

August 23, 2021

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

Dear Valued Customer,

In December 2020, Ortho Clinical Diagnostics provided customer letter (Ref. CL2020-302\_EU) regarding the possibility of falsely elevated Creatine Kinase MB results when using VITROS® Chemistry Products CKMB Slides.

In June 2021, Ortho provided a customer letter (Ref. CL2021-182\_EU) regarding revisions to the Technical Bulletin, adding the additional affected coating 0245 and removing expired coatings (Pub. No. J68416, Issued 2021-06-10).

### Technical Bulletin Revision

The Technical Bulletin has now been revised with the information below.

- An additional affected coating, **0246**, has been added.
- No expired coatings were removed.

No expired coatings were removed.		
Affected Product	Product Code (Unique Identifier)	Affected Coating ID's
VITROS® Chemistry Products CKMB Slides	8058232 (10758750004294)	0233, 0235, 0239, 0245, 0246 (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.		

Estimated CKMB Bias (U/L) by coating					
CK Activity (U/L)	Coating ID 0233	Coating ID 0235	Coating ID 0239	Coating ID 0245	Coating ID 0246
200	0.4	1.6	3.9	1.4	1.9
300	1.2	3.6	7.5	2.4	2.9
400	2.0	5.6	11.1	3.3	3.9
500	2.8	7.6	14.7	4.3	4.9
600	3.7	9.6	18.3	5.2	5.9
700	4.5	11.6	21.9	6.2	6.9
800	5.3	13.6	25.5	7.1	7.9
900	6.1	15.6	29.1	8.1	8.9
1000	6.9	17.6	32.7	9.0	9.9
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).					

**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.

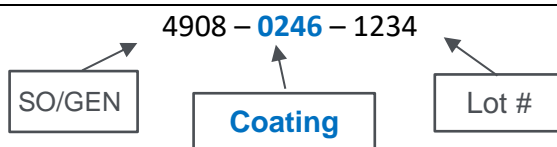
**Obtaining  
Technical  
Bulletin**

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.

**How to  
Determine  
Coating ID****Contact  
Information**

If you have questions, require assistance locating the current Technical Bulletin or require a copy of previous communication (Ref. CL2020-302a), please contact our Ortho Care™ Technical Solutions Center at 0800 181 4897 (Germany)

Enclosure: Technical Bulletin (Pub. No. J68416, Issued 2021-08-02)

## Confirmation of Receipt – Response Required

Communication ID: CL2021-214\_EU

Date of Issue: 24-08-2021

## FOLLOW-UP TO URGENT FIELD SAFETY NOTICE

### VITROS® Chemistry Products CKMB Slides Affected Coating Numbers Have Been Revised

Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:

**24-Sep-2021**

Send to: QRC DACH

e-Mail Address: [a-ocdde-bms-de@orthoclinicaldiagnostics.com](mailto:a-ocdde-bms-de@orthoclinicaldiagnostics.com)

DE: 0 800 183 35 61

Fax: AT und CH: +33 388 65 48 79

### Your Name and Address

Verify your name and mailing address:

Please complete this section if any of this information has changed

Institution/

Contact Name: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_

State/Prov: \_\_\_\_\_

Zip/Postal Code: \_\_\_\_\_

Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

e-Mail: \_\_\_\_\_

### Please Confirm

I received communication (Ref. CL2021-214\_EU), the follow-up to previous communications (Ref. CL2020-302\_EU/CL2021-182\_EU) regarding the potential for falsely elevated Creatine Kinase MB results when using an affected coating of VITROS CKMB Slides.

I understand the Affected Coating Numbers have been revised and now include Coating 0246 and that the Technical Bulletin has been updated with this information and I will adhere to these guidelines if my facility receives Coating 0246.

I am aware that if my facility did not receive the previous communications (Ref. CL2020-302\_EU/CL2021-182\_EU), I may request one by contacting Ortho Care™ Technical Solutions Center and that my laboratory must evaluate the CK activity of a sample, as CK activity may significantly affect the VITROS CKMB Slide results.

Print Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Date: \_\_\_\_\_

Your Comments: \_\_\_\_\_

Signature: \_\_\_\_\_

Required  
Your signature confirms  
that you have received  
and understand this  
communication