

Date Issued July 2017**Issue** Ortho Clinical Diagnostics (Ortho) determined that the unopened storage condition for VITROS Performance Verifier II, Lot K4852 requires revision when using VITROS Chemistry Products AST Slides or VITROS Chemistry Products ASTJ Slides.**Affected Product**

Product Name	Product Code (Unique Identifier)	Lot Number	Expiry
VITROS Performance Verifier II	8231474 (10758750004577)	K4852	22-FEB-2018

Investigation The Instructions for Use states that unopened VITROS Performance Verifier II can be stored either frozen until the expiration date or refrigerated for ≤6 months.Our stability testing determined that unopened vials for Lot K4852 did not meet the product's 6 month specification when stored refrigerated. All other lots are not affected.**Product that is stored frozen is not affected by this issue.** Customers can continue to use frozen-stored product through its expiration date.**The change in storage requirements only affects Lot K4852 when verifying the performance of VITROS AST or ASTJ Slides. No other analytes are affected.****Impact to Results**

Our data indicate that Quality Control results generated using VITROS AST Slides were negatively biased outside of the 2 Standard Deviation (SD) limit for unopened vials stored refrigerated. VITROS ASTJ Slides are similarly affected.

As this issue is related to the stability of the control fluids, there is no impact to previously reported patient results providing that your QC results were within acceptable limits.

ResolutionAs a result of this issue, unopened vials of VITROS Performance Verifier II, Lot K4852 can no longer be stored refrigerated when verifying the performance of VITROS AST or ASTJ Slides.**NOTE:** Ortho will provide credit for product that you discard due to this issue. (i.e., Lot K4852 currently store refrigerated). *If you do not use this lot to verify performance of VITROS AST or ASTJ Slides, you do not need to discard refrigerated product.***Required Actions**

- Unopened vials of Lot K4852 can no longer be stored refrigerated to verify the performance of VITROS AST or ASTJ Slides.
- Discard any remaining refrigerated inventory if used to verify VITROS AST or ASTJ Slides.
- Retain this notification as verification of the revised instructions.
- Complete the Confirmation of Receipt form and return by **July 24, 2017**.

**Contact
Information**

We apologize for the inconvenience this may cause your laboratory. We have anticipated some questions in the following Question and Answer section. If you have additional questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766.

Sincerely,



Jon Wong, QA Manager 14 July 2017

Enclosure: Confirmation of Receipt Form

Questions and Answers

1. What is the current storage and stability for VITROS Performance Verifier II?

The Instructions for Use states:

Reagent	Storage Condition	Stability
Unopened	Frozen $\leq -18^{\circ}\text{C}$ ($\leq 0^{\circ}\text{F}$)	Until expiration date
	Refrigerated $2-8^{\circ}\text{C}$ ($36-46^{\circ}\text{F}$)	≤ 6 months
Reconstituted	Refrigerated $2-8^{\circ}\text{C}$ ($36-46^{\circ}\text{F}$)	Store tightly stoppered*

2. Can I continue to use Lot K4852 stored in the refrigerator for other analytes?

Yes, the change in storage requirements only affects VITROS Performance Verifier II, Lot K4852 when used to verify the performance of VITROS AST or ASTJ Slides. Using Lot K4852 stored refrigerated to verify the performance of other supported assays is acceptable.

3. Will Ortho provide credit for product discarded?

If you discard any unopened product that is stored refrigerated, Ortho will credit your account as indicated on your Confirmation of Receipt form. As it is acceptable for continued use, credit will not be provided for unopened product stored frozen.

4. What is Ortho doing to resolve this issue?

Our investigation into the root cause implicates a specific AST enzyme stock solution used in the manufacturing of Lot K4852. Internal procedures are in place to help clarify optimal handling and storage of the stock solution.