



April xx, 2019

URGENT FIELD SAFETY NOTICE**Negative Drift in Results using VITROS® Chemistry Products CK Slides on VITROS 250 or 350 Chemistry Systems**

Dear Customer,

As part of a Field Safety Corrective Action, this notification provides information regarding a potential negative drift in results when using VITROS Chemistry Products CK Slides on VITROS 250 or 350 Systems.

Affected Product	Product Code (Unique ID No.)
VITROS® 250 Chemistry System	8132086 (10758750004409)
VITROS® 250AT Chemistry System	1758143 (10758750000036)
VITROS® 250 Chemistry System Refurbished	6801759 (10758750001330)
VITROS® 350 Chemistry System	6802153 (10758750002054)

Associated Products	Product Code (Unique ID No.)	Configuration	Affected Lots
VITROS® Chemistry Products CK Slides	8479396 (10758750004980)	60 Slides/Cartridge	This issue affects all expired, in-date and future lots released.
	8478034 (10758750004973)	18 Slides/Cartridge	
VITROS CK Slides quantitatively measure creatine kinase (CK) activity in serum and plasma using VITROS 250, 350, 5,1 FS & 4600 Chemistry Systems and VITROS 5600 & XT 7600 Integrated Systems.			

Issue Description

Ortho Clinical Diagnostics determined that VITROS CK Slides do not meet the current on-analyzer stability time of ≤ 1 week when using VITROS 250 or 350 Systems. An internal investigation has shown that quality control results drifted low (i.e., > 2 within lab Standard Deviations (SD) for VITROS Performance Verifiers) when using cartridges stored on the system for less than 7 days.

This issue is related to the humidity control of Slide Supply 2 on VITROS 250/350 Systems.

Ortho has confirmed that CK results generated using VITROS 4600, 5600, XT 7600 and 5,1 FS Systems are NOT affected by this issue.

Impact to Results

The impact to results is shown below.

CK Concentration (U/L)	Maximum Negative Drift at <u>4 Days</u> OAS (U/L)	Maximum Negative Drift at <u>7 Days</u> OAS (U/L)
169	-24	-37
190	-35	-51
854	-64	-113
962	-155	-217

Impact to Results (continued)

The VITROS CK assay can be used to detect inflammation of muscles or muscle damage. Negatively biased CK results could potentially delay the detection of mild to moderate CK elevation. A CK result is typically used in conjunction with patient's history, signs and symptoms and the results of other tests.

VITROS CK Slides together with VITROS CK-MB Slides may be used to aid in the diagnosis of myocardial infarction (MI). A negatively drifted CK result may generate a false high %MB leading to confusion. Although a %MB is not recommended for the diagnosis of MI by current practice guidelines, MI is typically diagnosed using troponin in conjunction with patient's risk factors, medical history, ECG, and clinical presentation.

A review of previous test results is not recommended. The within subject biological variation for CK is estimated to be 22% and the between subject biological variation is 40%*. Given these and the reference interval of the assay (Females: 30–135 U/L, Males: 55–170 U/L), the observed negative drift is likely close to the biological variations and may not be identified in reviewing the previous results in isolation. If you have any concerns, please discuss with your Medical Director for appropriate actions.

*Refer to <https://www.westgard.com/biodatabase1.html>.

REQUIRED ACTIONS

- As per the VITROS CK Slide Instructions for Use, perform Quality Control (QC) testing daily to help ensure the slides are performing within acceptable limits.
- If QC results are outside of the established ranges, discard the cartridge and repeat QC testing using a fresh cartridge of VITROS CK Slides.
- If multiple cartridges are loaded on the VITROS 250/350 System, daily QC testing must be performed for each cartridge prior to use.
- Consider loading one cartridge of VITROS CK Slides on board your system at a time.

NOTE: Refer to Questions and Answer section on page three for additional recommendations to help mitigate this issue.

- Post this notification by each system that processes VITROS CK Slides.
- Complete the Confirmation of Receipt form and return by **April xx, 2019**.
- Complete and return the Request for Credit form as needed to receive credit for affected cartridges.
- Forward this notification if you have distributed these products outside of your facility.

Resolution

Ortho is actively investigating to determine a possible mitigation for this issue.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Ortho Care™ Technical Solutions Center at **insert number**.

Insert signatory if appropriate in your region Enclosures:

1. Confirmation of Receipt Form
2. Request for Credit Form

Questions and Answers

1. What can I do minimize the impact to my CK results?

To help minimize the impact, please consider doing the following:

- Only load one cartridge of VITROS CK Slides at a time on your VITROS 250/350 System
- Consider switching to 18 slide cartridges if frequently discarding partially used 60 slide cartridges.
- Consider running QC more frequently than is stated in the VITROS CK Slide IFU.

2. Will daily Quality Control testing detect this issue?

Yes, performing daily QC testing will detect this issue if results have drifted outside of 2 within lab SDs when using VITROS Performance Verifiers.

3. How often should I replace VITROS CK Slide cartridges on my VITROS 250/350 System?

A within cartridge QC negative drift of ≤ 2 Performance Verifier SD is typically observed within the 7 day on analyzer stability time. However, if QC results are > 2 SD, replace the cartridge with a fresh one and rerun the QC fluids.

4. Are other assays in Slide Supply 2 affected

This issue is related to the humidity control of Slide Supply 2 on VITROS 250/350 Systems. Internal testing to date has shown no other assays or VITROS Systems are affected. Additional testing is being performed; we will notify you if appropriate

5. Are assays in Slide Supply 1 affected?

Ortho has had no indication that the assays in Slide Supply 1 are affected. Additional investigation is being performed, we will notify if appropriate.

6. How will a negative drift of CK results affect a derived test used in a calculation?

CK may be used in the calculation as follows:

$$\%MB = (CKMB/CK) \times 100$$

As stated in the Impact to Results section on page two, a negative drift in CK results may adversely affect a %MB calculation by increasing the result as described in the Impact to Result section on page two.

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Negative Drift in Results using VITROS® Chemistry Products CK Slides on VITROS 250 or 350 Chemistry Systems

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

DD-APR-2019

Send to: Name

e-Mail Address: email address

Fax: Fax Number

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 the Urgent Field Safety Notice regarding a potential negative drift in results when using VITROS Chemistry Products CK Slides on VITROS 250 or 350 Systems.

Please choose from the following:

- My laboratory uses a VITROS 250/350 System, but does not use VITROS CK Slides and therefore, is not affected by this issue.
My laboratory uses a VITROS 250/350 System to process VITROS CK Slides. I understand that I must follow the instructions provided.
My laboratory uses a VITROS 250/350 System to process VITROS CK Slides, we also use CK results to calculate % MB. I understand that I must follow the instructions provided.

Signature:

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

Print Name:

Phone Number:

Date:

Your Comments:

Request for Credit

Negative Drift in Results using VITROS® Chemistry Products CK Slides on VITROS 250 or 350 Chemistry Systems

Please complete and return this form to request credit for VITROS CK Slide cartridges discarded due to QC results that were outside of the established ranges prior to the 7 day on analyzer stability time.

Please make additional copies of this form on an as-needed basis.

FAX TO: insert name

FAX: insert number

Please credit my account for the cartridges of VITROS CK Slides in the quantities indicated below:

VITROS CK Slides Discarded Due to Negative Drift in QC		
Product Code	Name of Product	Quantity of slides remaining in partially used (opened) Cartridges

***Your signature attests that the affected product listed above has been destroyed.**

Your Name: _____

Job Title (optional): _____

Signed*: _____

Date: _____

Institution/Contact Name: _____

Address: _____

State/Province: _____ Postal Code _____

Fax Number: _____

Telephone Number: _____

J Number: _____

Institution: _____

Universal Customer Number: _____

Distributor Name (and location if known) if slides are purchased from a Distributor: _____