



May xx, 2018

URGENT FIELD SAFETY NOTICE**Potential for Imprecise Results using VITROS® Chemistry Products PHYT Slides**

Dear Customer,

As part of a Field Safety Corrective Action, Ortho Clinical Diagnostics initiated this Urgent Field Safety Notice due to imprecise results may occur when using the VITROS Chemistry Products PHYT Slides listed below.

Name (Unique Identifier No.)	Product Code	Affected Generation (GENs)	Coating ID	Expiry Dates
VITROS® Chemistry Products PHYT Slides (10758750004690)	8298671	GEN 16	Coating 0165	15 March 2018 Through 15 June 2018

[Refer to page two for a complete list of affected lots.](#)

VITROS Chemistry Products PHYT Slides quantitatively measure phenytoin (PHYT) concentration in serum and plasma using VITROS 250/350/5,1 FS and 4600 Chemistry Systems and VITROS 5600 Integrated Systems.

Description of Issue

Ortho confirmed customer complaints regarding the potential for imprecise results when using the VITROS PHYT Slides identified above. Our records indicate that you were shipped an affected lot.

Impact to Results

Ortho performed internal testing to confirm the issue using several lots of Coating 0165. The results obtained were either positively or negatively biased across the VITROS PHYT Slides measuring range of 3.00–40.00 µg/mL (11.88–158.40 µmol/L). Refer to Question and Answer 3 for detailed information.

Ortho advises that you review all previously reported results using the affected lots. Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

REQUIRED ACTIONS

- **Immediately discontinue** using and discard all remaining inventory of VITROS PHYT Slides for the affected lots.
- Complete the Confirmation of Receipt form no later than **May xx, 2018**. Ortho will replace your remaining inventory of the affected lots or credit your account.
- Post this notification by each VITROS System in your facility or with the user documentation.
- Forward this notification if the product was distributed outside of your facility.

Resolution

Our root cause investigation is ongoing; we will implement corrective actions as appropriate. Alternate in-date coatings have demonstrated acceptable precision during our investigation.

If you have any affected in-date lots remaining in your inventory, Ortho will replace or credit your account. Partial sales units can only be credited not replaced.

Contact Information

We apologize for any inconvenience this may cause in your laboratory. If you have questions, please contact Ortho Care™ Technical Solutions Center at **insert number.** **Insert signatory if appropriate.**

Questions and Answers

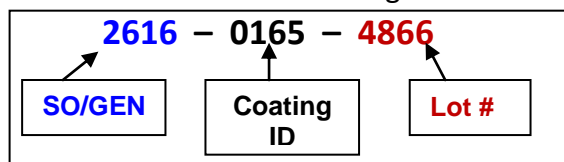
1. What lots are affected by this issue?

The following lots of VITROS PHYT Slides are affected:

Lot No.	Expiry Date	Lot No.	Expiry Date
2616-0165-4866	15 March 2018	2616-0165-6220	01 May 2018
2616-0165-4904		2616-0165-6221	
2616-0165-4870		2616-0165-6219	
2616-0165-4869		2616-0165-6276	
2616-0165-5266	01 April 2018	2616-0165-6791	01 June 2018
2616-0165-5307		2616-0165-6832	
2616-0165-5233		2616-0165-6792	
2616-0165-5232		2616-0165-6787	
2616-0165-5611	15 April 2018	2616-0165-7225	15 June 2018
2616-0165-5610		2616-0165-7226	
2616-0165-5648		2616-0165-7223	
2616-0165-5649		2616-0165-7214	
2616-0165-6218	01 May 2018	2616-0165-7222	
2616-0165-6275			

2. How can I determine the Coating and Lot Numbers for the VITROS PHYT Slides in my inventory?

Use the example below to determine the 12-digit lot number on the product packaging:



3. What is the impact to results?

Ortho performed internal testing to confirm the issue using several lots of Coating 0165. The results obtained were positive or negatively biased across the VITROS PHYT Slide measuring range of 3.00–40.00 µg/mL (11.88–158.40 µmol/L):

PHYT Concentration (µg/mL)	Maximum Positive Bias Observed (µg/mL)	Maximum Negative Bias Observed (µg/mL)
3.09	0.2	-0.1
15.82	0.6	-1.0
28.56	6.6	-3.8
44.53	5.0	-6.4
PHYT Concentration (µmol/L)	Maximum Positive Bias Observed (µmol/L)	Maximum Negative Bias Observed (µmol/L)
12.24	0.8	-0.4
62.65	2.4	-4.0
113.10	26.1	-15.0
176.34	19.8	-25.3

NOTE: These results were obtained by Ortho using several slide lots available for testing; you may observe different levels of bias based on the slide lot(s) used in your laboratory.

Questions and Answers (continued)

4. Should I take any action on previously reported results generated using the affected lots of VITROS PHYT Slides?

Ortho advises that you review all previously reported results using the affected lots. Discuss any concerns you may have regarding previously reported phenytoin results with your Laboratory Medical Director or with the requesting physician.

5. Will routine quality control detect the imprecision using the affected lots?

Due to the intermittent occurrence of the issue, routine daily quality control fluid testing for PHYT may not detect this issue.

6. When will my replacement order arrive?

Upon receipt of your Confirmation of Receipt form, your order will be sent to customer service so that we can expedite your replacement order. In order to supply product for all customers, allocation may be necessary.