

Urgent Field Safety Notice

SBN-RMD-2020-002

RDS/MolecularLab/**cobas**[®] 4800
Version 2

UPDATE **cobas z 480** dirty lens: Potential for invalid or false positive results

Product Name	cobas z 480 analyzer
GMMI / Part No	GMMI: 05200881001
Device Identifier	Device Identifier : 04015630929016
Production Identifier (Lot No./Serial No.)	Not Applicable
SW Version	Not Applicable
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

Roche is pleased to announce the availability of the Maintenance Checker software for the **cobas z 480** analyzer, which must be installed on all **cobas z 480** analyzers running any **cobas**[®] 4800 assay in the IVD workflow. This service tool aids in identifying conditions that could contribute to the generation of false positive results due to dirty optical lenses and spatial cross-talk. Stringent criteria have been established to identify a dirty lens before false positive results are generated.

The software extracts the raw data from the instrument's problem reports, which are automatically created by the system. If the tool calculates that the spatial crosstalk between the control and neighboring wells is too high, a pop up message will inform the user to call their local Roche service representative to schedule a cleaning of the unit's optical lens. As the Maintenance Checker calculates the spatial cross-talk every 7 days, using data from the last 10 test runs, the pop up message might appear again (one time) if less than 10 runs have been performed since the lens had been cleaned. If the pop up message continues to be generated, local Roche service representatives should be contacted for further service actions.

Important: assays utilizing the LightCycler[®] 480 software or the **cobas**[®] 4800 User Defined Software (UDF) are out of scope as they utilize a different algorithm than the affected IVD assays and are intended for research use only or general laboratory use, respectively, and not for diagnostic purposes. These customers have the ability to analyze raw data and review the displayed curves, where baseline shifts and false results would be detectable.

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Actions taken by Roche Diagnostics (if applicable)

Local Roche service representatives will be installing the Maintenance Checker software at their next scheduled site visit or will schedule a visit as needed. Installation of the Maintenance Checker is mandatory and must be completed by 18-Oct-2022.

Actions to be taken by the customer/user

If after installation of the Maintenance Checker software, the pop up message repeatedly appears on the instrument's Control Unit, please contact your local Roche service representative as instructed.

Contact your local affiliate organization if there is any allegation of invalid or false positive results with the **cobas**[®] 4800 system assays.

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:

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