

August 2023

URGENT PRODUCT CORRECTION NOTIFICATION
Out of Specification Proboscis/Piston Assembly for
VITROS 5,1 FS/XT 3400/4600 Chemistry Systems, VITROS 3600
Immunodiagnostic Systems, VITROS 5600/XT 7600 Integrated
Systems May Not Perform as Intended

Dear Distributor,

The purpose of this notification is to inform you of an issue affecting the Proboscis/Piston Assembly, which is a component used in various VITROS® Systems to aspirate and dispense reagent or sample fluids. Due to a manufacturing issue, some Proboscis/Piston Assemblies manufactured between 07-Apr-2022 and 19-Dec-2022 may not perform as intended.

Impacted Systems	Product Code (Unique Device Identifier)	Part No.
VITROS 5,1 FS Chemistry System	6801375 (10758750001132)	J55375
VITROS 5,1 Chemistry System (Refurbished)	6801890 (10758750001644)	
VITROS 3600 Immunodiagnostic System	6802783 (10758750002979)	
VITROS 3600 Immunodiagnostic System (Refurbished)	6802914 (10758750007103)	
VITROS 4600 Chemistry System	6802445 (10758750012343)	
VITROS 4600 Chemistry System (Refurbished)	6900440 (10758750033201)	
VITROS 5600 Integrated System	6802413 (10758750002740)	
VITROS 5600 Integrated System (Refurbished)	6802915 (10758750007110)	
VITROS XT 3400 Chemistry System	6844458 (10758750031986)	
VITROS XT 7600 Integrated System	6844461 (10758750031610)	

REQUIRED ACTION

- Send the enclosed customer letter and Confirmation of Receipt form to all of your customers who are using any of the potentially impacted systems listed above.
- Check if your facility has an affected spare part PP Assembly by checking the date code stamped into the barrel component. Discard all affected Assemblies within the date range of 040722 - 121922.
- If your facility has any of the potentially affected systems in inventory, check for affected PP Assemblies on the systems and in the Spare Parts Kits by checking the date code stamped into the barrel component. Discard all affected Assemblies within the date range of 040722 - 121922.
- QuidelOrtho will issue credit for all PP Assemblies that are discarded as per your Confirmation of Receipt form.
- Place an order for replacement PP Assemblies if required.
- Complete the enclosed Confirmation of Receipt form no later than **24 August 2023**.

Contact Information

We apologize for the inconvenience this will cause your laboratory. 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)

Enclosure:
Customer Letter
Confirmation of Receipt Form