

March 2023

IMPORTANT PRODUCT CORRECTION NOTIFICATION **VITROS® Chemistry Products ALTV Slides Do Not Meet** **Ascorbic Acid Specificity Concentration in Instructions For** **Use**

Dear Valued Customer,

This notification is to inform you that Ortho Clinical Diagnostics has found that the performance of certain coatings of VITROS Chemistry Products ALTV Slides do not meet the claim for ascorbic acid specificity stated in the Instructions For Use (IFU).

Affected Product	Product Code (Unique Device Identifier)	Affected Coatings*
VITROS Chemistry Products ALTV Slides	6844288 (10758750032136)	Coatings 3230, 3233, 3237, 3242, 3243 (all lot numbers)

*Until the IFU for VITROS ALTV Slides has been updated, the information conveyed in this communication applies to all future coatings.

Issue Description/Summary

From internal testing, Ortho became aware that coatings 3230, 3233, 3237, 3242, and 3243 do not meet the ascorbic acid specificity concentration of 100 mg/dL.

The concentration currently stated in the IFU is significantly higher than what is expected for routine patient samples and is significantly higher than what the Clinical and Laboratory Standards Institute specifies for ascorbic acid testing (5.25 mg/dL. [CLSI. Supplemental Tables for Interference Testing in Clinical Chemistry. 1st ed. CLSI supplement EP37. Wayne, PA: Clinical and Laboratory Standards Institute; 2018])

VITROS ALTV Slides meet all other specificity claims stated in the IFU.

Please note, this issue applies only to VITROS ALTV Slides and does not affect VITROS XT Chemistry Products ALTV-AST Slides which have an ascorbic acid specificity concentration of 6 mg/dL.

Impact To Results

Based on Ortho's internal testing, patient samples may be affected by a negative bias. The magnitude of bias is dependent on the concentration of ascorbic acid in the sample however a patient sample with concentrations as high as 100 mg/dL of ascorbic acid is unexpected and not seen in a routine blood sample.

Impact To Results (Cont'd)

Ortho's investigation has shown that ascorbic acid concentrations of 100 mg/dL may produce a bias greater than 8 U/L at ALT concentrations near 60 U/L or a bias greater than 24 U/L at ALT concentrations near 300 U/L.

All affected coatings were assessed and meet the specificity claim at an ascorbic acid concentration of 6 mg/dL.

When using VITROS ALTV Slides to diagnose and monitor liver disease, individual results with a negative bias are unlikely to result in misdiagnosis or failure to diagnose as other tests, clinical history and other modalities are used to determine diagnosis. Repeat results with a negative bias are also unlikely to result in misdiagnosis or failure to diagnose as ascorbic acid interference at the normal reference range is within the maximum allowable interference.

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.

Resolution

Ortho is in the process of re-assessing the ascorbic acid specificity concentration and will update the IFU for VITROS ALTV Slides once we have completed the assessment.

In the interim, customers may continue to use the affected coatings of VITROS ALTV Slides, as the ascorbic acid specificity concentration currently stated in the IFU is significantly higher than what is expected for routine patient samples and is significantly higher than what the Clinical and Laboratory Standards Institute specifies for ascorbic acid testing (5.25 mg/dL).

REQUIRED ACTION

- Complete the Confirmation of Receipt form no later than **17 March, 2023**.
- 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 System capable of processing VITROS MicroSlides until Ortho has updated the IFU for VITROS ALTV Slides.
- If your laboratory has experienced this issue and you have not already done so, please report the occurrence to your local Ortho representative or our Ortho Care™ Technical Solutions Centre.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre.

Sincerely,



Kevin Davies
Regional Product Support Manager (ASEAN & Korea)

Enclosure: CL2023-055_Conf