QuidelOrtho™

Important

August 2023

IMPORTANT PRODUCT CORRECTION NOTIFICATION

VITROS Chemistry Products ALKP and XT TBIL-ALKP Slides with Highly Elevated ALKP Activity Potentially Not Generating the Substrate Depletion Limit Code

Dear Valued Customer,

This notification is to inform you that Ortho Clinical Diagnostics (QuidelOrtho) has confirmed an issue involving VITROS Chemistry Products ALKP Slides and VITROS XT Chemistry Products TBIL-ALKP Slides. Samples with highly elevated ALKP activity may return a false-low result and not generate the Substrate Depletion Limit code (DP code).

Affected Products	**Product Code** (Unique Device Identifier)	**Affected Lot(s)**
VITROS Chemistry Products ALKP Slides	105 3180 (10758750008346)	All expired, current, and future, GENs[1]
VITROS XT Chemistry Products TBIL-ALKP* Slides	684 4296 (10758750031801)	

*VITROS Chemistry Products TBIL Slides are not impacted by this issue.

Summary

QuidelOrtho received 4 complaints (none required vigilance reporting) related to "under-recovery" when testing an elevated patient sample with VITROS ALKP Slides. VITROS Systems have algorithms designed to perform a check for substrate depletion when processing VITROS MicroSlides. This check is intended to prevent samples with high activity of ALKP (i.e., above the measuring range) from being reported as within the ALKP measuring range.

Samples containing high activity of ALKP (or an interfering substance) could deplete the available substrate in the reagent layer of a VITROS ALKP Slide and not post the DP code, which may result in the System reporting an incorrect result (lower than the actual activity).

To detect this issue, QuidelOrtho recommends performing a 10x dilution on sample results reported between 600 – 1500 U/L.

- If the 10x diluted result is below 1500 U/L after correcting for the dilution factor, then the original '*undiluted*' result should be reported.
- If the 10x diluted result is above 1500 U/L after correcting for the dilution factor, then the '*diluted*' result should be reported.
- *Undiluted* sample results above 1500 U/L should be diluted per the Instructions for Use (IFU) and your laboratories protocol.

Diluting specimens with results within the measuring range is typically not recommended by Ortho, however, due to this issue, a dilution within the measuring range is recommended to confirm the result does not exceed the upper end of the measuring range of 1500U/L on highly elevated samples.

Impact to Results

QuidelOrtho's analysis of data from e-Connected VITROS 5600 Systems, with a sample size of over 7 million non-zero results, has shown a calculated potential occurrence rate of 0.024%.

ALKP is typically tested in conjunction with other tests and discordance with the other tests may lower the risk of inappropriate medical intervention based on incorrect ALKP results. Any discordance would lead to further investigation or review.

QuidelOrtho does not recommend a review of previous results, given the remote likelihood of occurrence and its potential impact on patient management. 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. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

Resolution

[1]QuidelOrtho is actively investigating a resolution and will notify you once additional information is available.

REQUIRED ACTION

- When reviewing sample results generated using VITROS ALKP Slides or VITROS XT TBIL-ALKP Slides, any result between 600-1500 U/L should be diluted using a 10x dilution and retested.
- Complete the enclosed Confirmation of Receipt form no later than **7 September 2023**.
- Please forward this notification if the affected product was distributed outside your facility.
- Save this notification with your documentation or post this notification by each VITROS 250/350/FS 5,1/4600/5600/XT 3400/XT 7600 System until the issue has been resolved.
- If your laboratory has experienced this issue with the product and has not already done so, please report the occurrence to your local Ortho Care Technical Solutions Centre.

Contact Information

We apologise for the inconvenience this will cause your laboratory. If you have further questions, please contact your local QuidelOrtho representative or our Global Services Organisation.

Sincerely,

Kevin Davies
Regional Product Support Manager (ASEAN & Korea)

Enclosure: Confirmation of Receipt Form

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Q&A

1. **Q:** What are the DP Condition Codes?
   A: "U90-300: Substrate Depletion ID" for all VITROS Systems except for 250/350 instruments where the code is "6LA DP-PREDICTION * substrate depletion".

2. **Q:** Why does my laboratory need to dilute by 10x?
   A: QuidelOrtho's analysis of e-Connectivity data has shown that 10x dilution is required to bring the majority of potentially impacted samples into the current substrate depletion limit area.

3. **Q:** How should I interpret the diluted results?
   A: If the diluted result is below 1500 U/L, report the '*undiluted*' result. If the diluted result is above 1500 U/L, report the '*diluted*' result.