

Insert date

Intermittent Dispense Issues with VITROS® Chemistry Products Cl⁻ and K⁺ Slides

Dear Valued Customer,

This is a follow up to a previous notification issued in September 2019 (Ref. CL2019-248_EU). At that time, Ortho Clinical Diagnostics notified you of potential intermittent slide dispense issues with some lots of VITROS® Chemistry Products K⁺ Slide and VITROS® Chemistry Products Cl⁻ Slide cartridges.

It has come to our attention that the 8 lots listed below were inadvertently omitted from the “List of Potentially Affected VITROS Slides” provided in the previous communication.

Product Name	Product Code (Unique Identifier No.)	Previously Omitted Lots	Expiry Dates
VITROS® Chemistry Products Cl ⁻ Slides	8445207 (10758750004928)	4005-0678-9422	01OCT2019
		4005-0678-9423	01OCT2019
		4005-0680-9507	01OCT2019
		4005-0680-9508	01OCT2019
		4005-0682-0116	01NOV2019
		4005-0689-5392	01JUN2020
		4005-0689-5393	01JUN2020
		4005-0689-5394	01JUN2020

VITROS Chemistry Products Cl⁻ Slides quantitatively measure chloride (Cl⁻) concentration in serum and plasma using VITROS 250/350/5,1 FS/4600 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems.

Required Actions

- Continue to follow the instructions included with CL2019-248_EU.
- If you need another copy of the original letter, List of Potentially Affected VITROS Slide Lots or the Request for Credit form, please contact your Ortho Care™ Technical Solutions Center.

Contact Information

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

Insert signatory if appropriate in your region.



Insert Date, 2019

URGENT FIELD SAFETY NOTICE

Intermittent Dispense Issues with VITROS® Chemistry Products Cl⁻ and K⁺ Slides

Dear Customer,

As part of a Field Safety Corrective Action, this notification provides information regarding the potential for intermittent slide dispense issues with some VITROS® Chemistry Products Slide cartridges of the two products listed below. The dispense issues are due to the anti-backup platen failing to advance inside the cartridge.

Product Name	Product Code (Unique Identifier No.)	Coating ID No*.	Expiry Dates
VITROS® Chemistry Products Cl⁻ Slides	6844471 (10758750031658)	0679, 0681, 0683, 0684, 0687, 0690-0691, 0695, 0697, 0701, 0702, 0708	October 1, 2019 - January 1, 2021
VITROS Chemistry Products Cl ⁻ Slides quantitatively measure chloride (Cl ⁻) concentration in serum, plasma and urine using VITROS 250/350/5,1 FS/4600 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems.			
VITROS® Chemistry Products K⁺ Slides	8157596 (10758750010233)	0995-1002, 1004-1006, 1008-1010, 1012-1020	November 1, 2019 - January 1, 2021
VITROS Chemistry Products K ⁺ Slides quantitatively measure potassium (K ⁺) concentration in serum, plasma, and urine using VITROS 250/350/5,1 FS/4600 Chemistry Systems and the VITROS 5600/XT 7600 Integrated Systems.			

*Refer to enclosed “List of Potentially Affected VITROS Slides” for specific lot numbers that may be affected.

Issue Summary

The anti-backup platen (ABP) is a plastic platform that supports the slide stack inside the cartridge and is pushed along with the slides to the top of the cartridge during the slide dispense cycle. Our investigation found that during the manufacturing of specific lots of VITROS Cl⁻ and K⁺ Slides, some cartridges may have been sealed in a manner that restricts the movement of the ABP.

If the ABP is restricted within the cartridge body, a slide will not be properly positioned, and the system will generate a condition code. Condition codes that indicate a slide dispense issue are listed in the enclosed “Resolving Slide Dispense Issues” document.

NOTE: Our investigation determined the issue is intermittent and isolated to specific lots of VITROS Cl⁻ and K⁺ Slides. Refer to the enclosed “List of Potentially Affected VITROS Slides”.

REQUIRED ACTIONS

- Complete and return the Confirmation of Receipt form by **September 18, 2019**.
- If you experience a slide dispense issue, try to reposition the ABP by following the instructions in the enclosed “Resolving Slide Dispense Issues” document. Please place the instructions by each VITROS System in your facility that processes Microslides.
- If you are unable to reposition the ABP, remove the affected cartridge and replace it with a new one. Complete and return the Request for Credit form as needed to receive credit for the slides remaining within affected and discarded cartridges.
- Please forward this notification if the product was distributed outside of your facility.

Impact to Results

The issue does not affect the individual slides, it is specific to the cartridge itself. Patient results are not affected, the issue is limited to condition codes due to a mechanical malfunction.

It is acceptable to continue using a potentially affected lot.

Resolution

We have made modifications to our manufacturing process to help reduce the occurrence of this issue.

Ortho Clinical Diagnostics will provide credit for the slides remaining within affected cartridges for which you are unable to reposition the ABP.

Use the enclosed Request for Credit form to request credit for affected cartridges. We suggest listing several cartridges at a time on each form rather than completing a separate form each time you experience this issue. Please duplicate the Request for Credit form on an as-needed basis.

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 phone number*. *Insert signatory if appropriate in your region.*

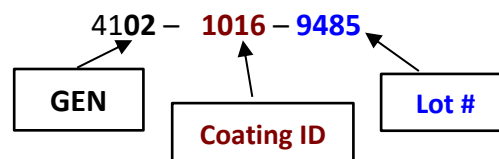
Enclosures:

1. List of Potentially Affected VITROS Slides
2. Resolving Slide Dispense Issues
3. Request for Credit Form

QUESTIONS AND ANSWERS

1. **How can I determine the Lot Number for the VITROS® Chemistry Product Slides in my inventory?**

Use the example below to determine the lot number:



2. **How long will this issue occur?**

Ortho has taken corrective action to prevent recurrence of this issue and therefore, only the lots listed in the enclosed List of Potentially Affected VITROS Slides are affected.

Confirmation of Receipt – Response Required

Communication ID: 2019-248_EU

Date of Issue: 2019-xx-xx

URGENT FIELD SAFETY NOTICE

Intermittent Dispense Issues with VITROS® Chemistry Products CL⁻ and K⁺ Slides

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

DD-SEP-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 (Ref. CL2019-248_EU) and understand that I may experience an increase in slide dispense issues when using specific lots of VITROS CL⁻ and/or K⁺ Slides.

I am aware that I may reposition the anti-backup platen (ABP) in the cartridge to resolve the issue by following the enclosed instructions. I understand that Ortho will credit my account for affected cartridges where the ABP cannot be repositioned. I will use the enclosed Request for Credit form to receive credit for slides discarded in affected cartridges.

Signature:

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

Print Name: _____

Phone Number: _____

Date: _____

Your Comments: _____