

Quality Notification

MY-QN-RDS-Molecular Lab-2024-033

RDS / Molecular Diagnostic

Nadzirah Md Akhir

Version 1

18-Jun-2024

Potential leakage of select lots of cobas® HBV and cobas® CMV tests for use on the cobas® 5800/6800/8800 Systems

Product	GMMI	Lot no.
KIT COBAS 58/68/8800 HBV 192T IVD	09040820190	K16824
KIT COBAS 58/68/8800 CMV 192T IVD	09040897190	K21440

Instrument/System	HBV quant.
	CMV quant.

Feedback Due Date	20-Sep-2024
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Dear Valued Customer,

Executive Summary

An Internal investigation identified that two (2) kit lots were associated with reagent leakage: the cobas® HBV test for use on the cobas® 5800/6800/8800 systems, lot K16824 and the cobas® CMV test for use on the cobas® 5800/6800/8800, lot K21440.

Therefore, customers are requested to visually inspect the kits prior to usage as per the Reagent Handling section of the respective test specific Method Sheet: "Before use, visually inspect each reagent cassette, diluent, lysis, reagent, and wash reagent to ensure that there are no signs of leakage. If there is any evidence of leakage, do not use that material for testing." Customers should dispose of any leaking reagent cassettes identified.

Subject

It was internally identified that the aforementioned kits were associated with possible reagent leakage.

The investigation determined that leaking reagents could cause invalid results when there is an insufficient volume in the reagent vessel.

The aforementioned kit lots, K16824 and K21440, met Quality Control (QC) release specifications prior to



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distribution. Roche performed additional inspections of the remaining inventory of the affected kit lots and discarded kits that showed signs of leakage. Roche is actively working on adding stock to our internal supply to prevent any future potential stock issues.

Therefore, customers are requested to visually inspect the kits prior to usage as per the Reagent Handling section of the respective test specific Method Sheet: "Before use, visually inspect each reagent cassette, diluent, lysis, reagent, and wash reagent to ensure that there are no signs of leakage. If there is any evidence of leakage, do not use that material for testing." Customers should dispose of any leaking reagent cassettes identified.

Root Cause

Roche has initiated a root cause investigation. Corrective and preventive actions will be implemented as appropriate.

Risk Assessment

Low or empty reagent volume can result in system-generated invalid flags; the error codes produced invalidate the run so that no erroneous results can be generated.

Frequency of Occurrence

No escalated cases have been filed against these lots for this issue. The issue was internally identified and kits found to be leaking were discarded.

Detectability

Low or empty reagent volume results in system-generated invalid flags and is highly detectable by the user.

Severity

No patient or diagnostic test results are affected and a medical risk to patients and users can be excluded.

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Action Required/Important Information

1. Visually inspect the kits prior to usage as per the Reagent Handling section of the respective test specific Method Sheet.
2. If there is any evidence of leakage, do not use that material for testing. Please dispose of any leaking reagent cassettes identified.
3. Submit the "Request for Complimentary Kit" via your electronic feedback on this Quality Notification where necessary.
4. By responding to the feedback, you will acknowledge that you have received the notification on 'Potential leakage of select lots of cobas® HBV and cobas® CMV tests for use on the cobas® 5800/6800/8800 Systems' of MY-QN-CPS-2024-033 and will proceed to perform the instructions as listed in MY-QN-CPS-2024-033.

Please submit your electronic feedback on this Quality Notification within 2 business days to acknowledge your reading and understanding of this notice.

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

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.



Nadzirah Md Akhir
MS Marketing Partner
Email: nadzirah.md_akhir.nm1@roche.com
Tel. +603-7967 2388



Ong Yean Ting
Head, Quality and Regulatory
Email: yeon_ting.ong@roche.com
Tel: +60 3 7967 2388