Quality Notification

MY- QN-RDS-MolecularLab-2024-031

RDS / Molecular Diagnostics
Amal Safiyyah
Version 1
05-Apr-2024

Discontinue use of select cobas® HCV GT Control Kits

Product	GMMI	Lot
KIT COBAS 4800 HCV GT CTLS 10T CE-IVD	06984339190	J30965, K06929 and K09615

Instrument/System	cobas® x 480 instrument cobas® z 480 analyzer
Component	Reagent
Target Group	Application
Details	Customer Information Customer Action
Feedback Due Date	01-Jul-2024

Discontinue use of select cobas® HCV GT Control Kits

Dear Valued Customer,

Executive Summary

Multiple complaints were received reporting positive control invalids while using select lots of the cobas® 4800 HCV GT test.

Previously, QN-RDS-Molecular Lab-2023-044 was released for this issue, instructing affiliates and customers to discontinue use of the cobas® 4800 System Sample Preparation Kit 2, lot J16283, which was noted to have been used by several customers reporting the invalid positive controls. Through the CAPA investigation, the root cause was ultimately determined to be related to the cobas® HCV GT Control Kits themselves, with the cobas® 4800 System Sample Preparation Kit 2, lot J16283 acting as a contributing factor.

Roche is requesting that customers discontinue use of and that customers and affiliates discard any remaining inventory of the cobas® HCV GT Control Kit lots J30965, K06929 and K09615, immediately.

Subject

Multiple complaints were received reporting positive control invalids while using the cobas® 4800 HCV GT test. Review of available customer data showed an increase in invalid runs due to invalid positive controls associated with an R20 failure mode.

Previously, QN-RDS-MolecularLab-2023-044 was released for this issue, while investigating the cobas® 4800 System Sample Preparation Kit 2, lot J16283 as the suspected cause. Additional internal investigative testing was performed through CAPA 290009116 and the root cause was determined to be related to the cobas® HCV GT Control Kits, with the cobas® 4800 System Sample Preparation Kit 2 being a contributing factor.

Roche is requesting that customers discontinue use of any remaining inventory of the cobas® HCV GT Control Kits J30965, K06929 and K09615, and discard any remaining inventory immediately.

Root Cause

The root cause was determined to be due to a drift in concentration of the Positive Control (PC) over time, caused by aging of the PC stock material and of the calibrators used in QC. The drift in the concentration of the PC stock material and calibrators, which are made from the same stock material, was slow and took several years to materialize into a performance issue in the field.

A contributing factor was determined to be the cobas® 4800 Sample Preparation 2 240T CE-IVD reagent kit lot J16283, which when used together with the cobas® HCV-GT test, caused the target Ct values to shift by approximately 1 Ct cycle (as previously described in QN-RDS-MolecularLab-2023-044). Although this effect is typical variability, for a PC with a low concentration, it increased the numbers of PC invalids as reported in the escalated cases.

Discontinue use of select cobas® HCV GT Control Kits

Risk Assessment

Frequency of Occurrence
Positive control invalids while using the cobas® 4800 HCV GT test has been escalated through 53 global complaints to date.

Detectability
The issue is highly detectable as the affected run will generate an R20 failure code for the cobas® 4800 HCV GT test positive control, which will invalidate the entire run.

Severity
No patient or diagnostic test results are affected as the affected cobas® 4800 HCV GT test will be invalidated. As the HCV GT assay is not intended for diagnostic use, there is no risk in the delay of diagnosis. Patients being tested have already been diagnosed with HCV. Since HCV is a slow progressing disease, it would not have clinical implications and because there is no valid result generated, the test would be repeated. Therefore, medical risk to patients and users can be excluded.

As a result, an HHE is not required

Actions

Discard any remaining cobas® HCV GT Control Kit lots J30965, K06929 and K09615.
Provide the number of discarded kits and the lot number in the acknowledgment receipt.

Contact

If you have any questions, please do not hesitate to contact your sales representative or our Customer Call Centre: **1800 88 8881**

Thank you.

Best regards,
ROCHE DIAGNOSTICS (M) SDN. BHD.

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Discontinue use of select cobas® HCV GT Control Kits

Customer Acknowledgement Receipt

Roche Diagnostics Malaysia
Fax Back: +603 7967 2399
Email: malaysia.diagnostics@roche.com

Attention: Customer Support Team

I acknowledge I have received notification on **"Discontinue use of select cobas® HCV GT Control Kits"** and will proceed as per recommended action.

Quantity of affected lot discarded.

Lot Number	**Number of kit discarded**
J30965	Not distributed in Malaysia
K06929	
K09615	

Thank you.

_____

Name:

Organization:

Stamp:

Date: