

November XX, 2010

URGENT FIELD SAFETY NOTICE
VITROS[®] Chemistry Products PHYT Slides, Coating 0115
Product Code 8298671

Dear Customer,

As part of a Field Safety Corrective Action, the purpose of this notification is to inform you about a performance issue with VITROS[®] Chemistry Products PHYT Slides, (Coating 0115, Product Code 8298671). Ortho Clinical Diagnostics (OCD) has received customer complaints concerning intermittent Immuno-Rate wash condition codes, imprecision, outliers, or shifts in control fluid values when using VITROS[®] PHYT Slides (from Coating number 0115 only). We are advising you to discontinue using and discard any remaining VITROS PHYT Slides, Coating 0115. Please note that you may have more than one lot of VITROS[®] PHYT Slides, Coating 0115 in your inventory. Please refer to Question #2 in the Q & A Section for information on how to identify the coating.

OCD's investigation into these issues is in progress and a specific root cause has not yet been identified. Some of the reported discrepancies include credible but biased values for patient samples.

The following issues may be observed when using VITROS[®] PHYT Slides, Coating 0115:

- Occasional biased but credible patient results that may not be detected by the laboratory.
- Occasional Quality Control failures or increased imprecision on control fluids.

The reported biases for Quality Control fluids were predominantly negative (>80% of the observations), and in the range of -4 to -10 µg/mL (-15.8 to -39.6 µmol/L). Less frequently, (<20% of observations), the reported biases in QC values were positive and in the range of +5 to +10 µg/mL (+19.8 to +39.6 µmol/L). Biases of the same magnitude and direction could be observed with patient samples. The table below summarizes the reported data for QC fluids.

Reported biases for QC fluids:	Result Range	Frequency
-4 to -10 µg/mL (-15.8 to -39.6 µmol/L)	15-30 µg/mL (59 – 119 µmol/L)	>80% of the reported biased QC results
+5 to +10 µg/mL (+19.8 to +39.6 µmol/L)	15-30 µg/mL (59 – 119 µmol/L)	<20% of the reported biased QC results

- Condition Codes requiring repeat testing.
- Calibration failures or successful calibrations that do not verify with control values within acceptable ranges.

If you suspect 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 do the following:

- Discontinue using and discard all remaining VITROS® PHYT Slides, Coating 0115.
- Complete and return the attached Confirmation of Receipt form upon receipt of this notification. Once the fax reply is received, we will begin the replacement order process.
- Forward this notification to all departments and areas that utilize the VITROS® PHYT Slides, Coating 0115.
- Post this notification by each VITROS® Chemistry Analyzer in your facility that utilizes the VITROS® PHYT Slides, Coating 0115 or with the 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 *insert appropriate phone number*. We thank you for your continued support of VITROS Chemistry Products.

Sincerely,

Insert Appropriate Name and Title

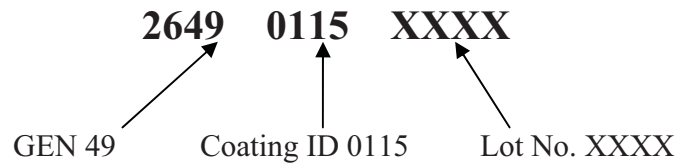
Questions and Answers

1. Should I take any action on previously reported patient results using VITROS® PHYT Slides, Coating 0115?

If you suspect 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.

2. How can I determine if I have the VITROS® Chemistry Products PHYT Slides Coating 0115 in my inventory?

The coating and lot number on the packaging (carton and foil wrapper) for VITROS® PHYT Slides, Coating 0115 will display as:



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

Any sample type (i.e., patient, quality control fluid, and proficiency fluids) could be affected.

4. How much bias has been observed when using VITROS® Chemistry Products PHYT Slides, Coating 0115?

The reported biases for Quality Control fluids were predominantly negative (>80% of the time), and in the range of -4 to -10 µg/mL (-15.8 to -39.6 µmol/L). Less frequently (<20% of observations), the reported biases in QC values were positive and in the range of +5 to +10 µg/mL (+19.8 to +39.6 µmol/L). Biases of the same magnitude and direction could be observed with patient samples. The table below summarizes the reported data for QC fluids.

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

Due to the random occurrence of the issue, it is likely that routine daily quality control fluid testing for PHYT may not detect this issue.

6. What are the Immuno-Rate wash condition codes that may occur with the affected coating?

The following condition codes have been observed:

Analyzer	Condition Code	Description
VITROS® 5600 Integrated System VITROS® 5,1 FS Chemistry System	U90-382	IR wash error ID: %s Assay: %s
VITROS® 350/250/250AT Chemistry Systems	6LU	6LU IR WASH DETECTION * IR wash failed
VITROS® 950/950AT Chemistry System	X3Q	X3Q WE-PREDICTION * IR wash failed

Confirmation of Receipt Important Response Required
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So that we can complete our records, please return this form **no later than November XX, 2010.**

FAX TO: *Insert Appropriate Name and Title*

FAX: *Insert Appropriate Fax Number*

Section 1 - Confirmation

I received Urgent Field Safety Notice (CL10-332a_EU) and understand that I must discontinue using and discard all remaining VITROS® PHYT Slides, Coating 0115. Please choose from the following options:

- I no longer have any VITROS® PHYT Slides from Coating 0115 remaining in my inventory.
- Upon inspection of my inventory, I have identified the following quantity of VITROS® PHYT Slides from Coating 0115. *(Please complete the table below to process your replacement order):*

Product Name	Lot No. (Fill in the last 4 numbers of the lot number)	No. of Sales Units to be replaced (90 slides/sales unit)
VITROS® PHYT Slides	2649-0115-	
	2649-0115-	
	2649-0115-	

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*.

***To be able to provide product for all customers, we may need to allocate orders until additional product is available.**

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: _____

Your comments are always welcome:
