



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.*

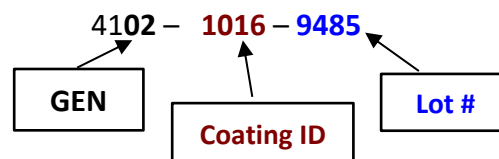
Enclosures:

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.

List of Potentially Affected VITROS Slides

Potentially Affected VITROS® Chemistry Products Cl⁻ and K⁺ Slides Lots

VITROS Chemistry Product K+ Slide Lots

4102-0995-0186	4102-1000-3719	4102-1005-5278	4102-1010-7603	4102-1016-9485
4102-0995-0196	4102-1000-3775	4102-1006-6822	4102-1010-7673	4102-1016-9504
4102-0995-0232	4102-1001-3798	4102-1006-6936	4102-1010-7674	4102-1016-9548
4102-0996-0330	4102-1001-3912	4102-1006-6947	4102-1012-7698	4102-1016-9628
4102-0996-0354	4102-1001-3938	4102-1006-6992	4102-1012-7910	4102-1016-9681
4102-0996-0373	4102-1001-3966	4102-1006-7044	4102-1012-7978	4102-1016-9705
4102-0996-0477	4102-1001-3996	4102-1006-7073	4102-1012-7985	4102-1016-9775
4102-0996-0495	4102-1001-4053	4102-1006-7109	4102-1012-8212	4102-1016-9822
4102-0996-0548	4102-1001-4061	4102-1006-7201	4102-1013-7302	4102-1016-9840
4102-0996-0590	4102-1001-4134	4102-1006-7205	4102-1013-8441	4102-1016-9870
4102-0996-0591	4102-1002-3496	4102-1006-7287	4102-1013-8469	4102-1017-0029
4102-0996-0625	4102-1002-3498	4102-1006-7304	4102-1013-8500	4102-1017-9951
4102-0996-0626	4102-1002-4095	4102-1008-5927	4102-1014-8567	4102-1017-9976
4102-0997-0685	4102-1002-4167	4102-1008-5928	4102-1014-8628	4102-1017-9986
4102-0997-0716	4102-1002-4196	4102-1008-5986	4102-1014-8716	4102-1018-0175
4102-0997-0763	4102-1002-4284	4102-1008-6101	4102-1014-8756	4102-1018-0214
4102-0997-0818	4102-1002-4342	4102-1008-6109	4102-1014-9025	4102-1018-0297
4102-0997-1322	4102-1002-4403	4102-1008-6142	4102-1014-9031	4102-1018-0349
4102-0997-1446	4102-1002-4438	4102-1008-6198	4102-1014-9051	4102-1018-0374
4102-0997-1447	4102-1002-4469	4102-1008-6287	4102-1014-9085	4102-1018-0376
4102-0997-1483	4102-1002-4506	4102-1008-6304	4102-1014-9117	4102-1018-0454
4102-0997-1484	4102-1004-4598	4102-1009-6368	4102-1014-9118	4102-1018-0492
4102-0997-1485	4102-1004-4699	4102-1009-6478	4102-1015-9091	4102-1018-0493
4102-0997-1602	4102-1004-4700	4102-1009-6494	4102-1015-9112	4102-1018-0632
4102-0997-1699	4102-1004-4751	4102-1009-6588	4102-1015-9179	4102-1018-0652
4102-0998-1652	4102-1004-4842	4102-1009-6658	4102-1015-9232	4102-1018-0686
4102-0998-1767	4102-1004-5037	4102-1009-6686	4102-1015-9262	4102-1018-9482
4102-0999-1938	4102-1004-5051	4102-1009-6701	4102-1015-9277	4102-1019-0174
4102-0999-1939	4102-1004-5095	4102-1009-6723	4102-1016-0143	4102-1019-0649
4102-1000-3291	4102-1004-5097	4102-1010-7327	4102-1016-9332	4102-1019-0676
4102-1000-3396	4102-1004-5186	4102-1010-7400	4102-1016-9337	4102-1019-0808
4102-1000-3507	4102-1005-4742	4102-1010-7489	4102-1016-9383	4102-1019-0828
4102-1000-3510	4102-1005-5198	4102-1010-7514	4102-1016-9384	4102-1019-0892
4102-1000-3645	4102-1005-5249	4102-1010-7551	4102-1016-9431	4102-1020-0457
4102-1000-3669				

List of Potentially Affected VITROS Slides

VITROS Chemistry Product CI- Slide Lots

4010-0679-8855	4010-0683-9699	4010-0687-1233	4010-0697-5883	4010-0702-8206
4010-0679-8920	4010-0683-9700	4010-0690-1842	4010-0697-7863	4010-0702-8207
4010-0679-8997	4010-0683-9745	4010-0690-1882	4010-0697-7864	4010-0702-8242
4010-0679-8998	4010-0684-0040	4010-0690-1909	4010-0701-7794	4010-0702-8243
4010-0679-9028	4010-0684-0092	4010-0690-1996	4010-0701-7795	4010-0702-8284
4010-0679-9092	4010-0684-9830	4010-0690-1997	4010-0701-7810	4010-0702-8285
4010-0679-9093	4010-0684-9832	4010-0691-3185	4010-0701-7811	4010-0702-8286
4010-0679-9138	4010-0684-9911	4010-0691-3259	4010-0701-8345	4010-0702-8287
4010-0679-9171	4010-0684-9912	4010-0691-3330	4010-0701-8346	4010-0708-0873
4010-0679-9195	4010-0684-9947	4010-0695-5372	4010-0701-8411	4010-0708-0875
4010-0679-9214	4010-0687-0874	4010-0695-5417	4010-0701-8412	4010-0708-0930
4010-0681-9270	4010-0687-1010	4010-0695-5503	4010-0701-8413	4010-0708-0931
4010-0681-9319	4010-0687-1011	4010-0695-5526	4010-0702-7860	4010-0708-0932
4010-0681-9320	4010-0687-1101	4010-0695-5598	4010-0702-7861	4010-0708-0933
4010-0681-9370	4010-0687-1102	4010-0695-5658	4010-0702-7926	4010-0708-1006
4010-0681-9538	4010-0687-1103	4010-0695-5693	4010-0702-7927	4010-0708-1007
4010-0681-9552	4010-0687-1164	4010-0695-5694	4010-0702-8173	4010-0708-1032
4010-0683-9594	4010-0687-1165	4010-0697-5807	4010-0702-8205	4010-0708-1055
4010-0683-9663	4010-0687-1232	4010-0697-5882		

Resolving Slide Dispense Issues

Slide Dispense Condition Codes

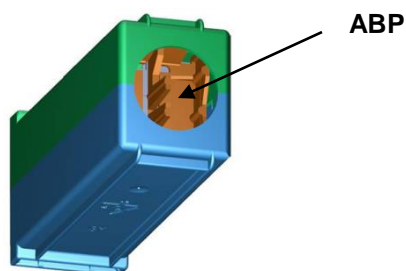
The most common condition codes to occur if the anti-backup platen (ABP) cannot advance inside the cartridge are presented in the table below:

Slide Dispense Condition Codes for VITROS Systems	
VITROS 250/350 Systems	
EAU	* SAMPLE METERING * WETNESS DETECTOR * No slide present.
7EH	PLUNGERS * Outer Plunger sensor malfunction
D03	* SLIDE TRANSPORT * DISPENSE BLADE * Position error *
D04	* DISPENSE BLADE * Sensor error *
VITROS 5,1 FS/4600/5600/XT 7600 Systems	
PVD-017	Reagent or diluent pack unusable
TA0-84G or TA1-84G	DISPENSE BLADE - Home to Tip Locator - No Slide Detected
TA0-6** or TA1-6**	SUPPLY 1 PLUNGER
TA0-2** or TA1-2**	SUPPLY 2 PLUNGER

Repositioning the Anti-Backup Platen (ABP)

If you experience one of the above condition codes, follow these steps:

1. Remove the affected cartridge from the Slide Supply. You may observe the following:
 - No slides are visible in the slide dispense window at the top of the cartridge.
 - Slide stack or ABP appears to be crooked.
 - Slides or ABP are restricted inside the cartridge.
2. Reposition the ABP:
 - a. Hold the cartridge in a vertical position.
 - b. Gently push up on the ABP located inside the bottom of the cartridge.
(Refer to the illustration below for the location of the ABP.)



- c. Continue to push gently until the top of the slide stack becomes visible in the slide dispense window at the top of the cartridge. You may hear a faint clicking sound indicating that the ABP is engaging the plastic teeth inside the cartridge.
3. Reload the cartridge onto the system.
 - If a slide dispense condition code occurs again on the same cartridge, remove the cartridge and replace with a new one.
 - Record discarded cartridges on the Credit Request form as needed and return the form to Ortho to receive credit for affected cartridges.

Request for Credit

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

Please complete and return this form to request credit for affected VITROS[®] Chemistry Products Cl⁻ and K⁺ Slides that your facility discarded due to slide dispense issues.

Please make additional copies of this form, as-needed.

Fax or Scan to PDF and email:

FAX TO: insert name

FAX: insert number

EMAIL: insert email

Please credit my account for the affected slides of VITROS Chemistry Products Cl⁻ and K⁺ Slides in the quantities indicated below:

VITROS [®] Chemistry Products Slides Discarded Due to Slide Dispense Issue			
Product Code	Name of Product	Lot Number	Quantity of Affected Slides
6844471	VITROS Cl ⁻ Slides		
8157596	VITROS K ⁺ Slides		

***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: _____