

February 03, 2026

**IMPORTANT PRODUCT CORRECTION NOTIFICATION**  
**VITROS™ Immunodiagnostic Products Progesterone 2 Calibrators –**  
**Potential for Calibration or Quality Control Failures**

Dear Valued Customer,

The purpose of this notification is to inform you that QuidelOrtho™ has confirmed an issue affecting VITROS™ Immunodiagnostic Products Progesterone 2 (Prog2) Calibrators, which impacts the VITROS™ Immunodiagnostic Products Progesterone 2 (Prog2) Reagent Pack.

Affected Product Name	Product Code (Unique Device Identifier)	Affected Lots	Expiry
VITROS™ Immunodiagnostic Products Progesterone 2 Calibrators	619 9455 (10758750035373)	0050	03-Feb-2026
		0060	04-Mar-2026
		0070	11-Mar-2026
		0080	31-Mar-2026
		0090	06-May-2026

Impacted Product Name	Product Code (Unique Device Identifier)	Impacted Lots	Expiry
VITROS™ Immunodiagnostic Products Progesterone 2 Reagent Pack	619 9454 (10758750035366)	0050	03-Feb-2026
		0060	04-Mar-2026
		0070	11-Mar-2026
		0080	31-Mar-2026
		0090	06-May-2026

**Investigation Summary**

QuidelOrtho identified the issue during our investigation of customer complaints on VITROS Prog2 Calibrators. The results of our investigation show an unexpected increase in signal over time in VITROS Prog2 Calibrators, Levels 2 and 3. This may cause:

- Calibration failures when attempting to calibrate impacted lots of VITROS Prog2 Reagent Pack.
- Quality control (QC) failures with results above the limit, due to a sub-optimal passing calibration, when performing QC on impacted lots of VITROS Prog2 Reagent Pack.

**Resolution**

QuidelOrtho performed additional testing and revised the calibration parameters found on the Assay Data Disk (ADD) and Magnetic Reagent Lot Calibration (MAG) Card to compensate for the unexpected increase in signal.

### Resolution (Cont.)

- **For VITROS 3600, 5600, and XT 7600 Systems:** The revised calibration parameters are available beginning on ADD DRV **6366** (and above). When available, load ADD DRV **6366** (or above) using the “All Assay Data” option.
  - After loading an ADD with the revised calibration parameters for the first time, VITROS Prog2 Reagent Packs will become uncalibrated and require recalibration (Please note that subsequently loaded ADD DRVs will not uncalibrate VITROS Prog2). ADD DRV **6366** will be automatically sent when available.
  - For e-Connected systems: Automatic download of ADD DRV **6366** will be available beginning on February 20, 2026.
- **For VITROS Eci/ECiQ Systems:** The revised calibration parameters will be available on an updated *yellow* MAG card. Upon receipt, scan the *yellow* MAG Card. After scanning the *yellow* MAG card, VITROS Prog2 Reagent Packs will require recalibration. Render unusable and discard the original, *green* MAG Card that was shipped with the calibrators. The updated *yellow* MAG card will be automatically sent to affected customers in February 2026.

Recalibration: Confirm your laboratory has sufficient inventory of the linked lot of VITROS Prog2 Calibrators available to recalibrate VITROS Prog2 Reagent Pack. If your laboratory does not have the required lot of VITROS Prog2 Calibrators available, complete the appropriate sections of the enclosed Confirmation of Receipt form, and QuidelOrtho will send an additional sales unit of that lot. If that lot is unavailable, QuidelOrtho will send a replacement reagent and calibrator lot.

Please note that due to the upcoming expiration, Lot 0050 has not received revised calibration parameters. If your laboratory has experienced the issue with Lot 0050, please contact your local QuidelOrtho account representative.

For more information, refer to the Questions and Answers included at the end of this notification.

### Impact to Results

Calibration or quality control failures may cause a delay in testing. However, based on the clinical utility of progesterone, such a delay is unlikely to significantly affect patient management.

QuidelOrtho does not recommend a review of previous results, as this issue affects the VITROS Prog2 Calibrators and Range Verifiers, and a sub-optimal calibration will be detectable by performing QC.

Discuss any concerns 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.

As of 02-Feb-2026, QuidelOrtho has received 125 complaints related to this issue, with no reports of adverse effects.

**REQUIRED ACTIONS**

- **For VITROS 3600, 5600, and XT 7600 Systems:** Upon receipt, load ADD DRV **6366** (or above) using the "Load All Data" option and recalibrate VITROS Prog2 Reagent Pack.
- **For VITROS ECi/ECiQ Systems:** Upon receipt, scan the *yellow* MAG Card and recalibrate VITROS Prog2 Reagent Pack. Render unusable and discard the original, *green* MAG Card that was shipped with the calibrators.
- Confirm your laboratory has sufficient inventory of the linked lot of VITROS Prog2 Calibrators available to recalibrate VITROS Prog2 Reagent Pack. If your laboratory does not have sufficient inventory, complete the enclosed Confirmation of Receipt form to receive an additional sales unit of VITROS Prog2 Calibrators.
- Complete the enclosed Confirmation of Receipt form no later than **13-Feb-2026**.
- Save this notification with your User Documentation or post this notification near each VITROS 3600/5600/XT 7600/ECi/ECiQ System in your laboratory until the issue has been resolved.
- Please forward this notification if the affected products were distributed outside of your facility.
- If your laboratory has experienced the issue described in this notification and you have not already done so, please report the occurrence to your local Technical Support team.

**Root Cause**

While we are still working to confirm root cause, we have implemented actions to prevent this issue from occurring in future lots.

**Contact Information**

We apologize for the inconvenience this may cause your laboratory. If you have further questions, please contact our Technical Support team.



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Enclosure: Confirmation of Receipt form (Ref. CL2026-003dm\_CofR)

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## Questions and Answers

- 1. If I obtained a successful calibration using affected lots of VITROS Progesterone 2 Calibrators, will I see a shift in results after loading ADD DRV 6366 and performing recalibration?**

A sub-optimal, successful calibration using affected lots of VITROS Progesterone 2 Calibrators may generate higher than expected results. After recalibration, a QC shift low may be observed.

- 2. Can I continue to use the affected lots of VITROS Progesterone 2 Calibrators until I receive ADD 6366 (or above)?**

If your QC is within acceptable range, you may continue to use the affected lots of VITROS Progesterone 2 Calibrators until your laboratory receives ADD DRV **6366**. However, after receiving and loading ADD DRV **6366** (or above), for the first time, a recalibration must be performed.

- 3. If I obtained a successful calibration using affected lots of VITROS Progesterone 2 Calibrators, are my patient results impacted by this issue?**

If your QC was within an acceptable range, your patient results are not impacted by this issue.