

# Ortho Clinical Diagnostics

PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

May 09, 2013

## IMPORTANT PRODUCT CORRECTION NOTIFICATION VITROS<sup>®</sup> Chemistry Products CRP Slides, Coatings 0766, 0767, and 0768 CAT Nos. 1926740 and 8097990

Dear Customer,

While performing an internal investigation, Ortho Clinical Diagnostics (OCD) determined that VITROS<sup>®</sup> Chemistry Products CRP Slides, Coatings 0766, 0767, and 0768 contain an amount of surfactant that is in excess of the amount indicated in the product specification. Surfactant is used in several VITROS<sup>®</sup> Slide Products. Our records indicate that you received one or more lots of VITROS<sup>®</sup> CRP Slides from the 3 coatings containing an excess amount of surfactant.

OCD has conducted testing that indicates that VITROS<sup>®</sup> CRP Slides made from Coatings 0766, 0767, and 0768 are currently meeting their intended use and performance specifications. However, at this time we are unable to determine the effect that the excess of surfactant may have on long-term product performance. If you have an alternate lot of VITROS<sup>®</sup> CRP Slides in your inventory, please use the alternate lots and discard the affected product. OCD will provide credit for the product you have discarded. If an alternate lot is not available, in order to minimize disruption to your laboratory, OCD recommends that you continue to use VITROS<sup>®</sup> CRP Slides from the affected coatings until you receive product replacements, which may take several weeks.

If you have technical questions or experience issues with these VITROS<sup>®</sup> CRP Slides prior to receiving your replacement product, please contact Customer Technical Services 1-800-421-3311.

*Please do the following:*

- Complete and return the attached Confirmation of Receipt Form by May 20, 2013.
- Once you have received your replacement slides, or if you have an alternate lot in your inventory, discontinue using VITROS<sup>®</sup> CRP Slides lots with Coatings 0766, 0767, and 0768 and discard any remaining inventory of these lots of product.
- Forward the information in this notification, if you have distributed this product outside of your facility.
- Post this notification by each VITROS<sup>®</sup> System running VITROS<sup>®</sup> CRP Slides in your facility place it with your VITROS<sup>®</sup> Product user documentation.

We apologize for any inconvenience this may cause your laboratory. We have anticipated some questions you may have in the following Questions and Answers section. If you have questions about your replacement order, please call our Customer Service Center at 1-800-828-6316.

Sincerely,



Jennifer Paine  
Worldwide Vice President Quality, Regulatory and Compliance

## Questions and Answers

**1. Are all VITROS® CRP Slide cartridges from these coatings affected?**

Yes. OCD has confirmed that VITROS® CRP Slides from Coatings 0766, 0767 and 0768 contain the excess amount of surfactant.

**2. How can I tell if I have Coating 0766, 0767 and/or 0768 of VITROS® CRP Slides?**

Please check the 12-digit code on all slide cartridges. All VITROS MicroSlide™ Products use the following lot identification format.

VITROS MicroSlide Lot Identification Format		
GEN No.	Coating	Lot No.
3773	0766	
3784	0767	XXXX
3785	0768	

**3. When will I receive my replacement product if I do not have an alternate lot available?**

In order to avoid any disruption to your laboratory, OCD is shipping your replacement product for delivery as soon as possible. It will be shipped to the same location as the previous shipment of this product. Please indicate on your Confirmation of Receipt form whether you want replacement product or, if you have an alternate lot available, credit for discarded product. If you have questions about your replacement order, please call our Customer Service Center at 1-800-828-6316.

**4. May I use my current lots of VITROS® CRP Slides with Coating 0766, 0767 and/or 0768?**

Yes. VITROS® CRP Slides, Coatings 0766, 0767, and 0768 are currently meeting their intended use and performance specifications. We will be replacing the product because the long term impact to product performance is unknown. Testing of quality control fluids and evaluation of control fluid results as per standard laboratory practice will identify any performance issues that could occur.

**Confirmation of Receipt - Important Response Required**  
**IMPORTANT PRODUCT CORRECTION NOTIFICATION**  
**VITROS® Chemistry Products CRP Slides, Coatings 0766, 0767, and 0768**  
**CAT Nos. 1926740 and 8097990**

*So that we can complete our records, please return this form to us no later than May 20, 2013.*

**FAX TO: Joe Falvo, Safety, Risk Management and Surveillance**

**FAX: 1-888-557-3759 or 585-453-4110**

**Section I: Confirmation**

I received the IMPORTANT Product Correction Notification (Ref. CL13-144\_CRP) and inspected my inventory for VITROS® CRP Slides, Coatings 0766, 0767, and 0768. *Please choose from the following options:*

1.  I confirm that we no longer have any of the affected lots of this product in our inventory.
2.  I have an alternate lot in my inventory and have discarded lots with the affected coating listed below. Please credit my account for discarded full pack quantities listed below.
3.  Please provide replacement product for full pack quantities listed below. I will discard the affected product upon receipt of my product replacement.

Product Code	Product Name	Affected Coating No.	Quantity of Packs* Discarded

*\*Product Code 1926740: 1 Pack = 250 Slides; Product Code 8097990: 1 Pack = 90 slides*

*Your signature provides confirmation that you have received and understood this notification.*

Your Name: \_\_\_\_\_ Job Title (optional): \_\_\_\_\_  
 Signed\*: \_\_\_\_\_ Date: \_\_\_\_\_  
 Fax Number: \_\_\_\_\_ Telephone Number: \_\_\_\_\_  
 J Number: \_\_\_\_\_ Institution: \_\_\_\_\_

*Your comments are always welcome:*

**Section II – Verification of your Name and Address**

Verify or provide your name and mailing address:

Please complete this section if your name and/or mailing address have changed:

Institution / Contact Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 City: \_\_\_\_\_ State/Province: \_\_\_\_\_ Zip/Postal Code: \_\_\_\_\_  
 Telephone: \_\_\_\_\_ FAX: \_\_\_\_\_