

March XX, 2013

URGENT FIELD SAFETY NOTICE

VITROS[®] Chemistry Products PHBR Slides

Product Code 8221384

Dear Customer,

As part of a Field Safety Corrective Action, 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 accuracy and control fluid values outside of expected intervals when using VITROS[®] Chemistry Products PHBR Slides. Our investigation confirmed that positively biased values for patient samples could be obtained that may not be detected by quality control fluids. As a result, you must immediately discontinue using and discard VITROS[®] PHBR Slides remaining in your inventory. The following Generation/Coatings are affected:

| | Generation (GEN) | Coating No. | Expiration Date Range |
|--|-------------------------|--------------------|------------------------------------|
| VITROS[®] Chemistry Products PHBR Slides | GEN 38 | 0060 | 01-Apr-2013 through 01-Feb-2014 |
| | GEN 39 | 0062 | |
| | GEN 40 | 0063 | |
| | GEN 41 | 0064 | |

VITROS[®] Chemistry Products PHBR Slides quantitatively measure phenobarbital (PHBR) concentration in serum and plasma using VITROS[®] 250/350/950/5,1 FS, 4600 Chemistry Systems and the VITROS[®] 5600 Integrated System.

Investigation Summary

Our investigation into this issue is in progress and a specific root cause has not yet been identified. Although the affected slides met all release testing specifications prior to distribution, the following observations have been reported when using VITROS[®] PHBR Slides:

- Positively biased but credible patient results that may not be detected by the laboratory.
- Occasional quality control failures or increased imprecision across all concentrations. We expect that positive and negative biases of the same magnitude could also be observed with patient and proficiency fluids.

Required Actions

- Discontinue using and discard all VITROS[®] PHBR Slides remaining in your inventory.
- Complete and return the attached Confirmation of Receipt form no later than **March XX, 2013**.
- Forward this notification to all laboratories within your facility that use VITROS[®] PHBR Slides.
- Post this notification by *each* VITROS[®] System that utilizes VITROS[®] PHBR Slides or with your VITROS[®] user documentation.

Impact to Results

OCD recommends that you consult with your Laboratory Medical Director and requesting physicians to resolve any concerns that you may have regarding previously reported patient results using the affected product. Although we have no known incidences; please contact OCD Customer Technical Services to report any adverse events that are identified for results generated using the affected slides. Refer to the information provided on page three for the magnitude of the imprecision and bias observed when using the affected slides.

Product Availability

OCD is unable to release new lots or provide any VITROS[®] PHBR Slides at this time. We are continuing to investigate the root cause of this issue and recommend that you use an alternate method until further notice. We regret that we are unable to provide you with a timeframe for re-establishing sufficient supply levels at this time. We are making every attempt to resolve this situation as soon as possible and will notify you when replacement product is available.

We apologize for the inconvenience this will cause your laboratory. We have anticipated some questions you may have in the following Questions and Answers section. If you have any additional questions, please contact Customer Technical Services at *insert appropriate number*.

Sincerely,

insert appropriate name
insert appropriate number

Questions and Answers

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

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

2. Should I take any action on previously reported patient results using VITROS® PHBR Slides?

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

3. What is the impact to results using VITROS® PHBR Slides that are affected?

OCD conducted an extensive investigation and identified three separate issues:

- Positively biased results as described below.
- Increased imprecision using the affected slides on VITROS® 5,1 FS, 4600 or 5600 Systems.
- Intermittent negatively biased results and/or imprecision after performing the Immuno-Wash Fluid (IWF) Maintenance procedure.

The table below shows the minimum to maximum bias observed by OCD:

| Result Range | Positive Bias Observed | Overall % Bias |
|---|--|----------------|
| 3.0 – 15.0 µg/mL (13 – 65 µmol/L) | 0.88 up to 2.53 µg/mL (3.8 up to 10.9 µmol/L) | 10.9 - 43.4% |
| 15.0 – 50.0 µg/mL (65 – 216 µmol/L) | 1.39 up to 6.07µg/mL (6.0 up to 26.2µmol/L) | 4.6 - 11.0% |
| > 50.0 µg/mL (>216 µmol/L) | 2.42 up to 5.40µg/mL (10.4 up to 23.3µmol/L) | 4.4 - 9.4% |

We have also confirmed reports of imprecision accompanied by a negative shift in results:

| PHBR Concentration | Range of Bias Observed |
|--------------------------------------|--|
| 10.0 µg/mL (43.1 µmol/L) | -3.7 to +5.4 µg/mL (-15.95 to +23.27 µmol/L) |
| 25.0 µg/mL (107.75 µmol/L) | - 11.3 to +6.1 µg/mL (-48.70 to +26.29 µmol/L) |
| 60 µg/mL (258.6 µmol/L) | -24.3 to +21.2 µg/mL (-104.73 to +91.37 µmol/L) |

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

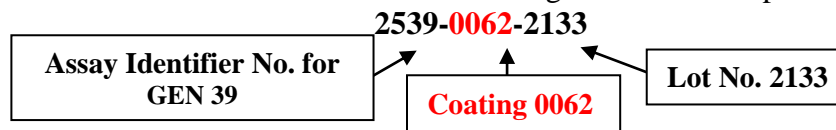
Quality control fluids are similarly affected by the precision issue; however, due to the random occurrence of this imprecision, it is possible that routine daily quality control fluid testing for phenobarbital may not detect this issue:

- Negatively biased results following the IWF Maintenance procedure would be detected provided that the required Quality Control testing was performed upon completion.
- Positively biased results may not be detected using VITROS® control fluids as the Range of Means established for VITROS® TDM Performance Verifiers was established using slides that are affected by this issue.

Questions and Answers (Continued)

5. How can I determine the GEN and Coating number of VITROS[®] PHBR Slides in my inventory?

Use the example below to determine the GEN and Coating number on the product packaging:



6. Will the Calibration Diskette and Assay Data Disk (ADD) continue to support the VITROS[®] PHBR Slides on my system?

OCD will remove the calibration data for VITROS[®] PHBR Slides from a future version of the Calibration Diskette and ADD in a few weeks. The history chart will document the Data Release Version (DRV) in which the change occurred. The PHBR assay target will continue to be available on your system. If you use the on board quality control program on your VITROS[®] System, we recommend that you perform a back up of the current quality control results.

7. If I cannot use my inventory of VITROS[®] PHBR Slides, what action shall I take for obtaining phenobarbital test results?

If your laboratory does not have an alternative phenobarbital method available, we recommend that you consider sending patient samples to another laboratory.

8. Are other slides affected by this issue?

No, this issue only affects VITROS[®] PHBR Slides. All other immuno-rate slide products are not affected (e.g., VITROS[®] CRP, PHYT, DGXN, CRBM Slides). It is acceptable to continue to use your inventory of the calibrators, performance verifiers and immuno-wash fluids for these assays.

9. What is OCD doing to help resolve this issue?

We are working to identify root cause, resolve this issue, and re-establish our inventory of VITROS[®] PHBR Slides. We will issue a follow up notification regarding future product availability.

Confirmation of Receipt - Important Response Required

URGENT FIELD SAFETY NOTICE
VITROS[®] Chemistry Products PHBR Slides
Product Code 8221384

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

FAX TO: *insert appropriate name*

FAX: *insert appropriate number*

Section I: Confirmation

I received the Urgent Field Safety Notice (Ref. CL13-097_EU) and agree to immediately discontinue using and discard all VITROS[®] PHBR Slides remaining in my inventory.

Please choose from the following options:

- My laboratory no longer uses VITROS[®] PHBR Slides and is not affected by this issue.
- I do not have any VITROS[®] PHBR Slides in my inventory.
- Upon inspection, I have identified the following quantity of VITROS[®] PHBR Slides remaining in my inventory.

| VITROS[®] Chemistry Products PHBR Slides Product Code 8221384 | Generation | Coating No. | Quantity of Sales Units Discarded* |
|---|-------------------|--------------------|---|
| | GEN 38 | 0060 | |
| | GEN 39 | 0062 | |
| | GEN 40 | 0063 | |
| | GEN 41 | 0064 | |

**One Sales Unit = 90 Slides (5 cartridges of 18 slides). OCD will credit your account for all slides that you have discarded.*

**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 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: _____