

December XX, 2024

URGENT FIELD SAFETY NOTICE

**Reagent Expired (RE) Result Code Potentially Not Being Produced
When Signal Reagent (SR) Pack Is Expired on VITROS® 3600, 5600
and XT 7600 Systems**

Dear Valued Customer,

The purpose of this notification is to inform you of an issue where the Reagent Expired (RE) Result Code is potentially not being generated for Microwell results when using an expired Signal Reagent (SR) Pack on VITROS® 3600 Immunodiagnostic System, VITROS® 5600 and XT 7600 Integrated Systems, with Software Version 3.8.0 and higher.

Affected Systems	Product Code (Unique Device Identifier)	Affected Assays
VITROS 5600 Integrated System	6802413 (10758750002740)	All MicroWell Assays
VITROS 5600 Integrated System – Certified/Refurbished	6802915 (10758750002740)	
VITROS 5600 Integrated System - China	6904001 (10758750035786)	
VITROS XT 7600 Integrated System	6844461 (10758750012343)	
VITROS XT 7600 System – Certified	6272222 (10758750012343)	
VITROS XT 7600 Integrated System - China	6904003 (10758750035809)	
VITROS 3600 Immunodiagnostic System	6802783 (10758750002979)	
VITROS 3600 Immunodiagnostic System – Certified/Refurbished	6802914 (10758750002979)	
VITROS 3600 Immunodiagnostic System - China	6904000 (10758750035779)	

Summary

During internal testing, QuidelOrtho™ identified that MicroWell assay results have the potential to be reported without the Reagent Expired (RE) result code, even when the Signal Reagent (SR) pack is past the expiry date. This can occur when an SR pack exceeds the on-board expiry and/or the shelf expiration date. This issue can affect any MicroWell assay regardless of whether or not the system is configured to use expired reagents.

As of 19-Dec-2024, QuidelOrtho has received no complaints relating to this issue.

Impact to Results

If an expired pack is used on the system, given that shelf-life claims are established by generating data beyond the labelled claim, the gradual signal loss overtime and typical customer usage patterns, we do not expect any significant biased patient results or quality control result failures. In the worst-case and unlikely scenario that an expired SR pack results in calibration failures there is the potential for a delayed patient result, depending on how long it takes to investigate and troubleshoot the failure. Delayed results could result in suboptimal management of critically ill patients.

Condition code PVG-021 correctly appears when Signal Reagent expires, either on-board or shelf expiration.

QuidelOrtho does not recommend a review of previous results in identifying patient results which may have been affected by this issue given the gradual signal decline and low likelihood of any significant bias. Discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action. The results from any diagnostic test should be evaluated in conjunction with a patient's history, risk factors, clinical presentations, signs, and symptoms as well as the results of other tests.

Root Cause

QuidelOrtho has identified the cause as a software anomaly. This issue will be corrected with the next software release, estimated for Q2 of 2025.

REQUIRED ACTION

- Do not use expired Signal Reagent packs. See the Questions & Answers section for more details.
- Complete the enclosed Confirmation of Receipt form no later than **Month DD, 2024**.
- Save this notification with your User Documentation or post this notification by each VITROS 3600/5600/XT 7600 System in your laboratory until the issue has been resolved.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Global Services Organization at **<insert phone number>**.

Insert signatory if applicable in your region.

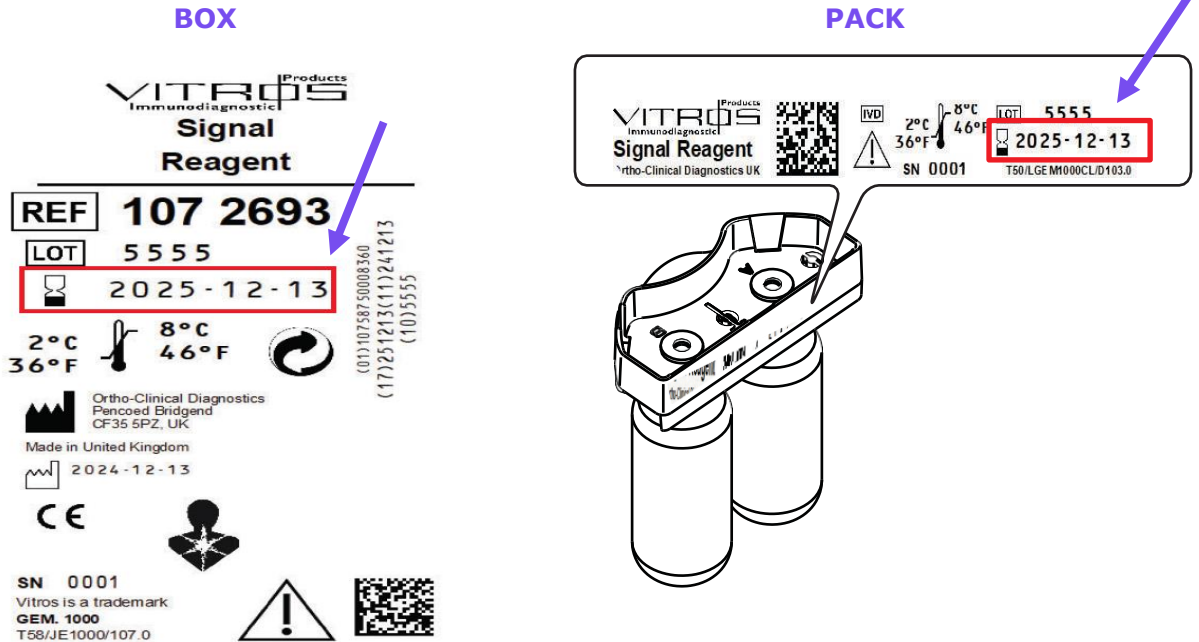
Enclosure: Confirmation of Receipt form (Ref. CL2024-312_CofR)

Ortho Clinical Diagnostics (Ortho), a wholly owned subsidiary of QuidelOrtho Corporation, is excited to share our new logo and brand with you. Due to legal and regulatory requirements for diagnostic products, you may continue to see the names and brands of Quidel and Ortho in addition to QuidelOrtho on our packaging, contracts, and marketing materials.

Questions and Answers (Q&A)

1. How do I tell if the Signal Reagent (SR) Pack is expired?

A: The shelf expiration date is located on the box, as well as on the barcode on the pack. The on-board expiration date is 7 days after loading onto the analyzer. Both the shelf expiration and the on-board expiration can be viewed for a loaded SR Pack, that has been scanned by the barcode reader, by navigating to **Reagents** → **View SR**.



2. Which Condition Code is associated with expired Signal Reagent?

PVG-021: SR Pack Slot %d, Lot %d has expired (raised with shelf expiration of the lot or open-container expiration of the particular container)