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Co-Dx

Instructions for Use for Logix Smart™ SARS-CoV-2

REF **COVID-R-002**

Logix Smart™ SARS-CoV-2 (COVID-R-002) 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™ SARS-CoV-2 (COVID-R-002) Research Use Only (**RUO**)** is a multiplex test, based on real-time polymerase chain reaction (qPCR) technology, for the simultaneous qualitative detection of SARS-CoV-2 (COVID-19) specific ribonucleic acid (RNA).

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

3 PRODUCT DESCRIPTION

The **Logix Smart™ SARS-CoV-2** 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™ SARS-CoV-2** RUO also includes a positive control (PC) which includes 3 synthetic RNA molecules carrying sequences that are homologous to the *RdRp* and *E* genes of *SARS*-CoV-2 (COVID-19) and are targeted by this multiplex assay. PCs represent a source of cross-contamination. Precautions should be taken to prevent and minimize risk.

CoPrimers™ in the **Logix Smart™ SARS-CoV-2** RUO include the following:

- CoPrimers™ that target the SARS-CoV-2 *E*-gene are labelled with the CAL Fluor® Orange 560 fluorophore
- CoPrimers™ that target SARS-CoV-2 *RdRp*-gene 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 RUO components.

Table 1

Logix Smart™ SARS-CoV-2 RUO Components

Lid Color	Component	Symbol	Catalog Number	Description	Amount
Brown	Logix Smart™ SARS-CoV-2 Master Mix	MM	COVID-MM- 002	Proprietary blend of CoPrimers™ and PCR reagents	1x500 µL (100 reactions) 1x1250 µL (250 reactions) 1x25000 µL (5000 reactions)
Red	Logix Smart™ COVID Positive Control	PC	COVID-PC- 002	Proprietary blend of target templates	1x500 µL (100 reactions) 1x1250 µL (250 reactions) 1x25000 µL (5000 reactions)
Clear	No Template Control	NC	COVID-NC-002	DNase/RNase-free water	1x500 µL (100 reactions) 1x1250 µL (250 reactions) 1x25000 µL (5000 reactions)

The **Logix Smart™ SARS-CoV-2 (COVID-R-002)** RUO product code is COVID-R-002. Contact Sales at (801) 438-1036 ext. 01 or at www.co-dx.com/contact/ to order.

5 STORAGE

Ensure the following during storage, handling, and disposal of this product:

- Contact your distributer for assistance if one or more of the components are not frozen upon arrival or are compromised during shipment. The **Logix Smart™ SARS-CoV-2** RUO is shipped on dry ice and the components of the RUO should arrive frozen.
- Follow internal procedures for quality control upon receipt of this RUO.
- Store all components immediately upon arrival at a temperature between -40°C and -16°C to prevent degradation of reagents.

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- Avoid repeated thawing and freezing of components (more than 4 times), specifically the master mix (MM), because doing so could affect the performance of the assay.
- Freeze the reagents in multiple aliquots if they are to be used intermittently.
- Do not store between +2°C and +8°C for more than 4 hours.
- Keep a back-up generator for your freezer as well as a temperature data log to ensure that the **Logix Smart™ SARS-CoV-2** RUO test remains frozen if you work in an area prone to power outages.
- Protect the MM from light.
- Do not use expired products, because the integrity of expired components cannot be guaranteed.
- See Safety Data Sheets (SDS) for hazard classification. The product is not a biological waste.
- When disposing, dispose of all components in accordance with applicable regional, national, and local laws and regulations.

6 MATERIALS REQUIRED BUT NOT INCLUDED

The following is a list of materials and devices that are required but are not provided:

- Appropriate 4-channel qPCR instrument, compatible with the fluorophores used in this test.
- Appropriate nucleic acid extraction system or RUO
- Vortex mixer
- Centrifuge with a rotor for 2 mL reaction tubes
- Pipettes (adjustable)
- Pipette tips with filters (disposable)
- Powder-free gloves (disposable)
- Ice
- Biosafety cabinet, ideally a BSL-2 facility

WARNING!

All instruments should be properly installed, calibrated, and maintained according to the manufacturer's instructions and recommendations. Do not use instruments with outdated calibration.

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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 REQUIRED BUT NOT INCLUDED

8.1 Thermocycler

Co-Diagnostics, Inc. can either directly, or through reagent rental programs, provide you with CoDx Box™ thermocycler machines (manufactured for Co-Diagnostics, Inc. by Bio Molecular Systems). **The Logix Smart™ SARS-CoV-2** 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™ SARS-CoV-2** 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 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 available for use with CoDx Box software in a windows-based operating system. The output device used with the CoDx Box thermocycler can be a printer or an 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™ SARS-CoV-2** 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™ SARS-CoV-2** RUO is the QIAamp Viral RNA Mini Kit, Qiagen, cat No. 52904 (50 preps) and cat No. 52906 (250 preps), and the QIAcube instrument.

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Other extraction kit options include the following:

- MagMax™ Viral/Pathogen Nucleic Acid Isolation kit
- MagMax™ Viral/Pathogen II Nucleic Acid Isolation Kit
- QuickGene Tissue II RNA kit, with KingFisher Flex and Myra instruments, (although no test Co-Diagnostics performance studies have been done with the current iteration of the **Logix Smart™ SARS-CoV-2** RUO)

Always use the most recent version of this document. More information that includes the latest study results can be downloaded for free at http://co-dx.com/resources/instructions-for-use/

9 WARNINGS AND PRECAUTIONS

WARNING!

Read this *Instructions for Use* 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 use of this product to personnel who are instructed and trained in the techniques of qPCR.
- Always treat samples as infectious and/or biohazardous material and use applicable standard precautions.
- Wear protective gloves, lab coat, and eye protection when handling samples. Always wear gloves when handling RUO components.
- Always use deoxyribonuclease (DNase)/ribonuclease (RNase)-free disposable pipette tips with filters.
- Use segregated working areas for sample preparation, reaction setup, and amplification/detection activities.
- Ensure the workflow in the laboratory proceeds in a unidirectional workflow. To prevent contamination, change personal protective equipment (PPE) between areas.
- Store and extract positive materials (specimens, 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.

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- Consult appropriate SDSs for safety. The SDS for the **Logix Smart™ SARS-CoV-2** RUO is provided with the shipment. If not provided with shipment the SDS can be retrieved from Co-Diagnostics website at 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 polymerase chain reaction (PCR) because this will not degrade the amplified nucleic acid and will pose a risk of the laboratory area to contamination.
- Do not use components of the RUO that have passed their 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

10.1 Sample Storage

Adhere to the following when storing samples:

- Only store specimens at a temperature between 2°C and 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).

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10.2 Sample Handling

Adhere to the following when handling samples:

- 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).

10.3 Sample Preparation

The quality of the extraction of the RNA from the samples is essential for the performance of **Logix Smart™ SARS-CoV-2**. Perform the extraction protocol by following the manufacturer's instructions or an internally validated protocol. The suitability of the nucleic acid extraction procedure for use with **Logix Smart™ SARS-CoV-2** must be validated by the user.

WARNING!

If your sample preparation system uses washing buffers that contain ethanol, ensure you 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 Real Time RT-PCR 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™ SARS-CoV-2** MM, PC, nuclease-free water (used as a no template control [NC]), and all sample tubes for 3 seconds.

11.1.1.4 Briefly spin the MM, PC, NC 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 NC,
- One for each sample you want to test, and
- One (or more) for each PC

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

PC	1
NC	1
Samples	5
Total wells required	**7**

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 NC into the appropriate wells (in addition to the 5 µL of MM already in the well).

Note: Ensure that at least one NC is included in each run and that enough space remains for at least one PC.

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 NC.
- Change pipette tips between samples and change pipette tips after pipetting each component.
- Pipet the PC last, if possible, to avoid contamination events.

11.1.2.4 Pipet 5 µL of sample or 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 RT-PCR instrument in the correct orientation and start the run.

11.2 Thermocycler Setup

11.2.1 Refer to the user manual for the respective instrument to obtain basic information regarding setup and programming of the different real-time PCR instruments.

11.2.2 Contact the Laboratory at (801) 438-1036 ext. 03 or at support@co-dx.com for programming instructions or questions regarding the use of other real-time PCR instruments.

11.2.3 Contact the Laboratory (801) 438-1036 ext. 03 or at support@co-dx.com for the template file to download if using Co-Diagnostics Inc. CoDx Box. The template file comes pre-programmed with the PCR instrument setup described in this section.

11.2.4 To achieve optimal performance when not using a template or using another device, ensure that the PCR instrument is compatible with the settings outlined in Table 2.

Table 2

PCR Instrument Settings

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

11.2.5 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	45	95˚C	3 seconds
			55˚C	32 seconds

11.2.6 Ensure that PCR instrument being used is compatible with fluorophores displayed in Table 4. Some devices may not have options for the quencher. If you need help or have questions, contact Co-Diagnostics Inc. Technical Support by calling (801) 438-1036 ext. 02 or emailing support@co-dx.com.

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Table 4

Fluorescence Detectors (dyes) Definitions

Target	Detector Name	Reporter	Quencher
COVID-19 (*RdRp gene)*	COVID-19 *RdRp* gene	FAM™	BHQ® - 1
COVID-19 (*E gene)*	COVID-19 *E* gene	CAL Fluor® Orange 560	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 real-time PCR instruments refer to the user manual of the respective instrument.

12.1 Positive and No Template Controls

12.1.1 Do the following to validate the test runs:

12.1.1.1 Ensure that both the PC and NC passed.

12.1.1.2 Ensure the control conditions displayed in Table 5 are met.

Table 5

Required Control Conditions

Control Type	Control Name	Purpose of Control	COVID-19 *RdRp gene* FAM channel	COVID-19 *E gene* CF560 channel	Internal Control (RNaseP) CF610 channel
COVID-19 Positive Control	COVID-19 *RdRp* (FAM™)	Verifies the performance of the master mix	+	+	+
	COVID-19 *E* (CF®560)				
	RNaseP IPC (CF®610)				
No Template Control	Master Mix + Water	Verifies the reagents are free of contamination	-	-	-

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12.1.1.3 If controls pass, interpret the sample results.

12.1.1.4 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, interpret the unknown samples for one of the following three possible outcomes:

- Positive
- Negative
- Invalid

A **Positive** result will show an amplification curve or cycle threshold value for either the COVID-19 *RdRp/E*. 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 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 will show no amplification for COVID-19 RdRp/E. The absence of a curve for COVID-19 RdRp/E 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.

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12.2.1.1 Use Table 6 to translate the results.

Table 6

Interpretation of Results

	Sample Result			Logix Smart™ SARS-CoV-2 Positive Control	No Template Control (NC) (Master Mix + Water)	Interpretation of Results
	COVID-19 RdRp (FAM™)	COVID-19 E (CF®560)	RNaseP IPC (CF®610)			
Instrument Reading	+	+	+	+	-	SARS-CoV-2 RNA +
	-	+	+	+	-	SARS-CoV-2 RNA +
	+	-	+	+	-	SARS-CoV-2 RNA +
	-	-	+	+	-	SARS-CoV-2 RNA -
	Any Result (+/-)		-	+	-	INVALID: See Troubleshooting
			+	-	-	
			+	+	+	

Amplification before 40 cycles is considered a positive reading (+). Amplification at or after 40 cycles is considered a negative reading (-).

When possible, check the medical history and/or symptoms to match the result before treatment.

13 TROUBLESHOOTING

Co-Diagnostics Inc. values customer feedback and we would like to be informed of any issues with the **Logix Smart™ SARS-CoV-2** RUO**,** even if the recommended steps for troubleshooting solve the issue. To give feedback, 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. It is not recommended to use expired RUO reagents, 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.

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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.

Users must do the following to help prevent user errors:

- Have experience in molecular biology and be familiar with proper pipetting technique to prevent errors such as splashes, crossover contamination, and errors on volume selection.
- Replace pipette tips must be after every pipetting.
- Replace gloves often.
- Calibrate equipment, such as pipettes and real-time PCR instruments, when applicable.

A 90-minute online training course for Good Laboratory Practices for Molecular Genetics Testing (Centers for Disease Control and Prevention, 2017) is available at the Centers for Disease Control (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™ SARS-Cov-2 PC Not Amplifying

No amplification from the PC could be the result of one or more of the following issues:

- Errors in pipetting (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™ SARS-CoV-2 MM** or **Logix Smart™ SARS-CoV-2 PC** degradation (a result of reagents being at temperatures above -16°C for an extended period)
- Use of expired reagents
- Use of the 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, 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

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the PC happens a third time after re-extraction and re-amplification, open a new **Logix Smart™ SARS-CoV-2** RUO PC or MM, and retest. If it is still failing, contact
Co-Diagnostics Inc. Technical Support by calling (801) 438-1036 ext. 02 or emailing support@co-dx.com.

13.3.2 The IPC RNAseP Not Amplifying in Samples

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

- Sample did not include enough nuclear material
- PCR inhibitors are present such as ethanol and heparin
- Extraction was performed incorrectly
- Extraction RUO used is not compatible or has a step that eliminates RNaseP DNA

Note: Positive amplification in the COVID-19 channel indicates a positive 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., cerebral spinal fluid, urine, cell lysates) may not contain the human RNaseP gene.

13.3.2.1 If no amplification occurs, do the following:

- Interpret the results as invalid and re-test using re-amplification.
- If the IPC fails again, re-extract samples and re-amplify.
- If the IPC fails a third time investigate to identify the 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 emailing support@co-dx.com.

13.3.3 No Template Control Showing Amplification

Amplification of COVID-19 *RdRp/E* 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. When amplification of a NC occurs, do the following:

13.3.3.1 Do not trust the results of the test.

13.3.3.2 Re-test by re-amplification.

13.3.3.3 If the NC fails a second time, investigate to identify possible causes for error and determine if reprocessing the test from extraction is needed (depending on the investigation results and risks identified in the process).

13.3.3.4 If the NC fails a third time after re-extraction and re-amplification, open a new nuclease-free water and retest.

13.3.3.5 If the NC fails a fourth time, contact Co-Diagnostics Inc. Technical Support by calling (801) 438-1036 ext. 02 or emailing support@co-dx.com.

14 REFERENCES

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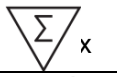
15 LEGEND OF PACKAGE SYMBOLS

A legend of package symbols is displayed in Table 7.

Table 7

Legend of Package Symbols

Icon	Description
	Catalog number
	Batch code
	Cap color
	Component
	Content/volume
	Number
	Use-by-date
	Contains sufficient for x 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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