



IMPORTANT

April 2023

IMPORTANT PRODUCT CORRECTION NOTIFICATION

VITROS® Chemistry Products ALTV Slides Do Not Meet Ascorbic Acid Specificity Concentration in Instructions For Use

Dear Valued Customer,

The purpose of this notification is to inform you that Ortho Clinical Diagnostics has determined the performance of certain coatings of VITROS Chemistry Products ALTV Slides do not meet the claim for ascorbic acid specificity concentration 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)

Issue Description/Summary

Through our 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. Ortho’s investigation has determined that the ascorbic acid specificity concentration in the IFU is inappropriate and requires re-assessment as 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 in 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.

To help determine if your laboratory has the affected coatings, refer to the Questions and Answers section on page 3.

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. 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 met the specificity claim at an ascorbic acid concentration of 6 mg/dL.



IMPORTANT

Impact To Results (Cont'd)

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 our 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**).

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

REQUIRED ACTION

- Complete the enclosed Confirmation of Receipt form acknowledging awareness of the new specificity information regarding ascorbic acid no later than **May 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 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 our Ortho Care™ Technical Solutions Center

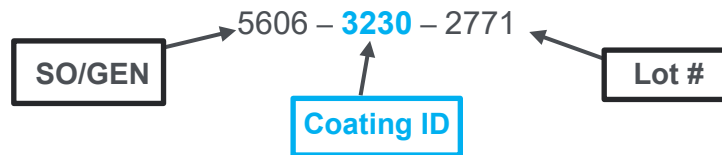


IMPORTANT

Questions and Answers

1. How can I determine the Coating Number for the VITROS ALTV Slides?

To determine the coating number, refer to the label on the cart or the individual product foil packaging. Of the 12-digit product number, the coating number is the *middle 4 digits*.



2. Are VITROS XT Chemistry Products XT ALTV-AST Slides affected?

No, VITROS XT ALTV-AST Slides have consistently met the ascorbic acid specificity concentration of 6 mg/dL.