

January 2024

**URGENT PRODUCT CORRECTION NOTIFICATION**  
**Potential For Aspiration From an Incorrect Sample Container During Sampling Centre Processing on VITROS® 3600 Immunodiagnostic Systems and VITROS® 5600/XT 7600 Integrated Systems**

Dear Distributor,

This notification is to inform you that the VITROS® Systems listed below may experience an anomaly involving the Sampling Centre, which may have been manufactured using a sub-optimal hardware part. For a list of potentially impacted serial numbers, see Appendix 1: "Potentially Impacted Serial Numbers" found at the end of this notification.

Affected Systems	Product Code (Unique Device Identifier)
VITROS 3600 Immunodiagnostic System	6802783 (10758750002979)
VITROS 3600 Immunodiagnostic System (Refurbished)	6802914 (10758750007103)
VITROS 5600 Integrated System	6802413 (10758750002740)
VITROS 5600 Integrated System (Refurbished)	6802915 (10758750007110)
VITROS XT 7600 Integrated System	6844461 (10758750031610)

**REQUIRED ACTIONS**

- Send the enclosed customer letter and customer Confirmation of Receipt form to all of your customers who have been shipped a VITROS System with the potentially impacted serial numbers (See Appendix 1).
- Acknowledge your understanding of this notification by completing the enclosed distributor Confirmation of Receipt form no later than **6 February 2024**.
- Please forward this notification if the VITROS Systems with the potentially impacted serial numbers were distributed outside your facility.

**Contact Information**

We apologise for any inconvenience this may cause your facility. If you have further questions, please contact your local QuidelOrtho representative or our Global Services Organisation.

Sincerely,



Kevin Davies  
Regional Product Support Manager (ASEAN & Korea)

Enclosures:

1. Customer letter (Ref. CL2024-014dm)
2. Customer Confirmation of Receipt form (Ref. CL2024-014\_Conf)
3. Distributor Confirmation of Receipt form (Ref. 2024-014 Reply Form)
4. FSCA Update Form (Ref. 2024-014 FSCA Update)

**Appendix 1: Potentially Impacted Serial Numbers**

VITROS System	Potentially Impacted Serial Numbers
VITROS 3600 Immunodiagnostic System	J36001164 through J36001692 (inclusive)
VITROS 5600 Integrated System	J56003170 through J56004741 (inclusive)
VITROS 5600 Integrated System*	J56000280, J56000330, J56000415, J56000631, J56000634, J56000721, J56000839, J56000871, J56001088, J56001209, J56001228, J56001265, J56001305, J56001355, J56001834, J56001855, J56001941, J56001998, J56002111, J56002239, J56002476, J56002492, J56002531, J56002561, J56002649, J56002655, J56002658, J56002691
VITROS XT 7600 Integrated System	J76000109 through J76001913 (inclusive)

**\*These specific VITROS 5600 Systems are impacted due to a service event involving the Sampling Center. Each number listed identifies an individual VITROS 5600 System.**