



URGENT

Ortho Clinical Diagnostics

Month DD, YYYY

URGENT FIELD SAFETY NOTICE

VITROS® Chemistry Products Calibrator Kit 9 Incorrect Calibration Parameters For VITROS® Chemistry Products PHYT Slides, GEN 22 on VITROS® 250/350 Chemistry Systems

Dear Valued Customer,

Ortho Clinical Diagnostics has confirmed an issue that will occur when attempting to calibrate Generation (GEN) 22 of VITROS PHYT Slides on VITROS 250/350 Chemistry Systems.

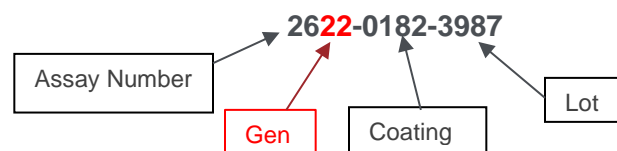
Issue Description

Ortho determined that Data Release Versions (DRV) 6194 through 6200 of the Calibration Diskette contain an erroneous value in the calibration mathematics for GEN 22 of VITROS PHYT Slides. This erroneous value prevents VITROS 250/350 Chemistry Systems from completing a successful calibration on *all lots* of GEN 22 of VITROS PHYT Slides. Attempting to calibrate GEN 22 of VITROS PHYT Slides using a DRV from the range listed above will result in condition code “6MD, Calibration malfunction” and a failed calibration.

Affected Product	Product Code (Unique Device Identifier)	Kit Lot	Expiration Date	Impacted Product
DRVs 6194 through 6200 supporting VITROS Calibrator Kit 9	8568040 (10758750005031)	0911	24-MAY-2023	VITROS Chemistry Products PHYT Slides, GEN 22, all lots
		0921	04-OCT-2023	
		0942	06-JUN-2024	
		0980	26-OCT-2022	
		0991	01-MAR-2023	

VITROS Chemistry Products Calibrator Kit 9 is used to calibrate VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems for the quantitative measurement of ACET, CRBM, DGXN, PHBR, and PHYT. VITROS Chemistry Products PHYT Slides quantitatively measure phenytoin (PHYT) concentration in serum and plasma using VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems.

To determine the GEN of the VITROS PHYT Slides in your inventory refer to the example below. This information can be found on the product packaging.





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Impact To Results

The inability to perform a successful calibration could lead to a delay in testing if an alternate GEN of VITROS PHYT Slides is not available. A delay in testing may lead to a delay in diagnosis and treatment.

Resolution

This issue will be corrected beginning with DRV 6201, which will be available on or after October 14, 2022. DRV 6201 will be automatically sent to customers affected by this issue. In the interim Ortho recommends performing VITROS PHYT Slide testing on an alternate supported VITROS System which does not require the Calibration Diskette or utilize an alternate GEN of VITROS PHYT Slides, if available.

REQUIRED ACTION

- Ortho recommends performing testing of VITROS PHYT Slides, Gen 22 on an alternate supported VITROS System or using an alternate GEN, if available.
- Upon availability load Calibration Diskette DRV 6201 or higher on your VITROS 250/350 Chemistry System and calibrate VITROS PHYT Slides, GEN 22 using VITROS Calibrator Kit 9.
- Complete the enclosed Confirmation of Receipt form no later than **Month ##, YYYY.**
- Please forward this notification if the affected product was distributed outside of your facility.
- Save this notification with your user documentation or post this notification by each VITROS 250/350 Chemistry System until Calibration Diskette DRV 6201 has been received and loaded by your facility.
- If your laboratory has experienced the issue with this product and you have not already done so, please report the occurrence to your local Ortho Care™ Technical Solutions Center.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact the Ortho Care Technical Solutions Center at **1-800-421-3311.**

Insert signatory if applicable in your region