Ortho Clinical Diagnostics	**URGENT FIELD SAFETY NOTICE** **Positively Biased Results using VITROS® Immunodiagnostic Products Total β-hCG II Reagent Packs** **IMMEDIATE RESPONSE REQUIRED**

Date Issued

February xx, 2016

Affected Product

Product Name (Unique Device Identifier No.)	**Product Code**	**Affected Lot No.** (Expiry Date)
VITROS® Immunodiagnostic Products Total β-hCG II Reagent Pack (10758750002320, 20758750002327)	6802220	**1410** (17-Jun-2016) **1420** (17-Jun-2016) **1430** (17-Jun-2016) **1440** (15-Aug-2016) **1450** (17-Aug-2016) **1460** (17-Aug-2016) **1470** (17-Aug-2016)
VITROS® Immunodiagnostic Products Total β-hCG II Calibrators (10758750002337, 20758750002334)	6802221	

Issue Description

As part of a Field Safety Corrective Action, Ortho Clinical Diagnostics (Ortho) has confirmed that when testing was conducted using the lots listed above, VITROS® Systems generated results within the measuring range for samples known to not contain measurable hCG. Customers reported that their VITROS® System reported results up to approximately 7.40 mIU/mL (IU/L) for patient samples that should have been less than the measuring range of the assay (<2.39 mIU/mL (IU/L)). Our records indicate that you were shipped an affected lot of this product.

Impact to Results

Ortho's investigation identified that results generated using plasma samples were positively biased compared to those using serum samples for the same patient. Our data indicates that samples expected to be less than the measuring range (<2.39 mIU/mL (IU/L)) may potentially be reported as high as 7.72 mIU/mL (IU/L).

Ortho advises that you review previously reported hCG results of ≤9.00 mIU/mL (IU/L) for plasma samples processed using the affected lots.

Discuss any concerns you may have regarding previously reported hCG results with your Laboratory Medical Director to determine the appropriate course of action. The results from this or any other diagnostic test should be used and interpreted only within the context of the overall clinical picture.

Required Actions

- Immediately discontinue using and discard all remaining inventory of the above-listed lots of VITROS® Total β-hCG II Calibrators and Reagent Packs. We will replace your remaining inventory or credit your account as indicated on your Confirmation of Receipt form.
- Review previously reported results using the affected lots of VITROS® Total β-hCG II Reagent Packs. Discuss any concerns regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.
- Post this notification by your VITROS® System or with your user documentation.
- Complete the Confirmation of Receipt form and return by **February xx, 2016**.

Contact Information

If you have any questions, contact Customer Technical Services at insert number.

Questions and Answers

1. **What is the intended use for the VITROS® Total β-hCG II assay?**

   The VITROS® Total β-hCG II assay is used for the quantitative measurement of human chorionic gonadotropin (hCG) and its β-subunit in human serum and plasma (heparin and EDTA) using VITROS® ECi/ECiQ Immunodiagnostic Systems, VITROS® 3600 Immunodiagnostic System and VITROS® 5600 Integrated Systems.

   The detection of hCG in urine or blood within 3-4 weeks of the last menstrual period is the most reliable indicator for the confirmation of pregnancy. hCG levels may also be elevated in patients with neoplasms, which may or may not be of trophoblastic origin (e.g. cancers of the small intestines, lung, testes, breast and prostate, hydatidiform mole, choriocarcinoma and cerebral metastases). Measurement of circulating hCG levels can be useful in monitoring the treatment of these conditions.

2. **What is the measuring range for the VITROS® Total β-hCG II assay?**

   The measuring range for the VITROS® Total β-hCG II assay is 2.39-15,000 mIU/mL (IU/L).

3. **What is the impact to my results?**

   Ortho's investigation identified that results generated using plasma samples were positively biased compared to those using serum samples for the same patient. Our data indicates that samples expected to be less than measuring range (<2.39 mIU/mL (IU/L)) may potentially be reported as high as 7.72 mIU/mL (IU/L).

   Ortho advises that you review previously reported hCG results of <u>≤9.00 mIU/mL (IU/L)</u> for <u>plasma</u> samples processed using the affected lots.

4. **Should I take any action on previously reported results generated using the affected lots of VITROS® Total β-hCG II?**

   If the hCG result is inconsistent with the other tests, clinical impressions and symptoms and is persistently elevated, the hCG result should be confirmed with a urine hCG test or by repeating the serum or plasma test on a different test system.

   Discuss any concerns you may have regarding previously reported hCG results with your Laboratory Medical Director to determine the appropriate course of action. The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.

5. **What should I do with my remaining inventory of the affected lots?**

   Immediately discontinue using and discard all remaining inventory of VITROS® Total β-hCG II Calibrators and Reagent Packs for the lots listed on Page 1 of this notification. We will replace your remaining inventory or credit your account as indicated on your Confirmation of Receipt form. Partial sales units can only be credited. In order to provide product for all customers, we need to allocate current orders until additional product is manufactured.

Confirmation of Receipt – Response Required

URGENT FIELD SAFETY NOTICE

Ortho Clinical Diagnostics

Positively Biased Results using VITROS® Immunodiagnostic Products Total β-hCG II Reagent Packs

*Please return completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than*: **DD-MM-YYYY**

Send to: Name e-Mail Address: email address Fax: Fax Number

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2016-043_EU) regarding positively biased results using specific lots of VITROS® Immunodiagnostic Products Total β-hCG II Reagent Packs. I understand that I must immediately discontinue using and discard all remaining inventory of the affected lots. In addition, I am advised to review previously reported hCG results using the affected lots as described in the customer letter.

Please choose from the following:

- ☐ My laboratory does not currently use VITROS® β-hCG II Reagent Packs and is not affected by this issue.
- ☐ My laboratory uses VITROS® β-hCG II Reagent Packs, but does not have any of the affected lots remaining in inventory.
- ☐ My laboratory has an affected lot of VITROS® β-hCG II Reagent Packs. I have discontinued using and discarded the quantity listed in the table below.

Please indicate your choice of credit or replacement:

- ☐ Credit my account (Credit can be issued for full or partial sales units.)
- ☐ Send a replacement order to the address listed below. (We can ship full sales units only.)

Product Name/Product Code/LOT	Quantity Discarded
VITROS® Immunodiagnostic Products Total β-hCG II Reagent Pack /6802220 / 1410	
VITROS® Immunodiagnostic Products Total β-hCG II Reagent Pack /6802220 / 1420	
VITROS® Immunodiagnostic Products Total β-hCG II Reagent Pack /6802220 / 1430	
VITROS® Immunodiagnostic Products Total β-hCG II Reagent Pack /6802220 / 1440	
VITROS® Immunodiagnostic Products Total β-hCG II Reagent Pack /6802220 / 1450	
VITROS® Immunodiagnostic Products Total β-hCG II Reagent Pack /6802220 / 1460	
VITROS® Immunodiagnostic Products Total β-hCG II Reagent Pack /6802220 / 1470	
One Sales Unit for VITROS® Total β-hCG II Reagent Packs (Product Code 6802220) = 1 Pack containing 100 wells	

In order to provide product for all customers, product allocation (i.e., partial shipments) may be necessary.

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

Your Name: _____ Signature: _____

Phone Number: _____ Date: _____ Required if sent by fax or a scanned PDF

Your Comments: _____

Your Name and Address

Verify your name and mailing address:

Please complete this section if any of this information has changed

Institution/
Contact Name: _____
Address: _____
City: _____ State/Prov: _____ Zip/Postal Code: _____
Phone: _____ Fax: _____
e-Mail: _____