



May ##, 2020

URGENT FIELD SAFETY NOTICE
VITROS® Chemistry Products AMYL Slides Imprecision

Dear Customer,

As part of a Field Safety Corrective Action, this notification provides important information regarding the precision of VITROS AMYL Slides.

Affected Product Name	Product Code (Unique Identifier)	Affected Lots
VITROS® Chemistry Products AMYL Slides Reagent	1202670 (10758750008513) 8112724 (10758750004393)	This issue affects all expired, in-date and future lots released. See enclosure for in-date affected AMYL slide coatings.

VITROS Chemistry Products AMYL Slides quantitatively measure amylase (AMYL) activity in serum, plasma, and urine using VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and VITROS 5600/XT 7600 Integrated Systems.

Impacted Product Name	Product Code (Unique Identifier)	Impacted Lots
VITROS® Chemistry Products Performance Verifier I and II	8067324 (10758750004317) 8231474 (10758750004577)	This issue impacts all expired, in-date and future lots.

VITROS Chemistry Products Performance Verifier is an assayed control used to monitor performance on VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems.

Background Information

Ortho Clinical Diagnostics publishes the estimated within-lab Standard Deviation (SD) for each assay on the Performance Verifier Control Assay Sheets. These values are representative of the performance of properly operating VITROS Systems in laboratories using multiple Performance Verifier lots. This estimated within-lab SD can then be used by individual laboratories to evaluate assay performance variability and to make daily quality control (QC) decisions.

Description of Issue

Ortho has observed an increase in complaints, and confirmed the imprecision observed, for quality control and patient samples when using VITROS AMYL Slides. Some laboratory’s quality control fluid record statistics have shown SDs that are larger than the estimated within-lab SD on the VITROS Performance Verifier Control Assay Sheets. Complaints have also been received regarding VITROS AMYL Slides QC data exceeding within-lab SD when using other manufacturers’ controls.

Impact to Results

Imprecision affects serum, urine and QC samples, however VITROS AMYL Slides performance continues to meet its intended clinical use. Therefore, **no lookback of results is recommended.**

QC results may fail current published recommendations (estimated within-lab SD, Range of Means or mean deltas). This could lead to unnecessary QC troubleshooting and a delay in result reporting.

Investigation

Ortho has investigated the imprecision complaints for VITROS AMYL Slides and determined that precision performance of VITROS AMYL Slides has changed since the original within-lab SD value was established. Some coatings/lots show more imprecision than others, however VITROS AMYL Slides still meet the intended clinical use.

The current estimated within-lab SD is too small and does not represent actual assay performance. The estimated within-lab SD has been revised. The estimated within-lab SD is used in the calculation of the Range of Means (ROM) and the mean deltas listed in the Performance Verifiers Training Module. Therefore, the ROM for all currently in-date VITROS AMYL GENs and the Delta tables will also be revised.

The need to revise the Instruction for Use precision tables is currently under evaluation.

Resolution

The VITROS Performance Verifiers I and II Control Assay Sheet estimated within-lab SD, Range of Means (ROM) and Delta table values were re-evaluated. A revised, larger within-lab SD has been established. The revised ROM will be wider, and the deltas will be larger.

The revised estimated within-lab SD and ROMs will be published on a future revision of the VITROS Performance Verifier I and II Control Assay Sheets (expected in June 2020). This update will be marked with a change bar in the margin.

The Delta tables will be updated in a future revision of the Performance Verifier Training Module.

In the meantime, use the revised estimated within-lab SD listed in the enclosed Information Sheet to evaluate your laboratory's quality control when using VITROS Performance Verifier I and II products.

REQUIRED ACTIONS

- Until the VITROS Control Assay Sheets are revised, use the revised VITROS Performance Verifier estimated within-lab SD in the enclosed Information Sheet to evaluate your laboratory's VITROS AMYL Slide quality control when using VITROS Performance Verifier I and II products.
- Once available on our website <https://www.orthoclinicaldiagnostics.com>, obtain the updated VITROS Performance Verifier Control Assay Sheets. Use these revised ROM to evaluate your laboratory's VITROS AMYL Slide quality control when using VITROS Performance Verifier I and II products.
- A review of previously reported patient results is **NOT** recommended because VITROS AMYL Slides meet their intended clinical use.
- Complete the Confirmation of Receipt form no later than **May xx, 2020**.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information

We apologize for any inconvenience this may cause in your laboratory. If you have questions, please contact Ortho Care Technical Solutions Center at **insert phone number**.

Insert signatory if appropriate in your region.

Enclosure: VITROS Chemistry Products AMYL Slides / VITROS Chemistry Products Performance Verifier I & II Information Sheet