

Urgent Field Safety Notice

SBN-RDS-POC-2021-010

RDS/ Point of Care / cobas® Liat®
Version 1

Discontinue Use of cobas® Liat® SARS-CoV-2 & Influenza A/B Lot 10119Z Due To Unexpected SARS-CoV-2 Positive Results

Product Name	cobas® SARS-CoV-2 & Influenza A/B Test for use on the cobas® Liat® System
GMMI / Part No	GMMI: 09211101190
Device Identifier	Device Identifier: 00875197006360
Production Identifier (Lot No./Serial No.)	Lot 10119Z
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Roche has received an increased number of complaints from customers when using **cobas® SARS-CoV-2 & Influenza A/B Test** for use on the **cobas® Liat® System**, lot 10119Z. Customers are alleging an increased number of initial positive SARS-CoV-2 results that were negative upon retests on the same platform and/or on other platforms. Investigative testing using returned kits from the field generated an unexpected SARS-CoV-2 positive rate of 7% with known negative samples.

For false positive SARS-CoV-2 results, there is a remote probability of adverse health consequences in high risk individuals:

- A false positive SARS-CoV-2 result may lead to a decision to cohort the tested individual with other COVID-19 positive individuals. If infection control measures are not comprehensive, cohorting may lead to SARS-CoV-2 exposure that could then further result in COVID-19 infection with potentially harmful sequelae. However, effective infection control programs should be associated with an overall low risk of hospital-acquired COVID-19 infection (Rhea et al. PMID: 32902653).
- Inappropriate treatment for COVID-19 could lead to worse outcomes from the true underlying cause of disease, such as could be the case with the administration of immunosuppressive medications in an individual with an underlying bacterial respiratory infection. Targeted COVID-19 treatments are generally well-tolerated and clinicians may keep a high suspicion for alternative etiologies or even treat empirically (such as with antibiotics) in cases of severe illness (Berlin et. al. PMID: 32412710). As per the Instructions for Use: 1) Clinical

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correlation with patient history and other diagnostic information is necessary to determine patient infection status, and 2) The agent detected may not be the definite cause of disease. Considering the involved hazards of the issue, there is a remote probability that use of the affected reagent lot will lead to adverse events in populations at greatest risk for infectious complications due to false positive SARS-CoV-2 results. Adverse health consequences are otherwise not likely.

Actions taken by Roche Diagnostics (if applicable)

Roche is requesting that customers and affiliates immediately discontinue the use of and discard any remaining inventory of the **cobas[®] SARS-CoV-2 & Influenza A/B Test** for use on the **cobas[®] Liat[®] System**, lot 10119Z.

Root Cause investigation is on-going. To date, no other lots of **cobas[®] SARS-CoV-2 & Influenza A/B test** have generated similar complaint rates comparable to that of Lot 10119Z. Investigative testing on additional lots manufactured during the same period of time as the affected kit lot 10119Z, did not generate unexpected SARS-CoV-2 positive results with known negative samples.

Actions to be taken by the customer/user

Customers should immediately discontinue the use of and discard any remaining inventory of the **cobas[®] SARS-CoV-2 & Influenza A/B Test** for use on the **cobas[®] Liat[®] System**, lot 10119Z.

For handling previous positive results generated with the **cobas[®] SARS-CoV-2 & Influenza A/B Test** for use on the **cobas[®] Liat[®] System**, lot 10119Z:

- Customers should follow their laboratory standard operating procedures to investigate the potential for false positive results.
- Customers may perform repeat testing using other **cobas[®] SARS-CoV-2 & Influenza A/B** lots or an alternative platform to confirm suspected false positive results.

Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied. (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact. (If appropriate).

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate).>

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

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Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com

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Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.