

Invalid Positive Control due to Aspiration Errors

Quality Notification

MY-QN-RDS-MolecularLab-2025-109

RDS / Molecular Diagnostics

Nadzirah Md Akhir

Version 1

09-Sep-2025

Invalid Positive Control due to Aspiration Errors

Product	GMMI	Lot No
KIT COBAS 58/68/8800 HBV/HCV/HIV RMC IVD	09040773190	M21098
Instrument/System	HCV quant.	
Feedback Due Date	22-Sep-2025	

Dear Valued Customer,

Executive Summary

To prevent potential aborted runs, Roche requests that customers visually inspect the individual control tubes from the **cobas® HBV/HCV/HIV-1 Control Kit, Lot M21098**. Any cassette that appears to have defective tubes should be discarded prior to use. This lot has been associated with an elevated number of complaints regarding aspiration error flags with the Low (+) Control (L+ control) on the **cobas® 5800/6800/8800 System**.

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Subject

Roche has received an increased number of customer complaints about invalid or aborted runs due to an aspiration error flag when using the L+ control from the cobas® HBV/HCV/HIV-1 Control Kit, Lot M21098. A preliminary investigation has identified that some individual control tubes within this lot may be defective, causing aspiration errors. The **defective control tubes have a flat bottom**, while normal control tubes have a conical bottom. These errors will appear as a **PO2T flag** with the cobas® 6800/8800 systems and **P08T** with the cobas® 5800. Please reference Figure 1 for comparison of normal control tubes versus defective control tubes.



Figure 1: The top two tubes are considered defective (flat bottom). The bottom six tubes are nondefective (conical).

Root Cause

Roche has initiated a root cause investigation, which is ongoing. Corrective and preventive measures will be implemented as appropriate.

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Risk Assessment

- **Frequency of Occurrence:**

An increased number of customer complaints have been received regarding invalid and/or aborted runs involving the cobas® HBV/HCV/HIV-1 Control Kit, Lot M21098.

- **Detectability:**

The issue is **highly detectable**. Affected runs are automatically flagged with an aspiration error and invalidated by the cobas® 5800/6800/8800 System due to a failure of the L+ positive control.

- **Severity:**

No patient or diagnostic test results are affected, and a medical risk to patients and users can be excluded. Erroneous results are not generated, as affected run batches are automatically invalidated. The primary impact is the need for repeat testing and the associated operational inconvenience.

Action Required/Important Information

1. **Visually inspect** each control tube from Lot M21098 before loading the cassette onto the system.
2. If there is any evidence of tubes appearing to be defective with a flat bottom, **discard the entire reagent cassette**.
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 MY-QN-RDS-MolecularLab-2025-109 Invalid Positive Control due to Aspiration Errors and will proceed to perform the instructions as listed in MY-QN-RDS-MolecularLab-2025-109 Invalid Positive Control due to Aspiration Errors.

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.

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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.

A handwritten signature in black ink, appearing to read "Nadzirah".

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

A handwritten signature in black ink, appearing to read "Ong Yean Ting".

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

Customer Acknowledgement Receipt

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

Attention: Molecular Diagnostics Team

I acknowledge I have received notification on Invalid Positive Control due to Aspiration Errors on cobas®
5800/6800/8800 System.

Thank you.

Name:

Organization:

Stamp:

Date: