (CF®610)					
No Template Control	Master Mix + Water	Verifies the reagents are free of contamination	-	-	-	-

12.1.1.1 If controls pass, interpret the sample results.

12.1.2 Invalid Test Run

12.1.2.1 If any of the controls fail, the run is invalid.

12.1.2.2 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 possible outcomes:

- Positive
- Negative
- Invalid

A **Positive** result will show an amplification curve or cycle threshold value for INFA, INFB, or 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 shows no amplification for INFA, INFB, or COVID-19; The absence of a curve for ABC indicates a negative result ONLY when the RNaseP (IPC) marker is positive.

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An **Inconclusive** result occurs if any of the controls fail. See the Troubleshooting section.

See Table 8 for results translation.

Table 8

Results Translation

	SARS-CoV-2	Influenza A	Influenza B	Internal Positive Control (RNaseP)	Logix Smart™ Positive Control	No Template Control (NTC) Logix Smart™ Master Mix + Nuclease-Free Water	Result
Instrument Reading	+	+	+	+	+	-	ABC +
	-	-	-	+	+	-	ABC -
	+	-	-	+	+	-	COVID-19 +
							INF A -
							INF B -
	-	+	-	+	+	-	COVID-19 -
							INF A +
							INF B -
	-	-	+	+	+	-	COVID-19 -
							INF A -
							INF B +
	+	+	-	+	+	-	COVID-19 +
							INF A +
							INF B -
	-	+	+	+	+	-	COVID-19 -
							INF A +
							INF B +
	+	-	+	+	+	-	COVID-19 +
							INF A -
							INF B +
	Any Result (+/-)			-	+	-	Inconclusive: See Troubleshooting
				+	-	-	
				+	+	+	

Anything before 40 cycles is considered a positive analyte reading (+). Anything after 40 cycles is considered a negative analyte reading (-). When possible, always check that the medical history and/or symptoms associated with the sample match the result.

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13 TROUBLESHOOTING

Co-Diagnostics Inc. values customer feedback and we would like to be informed of any issues with the **Logix Smart™ ABC 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. Currently, the expiration date of this product has been established as 12 months. Do not use expired reagents, because doing so may lead to inaccurate results.

Always use the most recent version of this document for updates as more stability information will be added when studies are completed.

13.2 User Errors

Good Laboratory Practices for Molecular Biology Diagnostics (Viana & Wallis, 2011) are necessary for the use of this product. This product is not intended to be used by untrained personnel.

To help prevent errors such as splashes, crossover contamination, and volume selection, it is essential that users have some molecular biology experience and be familiar with proper pipetting technique. Pipette tips must be replaced after every pipetting. Gloves must be replaced often. Equipment, such as pipettes and real-time PCR instruments, should be calibrated when applicable.

A 90-minute online training 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™ ABC** PC not Amplifying

13.3.2 No amplification from the PC could be the result of one or multiple factors, such as 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™ ABC** MM or PC degradation (result of reagents being stored at a temperature above -16°C for an extended period)

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- Use of expired reagents
- Wrong reagents being used

When this occurs, it is best to disregard the results from the samples and re-test by re-amplification. If the PC fails again, then an investigation should be conducted to identify possible causes for error, and the test must be reprocessed from extraction (or not, 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™ ABC** PC or MM, and retest. If still failing, please contact Co-Diagnostics Inc. Technical Support by calling (801) 438-1036 ext. 02 visiting support@co-dx.com.

13.3.3 IPC RNaseP is not Amplifying in Samples

13.3.4 No amplification from the RNaseP channel could be the result of one or multiple factors, such as:

- Not enough nuclear material in the sample
- PCR inhibitors such as ethanol and heparin
- Incorrect extraction
- Extraction system used is not compatible or has a step that eliminates RNaseP DNA

Note: Positive amplification in the INFA, INFB, or COVID-19 channel indicates a positive analyte result despite the lack of concurrent amplification in the IPC channel. The IPC amplification is dependent on the presence of human genomic DNA (gDNA) in the extraction 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, or cell lysates) may not contain the human RNaseP gene.

When this occurs, the results should be interpreted as invalid and re-testing by re-amplification should be performed. If the IPC fails again, then samples should be re-extracted and re-amplified. If it fails a third time an investigation should be conducted to identify possible causes for the error. If the cause for the error is clear, the test can either be singled out as invalid due to either PCR inhibitors being present or not enough nuclear material being present. If the cause for an error is unclear, contact Co-Diagnostics Inc. Technical Support by calling (801) 438-1036 ext. 02 or contact us at support@co-dx.com.

13.3.5 **No Template Control** Showing Amplification

13.3.5.1 Amplification of ABC in a No Template Control indicates contamination in one or more of the reagents, incorrect placement of plate or tube into the real-time PCR instrument, or pipetting errors.

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When this occurs, none of the results can be trusted and re-testing by re-amplification should be performed. If the NTC fails again, then an investigation should be conducted to identify possible causes for error, and the test must be 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 still failing, please contact Co-Diagnostics Inc. Technical Support by calling (801) 438-1036 ext. 02 or by visiting support@co-dx.com.

14 REFERENCES

Centers for Disease Control and Prevention. (2017, Oct 27). *CDC Laboratory Training: Good Laboratory Practices for Molecular Genetics Testing*. Retrieved Mar 5, 2019, from CDC: https://www.cdc.gov/labtraining/training-courses/good-lab-practices-molecular-genetics-testing.html

Poritz, M. A., & Ririe, K. M. (2014). Getting Things Backwards to Prevent Primer Dimers. *The Journal of Molecular Diagnostics, 16*(2), 159-162. doi:10.1016/j.jmoldx.2014.01.001

Satterfield, B. (2014, Mar). Cooperative primers: 2.5 million-fold improvement in the reduction of nonspecific amplification. *The Journal of Molecular Diagnostics, 16*(2), 163-173. doi:10.1016/j.jmoldx.2013.10.004

Viana, R. V., & Wallis, C. L. (2011). Good Clinical Laboratory Practices (GLCP) for Molecular Based Tests Used in Diagnostic Laboratories. In D. I. Akyar, *Wide Spectra of Quality Control* (pp. 29-52). InTech. Retrieved from http://www.intechopen.com/books/wide-spectra-of-quality-control/goodclinical-laboratory-practice-gclp-for-molecular-based-tests-used-in-diagnostic-laboratories

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15 LEGEND OF PACKAGE SYMBOLS

See Table 9 for the legend of package symbols.

Table 9

Legend of Package Symbols

Icon	Definition
REF	Catalog number
LOT	Batch Code
CAP	Cap color
COMP	Component
CONT	Content/Volume
NUM	Number
	Use-by-date
Σ X	Contains sufficient for X tests/ reactions X = 25 sample size X = 100 regular size
	Protect from light
	Temperature limit
	Consult Instructions for Use
NON STERILE	Non-Sterile product – Do not sterilize
	Manufacturer
RUO	Research Use Only

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