



LumiraDx SARS-CoV-2 RNA STAR

IVD

Product Insert SPEC-30077 Rev1 ART-00003 Rev3
For *in vitro* diagnostic use Emergency Use Authorization (EUA) only Rx Only

Intended use

LumiraDx SARS-CoV-2 RNA STAR is a non-isothermal nucleic acid amplification qSTAR (Selective Temperature Amplification Reaction) method intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal and oropharyngeal swabs) and bronchoalveolar lavage specimens collected from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories - certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 USC. §263a that meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

LumiraDx SARS-CoV-2 RNA STAR is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. LumiraDx SARS-CoV-2 RNA STAR is only for use under the Food and Drug Administration's Emergency Use Authorization.

Procedure/interpretation/limitations

Users should refer to the LumiraDx SARS-CoV-2 RNA STAR Instructions for Use posted on the FDA website for all IVD products used under Emergency Use Authorization, <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>.

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 false positive results. This Test is non-infectious. However, this Test should be handled in accordance with Good Laboratory Practices.

This Test has not been FDA cleared or approved; this Test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform high complexity tests.

This Test has been authorized only for the qualitative detection of nucleic acids from SARS-CoV-2 and not for any other viruses or pathogens.

This Test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Reagent complaints/questions

If you have a question/comment about this product, please contact LumiraDx by email at customerservices.US@lumiradx.com. Please include "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 Tests 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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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.
	In Vitro Diagnostic Product		Date of Manufacture
	Catalog Reference Number	100 Rxns	Contains sufficient reaction for 100 Tests
	Lot Number/Batch Code	Rx Only	Prescription Use Only

References

1. World Health Organization www.who.int.
2. Centers for Disease Control and Prevention www.cdc.org.