



June 2021

**IMPORTANT PRODUCT CORRECTION NOTIFICATION**  
**VITROS® Systems Configured to Use Expired Reagent**

Dear Customer,

Ortho Clinical Diagnostics has identified a situation in which some VITROS® 3600 Immunodiagnostic Systems and VITROS® 5600/XT 7600 Integrated Systems may have been inadvertently left after a service call with a configuration that allows the use of expired reagents.

Because your system is not e-connected or the e-connectivity information is inconclusive, Ortho cannot determine if your system is affected.

Affected Product	Product Code (Unique Identifier)	Software Version
VITROS® 3600 Immunodiagnostic System	6802783 (10758750002979)	V 3.3.2 and above
VITROS® 3600 Immunodiagnostic System, Refurbished	6802914 (10758750007103)	V 3.3.2 and above
VITROS® 5600 Integrated System	6802413 (10758750002740)	V 3.3.2 and above
VITROS® 5600 Integrated System, Refurbished	6802915 (10758750007110)	V 3.3.2 and above
VITROS® XT7600 Integrated System	6844461 (10758750031610)	V 3.4 and above

**REQUIRED ACTION**

- Verify your VITROS System is configured as your laboratory intended.
  - Navigate to **Options/Configuration => Configure System => Sample/Result Options**
    - Verify “Use Expired Reagents” is set as intended by your facility
    - Update the setting if necessary, and Save
- Complete the enclosed Confirmation of Receipt form no later than **15 July 2021**.

**Additional Information**

The VITROS System can be configured to use Expired Reagents using the Key Operator Access Code. If the VITROS System is configured to use Expired Reagents; expired diluents, expired reagents (MicroWell, MicroSlide or MicroTip), or expired calibrators can be used by the system. RE (Reagent Expired) and EC (Expired Calibrator) codes will appear with any results associated with expired assays.

**Note: Due to the potential for biased results, Ortho does not recommend the use of products beyond their labelled expiration date.**

## Impact to Results

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The use of expired reagents may result in the reporting of biased results. However, there are several *safeguards* to prevent this from unintentionally occurring:

- If the VITROS System is configured to use expired reagents, and the system has expired reagents onboard, the customer will see a “pop-up” window during the daily maintenance procedure. This window alerts the user that the system is configured to use expired reagents and there are reagents onboard which are expired or will become expired within the next 24 hours.
- Daily Quality Control is an indicator of assay performance. If assay performance is biased due to usage of expired reagents, QC results will show a similar bias.
- RE (Reagent Expired) and EC (Expired Calibrator) codes will appear with any results associated with expired assays.
- Laboratory Information Systems (LIS) may be configured to hold results with a code of RE or EC to be reviewed prior to release.

## Resolution

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The root cause of this issue was a tool that required Field Service Technicians to manually change the system’s configuration. The tool has been updated to prevent the future need for changing the VITROS System configuration.

## Contact Information

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We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre.

Sincerely,



Kevin Davies  
Regional Product Support Manager (ASEAN & Korea)