



Quality Notification

MY-QN-RDS-MolecularLab-2026-105

RDS / Molecular Diagnostics

Nadzirah Md Akhir

Version 1

7-Aug-2026

Deformed cobas omni Processing Plate 24 on cobas® 5800

Product	GMMI	Lot No
cobas omni Processing Plate 24	08413975001	25007504
cobas omni Processing Plate 24	08413975001	25009504
cobas omni Processing Plate 24	08413975001	25010504
cobas omni Processing Plate 24	08413975001	25011504
cobas omni Processing Plate 24	08413975001	25013504
cobas omni Processing Plate 24	08413975001	25014504
cobas omni Processing Plate 24	08413975001	25102504
cobas omni Processing Plate 24	08413975001	25103504
cobas omni Processing Plate 24	08413975001	25105504

Instrument/System	cobas® 5800 system
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Component	Consumables
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Target Group	Application Service
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Details	Customer information Customer Action
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Feedback Due Date	21-AUG-2026
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Deformed cobas omni Processing Plate 24 on cobas® 5800

Dear Valued Customer,

Executive Summary

This notification is to inform customers of defective plates identified in select lots of the cobas omni Processing Plate 24. Specific consumables exhibit curved sides, which prevent accurate positioning on the cobas® 5800 instrument deck, consequently causing hardware-related issues or the generation of invalid test results. The affected lots are listed in this document, as well as the required actions for customers.

A comprehensive investigation has been launched by Roche to determine the underlying root cause, and initial data suggests that this occurrence is not confined to any particular production lot.

Subject

Customer complaints were escalated reporting deformed cobas omni Processing Plate 24 consumables used in conjunction with the cobas® 5800 System. The affected plates show inward curved margins, which prevent correct placement on the separation station and heating station of the cobas® 5800 instruments (see Figure 1).



Figure 1: Right: Examples of a defective cobas omni Processing Plate 24. Left: Image showing defective plates incorrectly positioned within the processing station.

Deformed cobas omni Processing Plate 24 on cobas® 5800

Due to this structural irregularity, these consumables fail to remain level in their designated position. The cobas® 5800 system lacks the capability to detect such structural deformation in the plates during the loading.

Consequently, the processing will start and proceed until the consumable is positioned on the separation station. At that point of the process, the misalignment leads to run abort and/or invalid test results. Specifically, the following flags and errors have been observed:

- **Invalid with P07P flags** with specific pattern (multiple samples invalid in the same processing plate, all placed along the same rows or columns).
- **Y16-flags** (mechanical error of the process transfer head) denoting hardware-related problems at the processing transfer head.
- **Processing transfer head force control error** (*ErrorCode: 0x0303 / CDI: 0x00102100 / HD24: The start value is under the defined lower limit. Sensor may be defective*).

An investigation has been initiated at the supplier. It was confirmed that this occurrence is limited to specific manufacturing lots, which are listed in the “Instructions” section below.

A Non-Conformance was opened, and the supplier initiated an investigation to determine the root cause and a corrective and preventive action plan. The production has been stopped at the supplier and it will be resumed as soon as the corrective actions are implemented. Moreover, the affected lots have been put in quality hold at the APAC gateway since further investigation is on-going. The supply of Processing Plate 24 is guaranteed and a stockout situation is not anticipated.

Root Cause

Although the investigation is still on-going, the cause of the deformation is related to unexpected temperature fluctuation in a specific step of the processing plates manufacturing.

Risk Assessment

Frequency of Occurrence

A few escalated complaints have been reported as of the date of publishing of this notification.

Deformed cobas omni Processing Plate 24 on cobas® 5800

Detectability

The deformation is difficult to detect when observing the consumable. Additionally, the cobas® 5800 system has no capability to detect such structural deformation in the plates during the loading phase.

Severity

The usage of bent cobas omni Processing Plate 24 may cause run aborts and invalid sample results. No results discrepancy may occur. A Health Hazard Evaluation is not required.

Action Required/Important Information

Discontinuation of use

Customers are requested to discontinue the usage of the cobas omni Processing Plates 24 lots listed in Table 1 and discard immediately.

Processing Plate 24 lots to be discontinued
25007504
25009504
25010504
25011504
25013504*
25014504*
25102504*
25103504*
25105504*

Table 1: List of cobas omni Processing Plate 24 lots that require immediate discontinuation. Lot numbers designated with an asterisk (*) have already been escalated via global complaint investigations.



Deformed cobas omni Processing Plate 24 on cobas® 5800

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

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

By responding to the feedback, you will acknowledge that you have received the notification on MY-QN-RDS-MolecularLab-2026-105 Deformed cobas omni Processing Plate 24 on cobas® 5800 and will proceed to perform the instructions as listed in MY-QN-RDS-MolecularLab-2026-105 Deformed cobas omni Processing Plate 24 on cobas® 5800.

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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