

<Insert Date>

IMPORTANT NOTIFICATION

Availability of VITROS[®] Immunodiagnostic Products Anti-HBs Reagent Packs and VITROS[®] Immunodiagnostic Products Anti-HBs Calibrators (Product Codes 1787753 and 1524693)

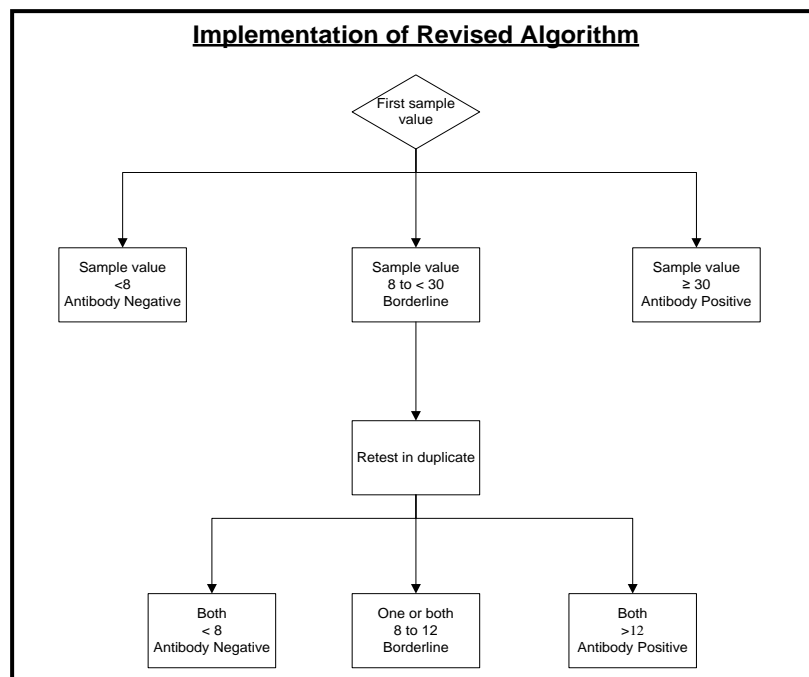
Dear Customer,

This notification provides information regarding the availability of VITROS[®] Immunodiagnostic Products Anti-HBs Reagent Packs and VITROS[®] Immunodiagnostic Products Anti-HBs Calibrators. Recently, Ortho-Clinical Diagnostics Inc. (OCD) alerted you of a supply issue that prevented us from releasing new lots of product (Ref. CL13-303a).

The purpose of this notification is to inform you that OCD has revised the protocol used with the VITROS[®] Anti-HBs assay, beginning with Lot 2500 and above. The Borderline range has been increased to 8 to < 30 mIU/mL for the initial result only. This is necessary as we have implemented a *new* algorithm that must be used with these lots until further notice.

New Interpretation of Results Algorithm

OCD has become aware of the potential for a low number of non-reproducible and unexpected positive results for the VITROS[®] Anti-HBs assay†. These affected results have the potential to cause a sample that is negative for anti-HBs, to give a result that will be flagged as either Borderline or Antibody Positive. A truly negative sample that is flagged as Borderline or Antibody Positive is very unlikely to give a similar repeat result. In order to detect and resolve these non-reproducible and unexpected positive results, the following algorithm should be applied to all VITROS[®] Anti-HBs results when using Lots 2500 and above, until further notice.



The new classification ranges apply ONLY to the initial sample result. The resolution of initially Borderline results following duplicate testing should be interpreted in accordance with the result interpretation categories in the current Instructions for Use (IFU), as shown in the revised algorithm.

Classification Ranges

The table below describes the current and the *new* classification ranges.

Current Instructions for Use for Lots <2500		New Ranges for Initial Interpretation for Lots 2500 & Above	
VITROS Anti-HBs Test Result	Result Text	VITROS Anti-HBs Test Result	Result Text
< 8 mIU/mL	Antibody Negative	< 8 mIU/mL	Antibody Negative
8 to 12 mIU/mL	Borderline	8 to < 30 mIU/mL	Borderline*
>12 mIU/mL	Antibody Positive	≥ 30 mIU/mL	Antibody Positive

* **An initially Borderline result requires duplicate testing as per the revised algorithm.**

Required Actions

We have also included an insert sheet in the VITROS® Anti-HBs Calibrators for Lot 2500 and above, as a reminder of the instructions below.

- If your Laboratory Information System (LIS) or middleware has setup ranges to determine the result classifications, it will require a change to implement the new range for the Borderline and Antibody Positive classifications. This should be done **before** the ADD/Magnetic Cards containing the update are implemented on your VITROS® System. Please consult your LIS provider for advice on making the required changes.
- All results flagged as Borderline must be interpreted following the revised algorithm and entered into the LIS manually.
- If your laboratory has made customized changes to your LIS, please review to determine if any changes are required to align with the new algorithm.
- Implement the *revised* algorithm (described on page one) with VITROS® Anti-HBs Reagent Packs and Calibrators, **Lots 2500 & above**, until further notice, and post the enclosed instruction sheets near your VITROS® analyzer for reference.
- **VITROS® 3600 & 5600 Systems:**
Your laboratory should attempt to use all remaining inventory of **Lots below 2500**, prior to implementing the new protocol and algorithm. The new protocol information for **Lots 2500 and above** is contained on the Assay Data Diskette (ADD) Data Release Version (DRV) 5763. Refer to the enclosed instructions to assist you in managing this protocol change in your laboratory. **
(Ref. *Instruction Sheet Revised Protocol on VITROS® 3600 & 5600 Systems*).
- ** Please be advised that if Lots below 2500 are used following the installation of ADD5763 or above, the new ranges will be applied to your results. The new algorithm does not have to be acted upon for Lots below 2500.
- **VITROS® ECi/ECiQ Systems:**
The new protocol information for **Lots 2500 and above** is contained on the magnetic Protocol and Lot cards. Refer to the enclosed instructions to assist you in managing this protocol change in your laboratory.
(Ref. *Instruction Sheet Revised Protocol on VITROS® ECi/ECiQ Systems*)
- If the ADD/Magnetic Card must be loaded before the LIS updates have been made, manually interpret your VITROS® Anti-HBs data using the information provided in the enclosed Instruction Sheets.
- Please forward the information in this notification to anyone you may have distributed this product outside of your facility.

We anticipate that VITROS[®] Anti-HBs Reagent Packs and Calibrators, Lot 2500 will be available in our Distribution Centers the week of 16-December-2013. If you have any questions regarding this notification, please contact Customer Technical Services at *<Insert appropriate number>*.

Sincerely,

<Insert appropriate name>

<Insert appropriate title>

Enclosures:

- Instruction Sheet Revised Protocol on VITROS[®] ECi/ECiQ Systems
- Instruction Sheet Revised on VITROS[®] 3600 & 5600 Systems

†The VITROS[®] Anti-HBs assay is performed using the VITROS[®] Immunodiagnostic Products Anti-HBs Reagent Pack and the VITROS[®] Immunodiagnostic Products Anti-HBs Calibrator on the VITROS[®] ECi/ECiQ System, the VITROS[®] 3600 System and the VITROS[®] 5600 System.