



LumiraDx SARS-CoV-2 RNA STAR



Product Insert

SPEC-30130 Rev1

ART-00048 Rev1

For Research Use Only (RUO)

Not for use in diagnostic procedures

Summary and Explanation

LumiraDx SARS-CoV-2 RNA STAR has been designed to detect ORF1a genes from nucleic acid sequences from the genome of the SARS-CoV-2 RNA. LumiraDx SARS-CoV-2 RNA STAR reagents are for research use only and not for use in diagnostic procedures.

Procedure/interpretation/limitations

For the RUO version of the LumiraDx SARS-CoV-2 RNA STAR Instructions for Use, users should refer to the website or contact LumiraDx by email at: customerservices.US@lumiradx.com.

Package contents

Component	Description	Amount	Storage
LumiraDx SARS-CoV-2 RNA STAR Master Mix	COVID-19 Master Mix	1.0mL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR 50X Internal Control & Primer Mix (50X IC/P Mix)	COVID-19 Internal Control & Primer Mix	50µL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR 10X Salt Mix	COVID-19 Salt Mix	250µL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR Positive Extraction Control (Pos. Ext. Ctrl.)	COVID-19 Positive Control (ZeptoMetrix 50,000cp/mL)	0.5mL	2°C to 8°C (-25°C to -15°C)
LumiraDx SARS-CoV-2 RNA STAR Negative Extraction Control (Neg. Ext. Ctrl.)	Molecular Grade Water	1.5mL	-25°C to -15°C

Storage instructions

Upon receipt, store Master Mix, 50X IC/P Mix, 10X Salt Mix and Neg. Ext. Ctrl. at ≤ -15 °C; store Pos. Ext. Ctrl. at 2 °C to 8 °C. Refer to the LumiraDx SARS-CoV-2 RNA STAR Instructions for Use before opening and preparing reagents for use.

Precautions

The Controls should be handled in an approved BSL-2 handling area to avoid contamination of laboratory equipment and reagents that could cause erroneous results. This Test is non-infectious. However, this Test should be handled in accordance with Good Laboratory Practices.

Reagent complaints/questions

If you have a question/comment about this product, please contact LumiraDx by email at customerservices.US@lumiradx.com. Please include "RUO LumiraDx SARS-CoV-2 RNA STAR" in the subject line.

For return policy

If there is a problem with LumiraDx SARS-CoV-2 RNA STAR you may be asked to return the item. Before returning, please obtain a return authorization number from LumiraDx Customer Services (customerservices.US@lumiradx.com). This return authorization number must be on the shipping carton for return. For ordinary returns following purchase, please contact LumiraDx Customer Services for terms and conditions.

Limited warranty

LumiraDx SARS-CoV-2 RNA STAR – As per shelf life. Unused Tests must be stored according to the required storage conditions as printed in this product insert and they can be used only up to the expiry date printed on packaging. For the applicable warranty period, LumiraDx warrants that each product shall be (i) of good quality and free of material defects, (ii) function in accordance with the material specifications referenced in the product insert, and (iii) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). If the product fails to meet the requirements of the limited warranty, then as customer's sole remedy, LumiraDx shall either repair or replace, at LumiraDx's discretion, the Test. Except for the limited warranty stated in this section, LumiraDx disclaims any and all warranties, express or implied, including but not limited to, any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. LumiraDx's maximum liability with any customer claim shall not exceed the net product price paid by the customer. Neither party shall be liable to the other party for special, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result. The Limited Warranty above shall not apply if the customer has subjected LumiraDx SARS-CoV-2 RNA STAR to physical abuse, misuse, abnormal use, use inconsistent with product insert provided, fraud, tampering, unusual physical stress, negligence or accidents. Any warranty claim by customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

Intellectual property

The LumiraDx Test and all provided LumiraDx documentation ('Products') are protected by law. The Intellectual Property of the LumiraDx Products remains at LumiraDx. Details of relevant Intellectual Property regarding our products can be found at lumiradx.com/IP.

Legal notices

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Manufacturer information

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LumiraDx US Office

221 Crescent St, Suite 502, Waltham, MA 02453. Telephone: (617) 621-9775.

Symbols Glossary



Temperature limitation



Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used.



Manufacturer



Refer to instructions for use.



Research Use Only - Not for use in diagnostic procedures



Date of Manufacture



Catalog Reference Number



Contains sufficient reaction for 100 Tests



Lot Number/Batch Code
