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| Ortho Clinical Diagnostics | <b>IMPORTANT PRODUCT CORRECTION NOTIFICATION</b><br><b>Unsuccessful Calibration using VITROS® Immunodiagnostic Products NT-proBNP Reagent Packs, Lot 1620</b> |
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**Date**                      **May 2017**

**Issue**                      This notification provides information regarding potential calibration failures when using VITROS NT-proBNP Reagent Packs, Lot 1620. Our records indicate that you were shipped the affected lot.

**Affected Products**

| Product Name<br>(Unique Device Identifier No.)                              | Product Code | Affected Lot No.<br>(Expiry Date) |
|---|--------------|-----------------------------------|
| VITROS Immunodiagnostic Products NT-proBNP Reagent Pack<br>(10758750002061) | 6802156      | <b>Lot 1620</b><br>(06-JUL-2017)  |

**Investigation**      Ortho Clinical Diagnostics (Ortho) confirmed that VITROS NT-proBNP Reagent Packs, Lot 1620 exhibited the potential for an increased frequency of calibration failures, with an increase in signal for the Level 1 calibrator causing a failure of the calibration parameters. Our testing indicates that the calibration failure is related to a component of the VITROS NT-proBNP Reagent Pack and is not associated with the VITROS NT-proBNP Calibrators.

**Our investigation has confirmed that the increase in signal does not affect sample results (i.e., quality control or patient samples) within the 28 day calibration cycle.**

**Resolution**              If your laboratory is able to successfully calibrate VITROS NT-proBNP Reagent Packs and your quality control results are acceptable; you may continue using your existing inventory.

To help ensure that future calibrations are successful, Ortho will send revised Master Calibration data.

**NOTE:** Current calibrations for these lots will become invalid after updating the Master Calibration data and will require recalibration.

For VITROS ECi/ECiQ Systems, the revisions are contained on a yellow Magnetic Lot Card.

For VITROS 3600 or 5600 Systems, the revisions are contained on Assay Data Diskette (ADD) DRV 5932 and above.

**Upon availability, the ADD and yellow Magnetic Lot Cards will be sent in a separate notification.**

**Impact to Results**              Previously reported patient results using Lot 1620 are valid providing that quality control results were within your acceptance range.

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**Required  
Actions**

- **If you are able to calibrate Lot 1620**, implement the revisions on your system:
  - **For VITROS Eci/ECiQ Systems:** At your next scheduled calibration, scan the yellow Magnetic Lot Card for Lot 1620. Discard/destroy the original (green) Magnetic Lot Card that was shipped with the product.
  - **For VITROS 3600, 5600 Systems:** Install ADD DRV 5932 & above **using the “Full Load” (All Assay Data) option**. After loading the ADD for the first time, VITROS NT-proBNP Reagent Packs will become un-calibrated and **will require recalibration**. Following a successful calibration and quality control assessment, it is acceptable to use your remaining inventory.  
**NOTE:** For e-Connected systems, download will be available by May 13, 2017.
- **If you are unable to calibrate Lot 1620**, when available, use the new Magnetic Lot Card or ADD DRV 5932 to calibrate.
- **If you experience this issue and no longer wish to use this product**, Ortho will credit your account for product discarded. Resubmit the Confirmation of Receipt form to indicate the quantity that requires credit.
- Post this notification by each system that processes VITROS NT-proBNP Reagent Packs.
- Complete the Confirmation of Receipt form and return by **May 19, 2017**.
- Forward this notification if you have distributed these products outside of your facility.

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**Contact  
Information**

We apologize for any inconvenience this may have caused your laboratory. If you have questions, please contact your local Ortho representative or our Ortho Care<sup>TM</sup> Technical Solutions Centre at 1800 5646766.

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Sincerely,



Jon Wong, Quality Manager, 10 May 2017