

June 25, 2011

URGENT PRODUCT CORRECTION NOTIFICATION

**VITROS® Chemistry Products PHBR Slides
Lots Manufactured from Coating 0053 (Product Code 8221384)**

Dear Customer,

The purpose of this notification is to inform you that Ortho Clinical Diagnostics (OCD) has received customer complaints of intermittent imprecision, outliers, or shifts in control fluid values when using various lots of VITROS® Chemistry Products PHBR Slides (phenobarbital) from Coating 0053. Our investigation has confirmed that biased values for patient samples could be obtained that may or may not be detected by quality control fluids. For this reason, you must discontinue using and discard *all* remaining lots of VITROS® PHBR Slides manufactured from Coating 0053. Please note that you may have multiple lots of VITROS® PHBR Slides from Coating 0053 in your inventory.

Our investigation into this issue is in progress and a specific root cause has not yet been identified. At this time, we believe that only VITROS® PHBR Slides from Coating 0053 are affected by this issue; however, all lots from this coating may potentially be affected. Please refer to the attached Questions and Answers Section for information on how to identify the affected coating.

The following observations have been reported when using VITROS® PHBR Slides, Coating 0053:

- Occasionally biased but credible patient results that may not be detected by the laboratory.
- Failed calibrations or successful calibrations that do not verify with control values within acceptable ranges.
- Occasional quality control failures or increased imprecision on control fluids across all concentrations. We expect that biases of the same magnitude and direction could be observed with patient and proficiency fluids.
 - Approximately 70% of the reported discrepancies in QC values were negatively biased with ranges identified in the table below.
 - Approximately 30% of the reported discrepancies in QC values were positively biased with ranges identified in the table below.

Expected Result Range	Reported Negative Biases for QC Fluids	Reported Positive Biases for QC Fluids
3 - 15 µg/mL (13 - 65 µmol/L)	0 to -5 µg/mL (0 to -22 µmol/L)	0 to 4 µg/mL (0 to 17 µmol/L)
15 - 50 µg/mL (65 - 216 µmol/L)	-6 to -27 µg/mL (-26 to 116 µmol/L)	None reported
> 50 µg/mL (>216 µmol/L)	-12 to -25 µg/mL (-52 to -108 µmol/L)	11 to 24 µg/mL (47 to 103 µmol/L)

OCD recommends that you consult with your Laboratory Medical Director and requesting physician to resolve any concerns you may have regarding previously reported patient results. Please contact OCD Customer Technical Services at 01 464 5064 to report any adverse events that are identified.

Please do the following:

- Discontinue using and discard all remaining lots of VITROS® PHBR Slides, Coating 0053.
- Complete and return the attached Confirmation of Receipt form upon receipt of this notification. Once the Confirmation of Receipt form is received, we will begin the replacement order process.
- Forward this notification to all departments that utilize the VITROS® PHBR Slides.
- Post this notification by each VITROS® 250/350, 950, 5,1 FS or 5600 Integrated Chemistry System in your facility that utilizes the VITROS® PHBR Slides, or with your VITROS® user documentation.

Please refer to the Questions and Answers section for additional information. If you have any questions regarding this notification, please call Customer Technical Services at 01 464 5064. We thank you for your continued support of VITROS Chemistry Products.

Sincerely,

*Yahya Wadi
Area Service Manager
Central Region
Clinical & Dental Radiology*

Enclosure:

Confirmation of Receipt Form

Questions and Answers

1. What type of samples can be affected by this issue?

Biases of the same magnitude and direction could be observed with quality control fluids, patient samples and proficiency samples.

2. Will this issue be detected by routine quality control fluid testing?

Quality control fluids are similarly affected by this issue; however, due to the random occurrence of this imprecision, it is possible that routine daily quality control fluid testing for phenobarbital may not detect this issue.

3. Should I take any action on previously reported patient results using VITROS® PHBR Slides from Coating 0053?

If you suspect that patient results were affected at your facility, consult with your Laboratory Medical Director and requesting physician to resolve any concerns you may have regarding previously reported patient results. Please contact OCD Customer Technical Services at 01 464 5064 to report any adverse events that are identified.

4. How can I determine if I have the affected lots of VITROS® Chemistry Products PHBR Slides in my inventory?

We believe that this issue affects only VITROS® PHBR Slides from Coating 0053; however, all lots from this coating may potentially be affected. For this reason, you must discontinue using and discard *all* remaining lots of VITROS® PHBR Slides from Coating 0053. The coating and lot number on the packaging (carton and foil wrapper) for VITROS® PHBR Slides, Coating 0053 can be identified as follows:

2532	0053	XXXX
GEN 32	Coating 0053	4 Digit Lot #

5. What is the bias that has been observed when using VITROS® PHBR Slides, Coating 0053?

- Approximately 70% of the reported discrepancies in QC values were negatively biased with ranges identified in the table below.
- Approximately 30% of the reported discrepancies in QC values were positively biased with ranges identified in the table below.

Expected Result Range	Reported negative biases for QC Fluids:	Reported Positive biases for QC Fluids:
3 - 15 µg/mL (13 – 65 µmol/L)	0 to -5 µg/mL (0 to -22 µmol/L)	0 to 4 µg/mL (0 to 17 µmol/L)
15 - 50 µg/mL (65 – 216 µmol/L)	-6 to -27 µg/mL (-26 to 116 µmol/L)	None reported
> 50 µg/mL (>216 µmol/L)	-12 to -25 µg/mL (-52 to -108 µmol/L)	11 to 24 µg/mL (47 to 103 µmol/L)

Confirmation of Receipt Important Response Required
URGENT PRODUCT CORRECTION NOTIFICATION

VITROS® Chemistry Products PHBR Slides
Lots Manufactured from Coating 0053 (Product Code 8221384)

So that we can complete our records, please return this form **no later than July 25, 2011**.

FAX TO: *Yahya Wadi*

FAX: 01 465 7912

Section 1 - Confirmation

- I received Urgent Product Correction Notification (Ref. CL11-185a) and understand that I must discontinue using and discard all remaining VITROS® PHBR Slides, Coating 0053. Please select from the following options:
 - I no longer have any VITROS® PHBR Slides from Coating 0053 remaining in my inventory.
 - Upon inspection of my inventory, I have identified the following quantity of VITROS® PHBR Slides from Coating 0053. *(Please complete the table below to process your replacement order):*

VITROS® PHBR Slides, Coating 0053			
Lot No.	Number of Sales Units Discarded	Lot No.	Number of Sales Units Discarded
2532-0053-0144		2532-0053-1489	
2532-0053-0149		2532-0053-1490	
2532-0053-0217		2532-0053-4961	
2532-0053-0615		2532-0053-4984	
2532-0053-0616		2532-0053-4996	
2532-0053-1472		2532-0053-4997	
2532-0053-1488			

- Please indicate your choice of product replacement or credit by checking the appropriate box below:
 - Credit my account for the quantities of product indicated above.
 - Send replacement product in the quantities indicated above*.

***Note: In order to provide product for all customers, we may need to allocate orders until additional product is available.**

Your Name: _____ Name of Facility: _____

*Your Signature/Date: _____ Telephone: _____

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

Section II – Verify 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: _____