

Month XX, 2021

URGENT FIELD SAFETY NOTICE FOLLOW-UP:

Technical Bulletin - VITROS® Chemistry Products CKMB Slides Potential for Falsely Elevated Results Due to CK-MM Interference

Dear Valued Customer,

This communication is a follow-up to a Field Safety Corrective Action. In December 2020, Ortho Clinical Diagnostics provided customer letter (Ref. CL2020-302) regarding the possibility of falsely elevated Creatine Kinase MB results when using VITROS® Chemistry Products CKMB Slides. In February 2021, Ortho provided customer letter (Ref. CL2021-049) to deliver the current Technical Bulletin (Pub. No. J68416, Issued 2021-01-14).

Current Technical Bulletin

The current Technical Bulletin is located, along with the Instructions for Use, on our website: <https://www.orthoclinicaldiagnostics.com>.

Resources / Technical Documents / Instructions for Use

Our website is the official source of information for all VITROS Products.

Future Technical Bulletin Revision

The Technical Bulletin will be revised with the information below and provided to your facility at a future date (expected early July 2021)

- An additional affected coating, **0245**, will be added.
- Expired affected coatings will be removed.

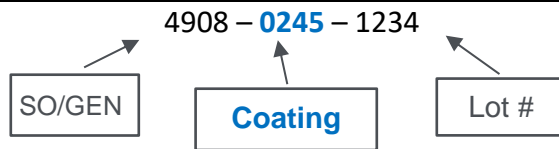
Affected Product	Product Code (Unique Identifier)	Affected Coating ID's
VITROS® Chemistry Products CKMB Slides	8058232 (10758750004294)	0233, 0235, 0239, 0245 (all lot numbers)
	8001133 (10758750004201)	
VITROS Chemistry Products Slides quantitatively measure creatine kinase MB (CK-MB) activity in serum using VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems.		

CK Activity (U/L)	Estimated CKMB Bias (U/L) by coating			
	Coating ID 0233	Coating ID 0235	Coating ID 0239	Coating ID 0245
200	0.4	1.6	3.9	1.4
300	1.2	3.6	7.5	2.4
400	2.0	5.6	11.1	3.3
500	2.8	7.6	14.7	4.3
600	3.7	9.6	18.3	5.2
700	4.5	11.6	21.9	6.2
800	5.3	13.6	25.5	7.1
900	6.1	15.6	29.1	8.1
1000	6.9	17.6	32.7	9.0
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).				

**Future
Technical
Bulletin
Revision
(cont'd)**

NOTE: Coating IDs not listed in the *revised* Technical Bulletin perform as stated in the current VITROS CKMB Slides Instructions for Use and do not demonstrate elevated results due to CK-MM Interference up to 1000 U/L Total CK.

**How to
Determine
Coating ID**



**Contact
Information**

If you have questions, require assistance locating the current Technical Bulletin or require a copy of the previous communication (Ref. CL2020-302), please contact our Ortho Care™ Technical Solutions Center at **insert phone number.**

Insert signatory if appropriate in your region.
