Ortho Clinical Diagnostics

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

February 22, 2016

URGENT PRODUCT CORRECTION NOTIFICATION

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

Please distribute this information to the appropriate personnel at your facility

Dear Valued Customer,

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	

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 Result

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.

Actions Required from You

1. 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.
2. 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.
3. Post this notification by your VITROS® System or with your user documentation.
4. Complete the Confirmation of Receipt form and return within **(2) two business days** to indicate that you have been informed of this Product Correction.

If you have any questions, please contact Customer Technical Services at **1800 5646 766.**

Yours sincerely,

[redacted]

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Lee, Ching Hwee
Senior Regulatory Affairs Specialist

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 to aid in the early detection of pregnancy.

   As a reminder, the assay's intended use in the US is solely to aid in the early detection of pregnancy, whereas the product has different intended uses outside of the US.

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 <9.00 mIU/mL (IU/L) for plasma 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.