



# LOGIX SMART CORONAVIRUS DISEASE 2019 (COVID-19)

## Packaging Information

COVID-K-001

Co-Diagnostics, Inc.  
[www.codiagnosics.com](http://www.codiagnosics.com)



TABLE OF CONTENTS

1 About the Company ..... 3

1.1 Manufacturer..... 3

1.2 European Representative ..... 3

2 About the Product Logix Smart™ Coronavirus Disease 2019 (COVID-19)..... 3

2.1 Device Description ..... 3

2.2 Components ..... 4

3 Labeling ..... 4

3.1 Primary packaging ..... 4

3.2 Secondary Packaging ..... 6

3.3 Tertiary Packaging ..... 8

4 References ..... 10



## 1 ABOUT THE COMPANY

Co-Diagnostics, Inc. (“Co-Diagnostics”, “CoDx,”), is a corporation headquartered in Salt Lake City, Utah. It is a molecular diagnostics company that develops, manufactures, and markets a patented, state-of-the-art diagnostics technology called CoPrimers™. The CoPrimer™ technology uses unique mathematical models instead of relying on costly laboratory infrastructure for development of the primers and probes used in its products.

### 1.1 MANUFACTURER



**Co-Diagnostics, Inc.**

2401 S Foothill Dr. Suite D

Salt Lake City, UT 84109

USA

Phone: +1 (801) 438-1036

Email: [info@codiagnostics.com](mailto:info@codiagnostics.com)

Website: [www.codiagnostics.com](http://www.codiagnostics.com)

### 1.2 EUROPEAN REPRESENTATIVE



**mdi Europa GmbH**

Langenhagener Str. 71

D-30855 Hannover – Langenhagen

Germany

Phone: +49 511 39 08 95 30

Email: [info@mdi-europa.com](mailto:info@mdi-europa.com)

Website: [www.mdi-europa.com](http://www.mdi-europa.com)

## 2 ABOUT THE PRODUCT LOGIX SMART™ CORONAVIRUS DISEASE 2019 (COVID-19)

### 2.1 DEVICE DESCRIPTION

The **Logix Smart Coronavirus Disease 2019 (COVID-19)** kit is an *in vitro* diagnostic test, based on real-time PCR (qPCR) technology, for the qualitative detection of the ribonucleic acid (RNA) from SARS-CoV-2 (COVID-19) in lower respiratory specimen (e.g. bronchoalveolar lavage, sputum, tracheal aspirate), upper respiratory tract (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



the WHO (WHO, 2020) and the US CDC (CDC, 2020) (e.g. fever, cough, shortness of breath, travel history to endemic areas).

## 2.2 COMPONENTS

*Table 2.1 Components of Logix Smart Coronavirus Disease 2019 (COVID-19)*

Product Code	Name	Description	Number of units per tube
<b>COVID-MM-001</b>	Logix Smart™ COVID-19 Master Mix	Ready-to-use mixture that includes a proprietary blend of buffers, Hot Start Taq polymerase, and labeled and unlabeled CoPrimers™.	100 reactions (500µL) or 250 reactions (1250µL)
<b>COVID-PC-001</b>	Logix Smart™ COVID-19 Positive Control	Mixture of synthetic SARS-CoV-2 RNA templates, and a DNA RNaseP template.	100 reactions (500µL) or 250 reactions (1250µL)
<b>GEN-NF-001</b>	Nuclease Free Water	Nuclease Free Water. Water Free of RNase (ribonuclease) or DNase (deoxyribonuclease) activity.	100 reactions (500µL) or 250 reactions (1250µL)

## 3 LABELING

### 3.1 PRIMARY PACKAGING

The following components are pieces of the primary packaging and appropriate labeling associated with the primary packaging of the Logix Smart™ Coronavirus disease 2019 (COVID-19) kit (COVID-K-001).

#### 3.1.1 Components



*Figure 8.1 Scientific Amber or Black 2mL Self Standing Master Mix*



*Figure 8.2 USA Scientific 2mL Clear with Red Cap Self Standing Positive Control Tube*



*Figure 8.3 USA Scientific Clear with Clear Cap Self Standing Nuclease Free Water Tube*

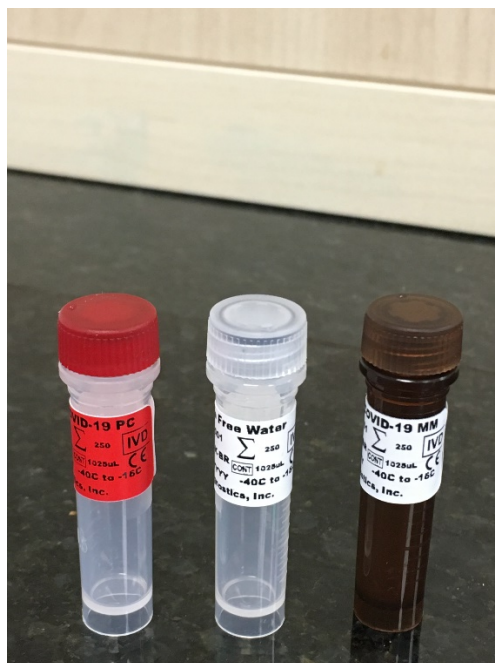


Figure 8.4 Labelled tubes for the Logix Smart Coronavirus Disease 2019 (COVID-19). 3 tubes of 2.0mL each containing from 500 $\mu$ L (100 reactions) to 1250  $\mu$ L (250 reactions) for Master Mix (COVID-MM-001), Positive Control (COVID-PC-001) and Nuclease Free Water (GEN-NF-001)

### 3.1.2 Primary Packaging Details

Self-standing microcentrifuge tubes with screw cap lids are RNase, DNase, DNA, and pyrogen free. The tubes can withstand up to 20,000 x g centrifugation, vapor-phase liquid nitrogen storage, boiling, and autoclaving. Each lid has an O-ring. The black or amber tube is used for the master mix due to the light sensitivity of the mixture. The red cap is used to help identify the positive control mix.

### 3.1.3 Labeling of Primary Packaging

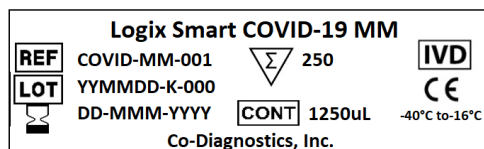


Figure 8.5 Labeling of Master Mix Tube, placed horizontally around 2mL Amber or Black Tube. Label will discriminate the total number of reactions. It will be 100 reactions with total volume of 500 $\mu$ L or 250 reactions with a total volume of 1250 $\mu$ L.

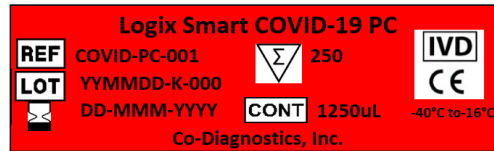


Figure 8.6 Labeling of Positive Control Tube, placed horizontally around 2mL Clear Tube with Red Cap. Label will discriminate the total number of reactions. It will be 100 reactions with total volume of 500 $\mu$ L or 250 reactions with a total volume of 1250 $\mu$ L.

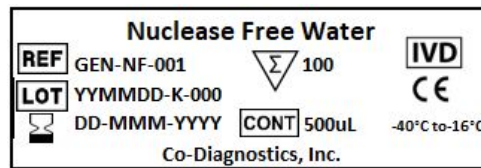


Figure 8.7 Labeling of Positive Control Tube, placed horizontally around 2mL Clear Tube with Red Cap. Label will discriminate the total number of reactions. It will be 100 reactions with total volume of 500 $\mu$ L or 250 reactions with a total volume of 1250 $\mu$ L.

### 3.1.4 Primary Packaging Labeling Details

The tubes have affixed labels that are resistant to water, cold, and heat. Permanent printing is utilized for each label.

## 3.2 SECONDARY PACKAGING

The following component is the secondary packaging of the Logix Smart COVID-19 (COVID-K-001):



### 3.2.1 Components



Figure 8.8 Utah Paper Box small, 5x4x1.5cm dimensions vial box, contains 3, 2mL self-standing tubes. Label will discriminate the total number of reactions. It will be 100 reactions with total volume of 500 $\mu$ L or 250 reactions with a total volume of 1250 $\mu$ L.

### 3.2.1 Secondary Packaging Details

The small box is made of pharmaceutical grade solid bleach sulfate (0.016) cardboard stock. The box is closed, and a Co-Diagnostics' logo sticker placed across the top





### 3.2.2 Labeling of Secondary Packaging



<b>Logix Smart COVID-19 Test Kit</b>	
<b>REF</b>	COVID-K-001
<b>COMP</b>	Master Mix  250
Positive Control	
Nuclease Free Water	
-40°C to -16°C	
 DD-MMM-YYYY	<b>IVD</b>
<b>LOT</b> YYMMDD-K-000	<b>CE</b>
Co-Diagnostics, Inc. 2401 S Foothill Drive, Ste. D Salt Lake City, UT 84109 USA	

Figure 8.9 Label for the front of the secondary packaging box, containing appropriate symbols. Label will discriminate the total number of reactions. It will be 100 reactions with total volume of 500µL or 250 reactions with a total volume of 1250µL.

<b>Logix Smart COVID-19 Test Kit</b> 	
	Co-Diagnostics, Inc. 2401 S. Foothill Drive Ste. D Salt Lake City, UT 84109 USA Phone: +1 (801) 438-1036 Email: info@codiagnostics.com Website: www.codiagnostics.com
<b>EC REP</b>	mdi Europa GmbH Langenhagener Str. 71 D-30855 Hannover-Langenhagen Germany Phone: +49 511 39 08 95 30 Email: info@mdi-europa.com Website: www.mdi-europa.com
	 -20°C  <b>IVD</b> <b>CE</b>

Figure 8.10 Contents Label placed on the back of the secondary packaging box. Indicates manufacturer name and contact information, as well as Authorized Representative in Europe name and contact information. Also, essential symbols.

### 3.2.3 Secondary Packaging Labeling Details

Name and contact information of manufacturer with product information and relevant symbols for handling and expiration date.

The secondary packaging can be sold separately by distributors.

## 3.3 TERTIARY PACKAGING

This box is used for better accommodation of product during distribution. Distributors will receive the 100 reactions and 250 reactions kits inside a tertiary box. Then distributors will sell the kits inside the secondary box to laboratories.





All boxes are made of pharmaceutical grade solid bleach sulfate (0.016) cardboard stock. The box is closed, and a Co-Diagnostics logo sticker is placed across the top.

### 3.3.1 Components



Figure 8.11 Utah Paper Box large, 5x6.5x4.24cm dimensions packaging box, contains 4 small boxes each containing 3 tubes

### 3.3.2 Tertiary Packaging Details

The large box is made of pharmaceutical grade solid bleach sulfate (0.016) cardboard stock. The box is closed, and a Co-Diagnostics' logo sticker is placed across the top.



### 3.3.3 Labeling of Tertiary Packaging

Logix Smart COVID-19 Test Kit		
COMP	NUM x CONT	
Master Mix	4 x 1250 µl	IVD
Positive Control	4 x 1250 µl	CE
Nuclease-Free Water	4 x 1250 µl	Σ 250
YYYY-MM-DD	REF COVID-K-001	LOT YYMMDD-K-XXX

Figure 8.12 Contents Label placed on the front of the large packaging box. Indicates cap color, number of tubes, and volume of tubes contained within. Also indicates kit expiration, kit reference ID number, and lot number. Label will discriminate the total number of reactions. It will be 100 reactions with total volume of 500µL or 250 reactions with a total volume of 1250µL.

### 3.3.4 Tertiary Packaging Labeling Details

Tertiary packaging has two labels, one in the front and the second in the back. These labels contain product name, description, handling information and symbols. Name and full contact information for the manufacturer and European Representative.

## 4 REFERENCES

- 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>

Document Revision History		
Revision Number	Month & Year of Revision	Changes
00	March 2020	New Document