QuidelOrtho™

URGENT

November 6th, 2023

URGENT FIELD SAFETY NOTICE
Potential for Falsely Elevated Results Due to CK-MM Interference When Using VITROS® Chemistry Products CKMB Slides

Dear Valued Customer,

The purpose of this notification is to inform you of the potential for falsely elevated Creatine Kinase MB results when using lots of VITROS® Chemistry Products CKMB Slides manufactured from Coating 0261.

Product Name	Product Code (Unique Device Identifier)	Affected Coating
VITROS Chemistry Products CKMB Slides (60 Slides)	8058232 (10758750004294)	Coating 0261 (All Lots)
VITROS Chemistry Products CKMB Slides (18 Slides)	8001133 (10758750004201)	
For in vitro diagnostic use only. VITROS Chemistry Products CKMB Slides quantitatively measure creatine kinase MB (CK-MB) activity in serum using VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems.		

Summary
Per the VITROS CKMB Slides Instructions for Use (IFU) "Principals of the Procedure" section, the spread layer of the CKMB slide contains goat antihuman CK-MM antibodies, which inhibit CK-MM (muscle) activity and ~50% of the CK-MB (heart) activity. The remaining CK activity represents 50% of the total CK-MB isoenzyme activity plus any CK-BB (which is relatively rare).

Per the current VITROS CKMB Slides IFU "Known Interferences" Section, a Total CK activity greater than 1000 U/L may result in falsely elevated CK-MB results. It is limited at 1000 U/L by design, which is due to the level of goat antihuman CK-MM antibodies added during manufacturing. Samples with Total CK >1000 U/L should be diluted prior to analysis. Therefore, CK will not typically impact VITROS CKMB results below the CK result of 1000 U/L.

Ortho Clinical Diagnostics (QuidelOrtho) has confirmed the issue and determined that lots manufactured from Coating 0261 of VITROS CKMB Slides do not adequately inhibit CK-MM up to a total CK >1000 U/L (as stated in the IFU).

Impact to Results
VITROS CKMB Slides results may be falsely elevated when testing samples with a total CK value greater than 800 U/L. Refer to the table below for the estimated bias of CKMB at increasing levels of CK activity. CK activity at which the bias becomes significant is >6 U/L. The rows shaded in gray indicate where the total CK activity may cause significant bias of the predicted CKMB result.

CK Activity (U/L)	Estimated CKMB Bias (U/L)
200	-2.0
300	-0.7
400	0.5
500	1.8
600	3.1
700	4.3
800*	5.6
900	6.9
1000	8.2

The CKMB result will have an estimated bias based on the total CK activity of the sample. The bias is fixed across the entire CKMB reportable range. The gray shading indicates where the total CK activity level could cause significant bias of CKMB (> 6 U/L).
**At 800 U/L, an estimated CKMB bias of 5.6 U/L is not considered significant however, QuidelOrtho does not have data for the specific level of CK activity greater than 800 U/L at which the CKMB bias will become significant. Therefore, QuidelOrtho advises that CK activity >800 U/L may cause significant bias.*

QuidelOrtho performed an assessment of e-Connectivity data from VITROS 5600 Systems and determined that, out of 64,545 samples tested for CKMB, approximately 97% were associated with CK activity <800 U/L. *Please note: this data may not represent the patient population of your laboratory.*

As this issue affects only Coating 0261, a review of previously reported results is not recommended.

The CKMB test is still used in some regions to diagnose myocardial infarction (in conjunction with troponin or clinical signs and symptoms) and may also be used to diagnose post percutaneous coronary intervention and coronary artery bypass grafting myocardial infarction. In these instances, falsely elevated CKMB results in the presence of high CK levels may falsely indicate myocardial infarction or re-infarction. Patients may unnecessarily receive additional lab tests, a stress test, be admitted for a longer observation period,

Impact to Results (Cont.)
receive anti-coagulation or anti-platelet medications, or receive a diagnostic cardiogram. These tests are considered mainly safe; however, the risk of patient injury is not unlikely.

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.

REQUIRED ACTIONS

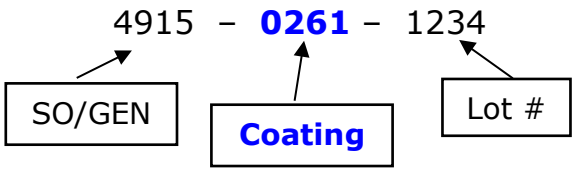
- Per the VITROS CKMB Slides IFU, evaluate the Total CK of the sample. Elevated Total CK activity (>800 U/L) may cause a significantly elevated VITROS CKMB Slides result. If the CK activity exceeds 800 U/L, consult with your Medical Director.
- Consider an alternate method of testing for samples with CK activity greater than 800 U/L.
- Complete the enclosed Confirmation of Receipt form no later than **December 6th, 2023**.
- If your laboratory chooses not to use lots from the affected coating, QuidelOrtho will credit your account.
- Save this notification with your User Documentation or post this notification by each VITROS 250/350/5,1 FS/4600/5600/XT 3400/XT 7600 System until the issue is resolved.
- Please forward this notification if the product is distributed outside of your facility.

Resolution
QuidelOrtho's investigation has identified root cause to be related to a specific raw material and we are working to resolve the issue. In the interim, we will issue a Technical Bulletin that contains the same information provided in this notification. We will continue to perform testing on all future coatings to evaluate CK-MM inhibition and will update the Technical Bulletin as needed.

Enclosure: Confirmation of Receipt Form (Ref. CL2023-244_EU_CofR)

Questions and Answers

1. **How can I determine the Coating Number for VITROS® Chemistry Products CKMB Slides?**



2. **Can I dilute samples with CK <1000 U/L?**

   QuidelOrtho does not currently support dilution of samples with a CK activity <1000 U/L.

3. **Will performing Quality Control detect this issue?**

   No, this issue is specific to patient samples with elevated CK. Performing quality control will not detect when this issue occurs. This issue can only be identified by reviewing the Total CK activity in the sample.