

August xx, 2010

**IMPORTANT NOTIFICATION**

**Upper Limit of the Measuring (Reportable) Range for Generation 5 & Above  
VITROS® Chemistry Products mALB Reagent (CAT No. 6801740)**

Dear Customer,

This is a follow up to previous Urgent Field Safety Notice (Ref. CL10-219\_EU) that was issued in July 2010 regarding VITROS® Chemistry Products mALB Reagent, Generations (GENs) 2, 3, and 4. At that time, we notified you of lower than expected albumin results for samples that were expected to generate results *significantly* above the Measuring (Reportable) Range of 0.6 – 19.0 mg/dL (6.0 – 190.0 mg/L). As a result of our findings, Ortho Clinical Diagnostics (OCD) *temporarily* decreased the upper limit of the Reportable Range.

Our investigation subsequently determined that the antigen excess capability of the reagent was sub-optimal for GENs 2, 3 and 4. Beginning with GEN 5, this issue has been addressed, and additional release testing has been implemented to verify this characteristic with all future lots of reagent. We are continuing to work with our supplier to identify additional preventative measures to avoid recurrence.

The new release test allows us to restore the upper limit of the Reportable Range for VITROS® mALB Reagent back to 19.0 mg/dL (190.0 mg/L) beginning with GEN 5 as defined below.

Product Name	GENs Affected	Reportable Range (Conventional/SI Units)
VITROS® Chemistry Products mALB Reagent	GENs 2, 3, 4 (Range Temporarily Decreased)	0.6 – <b>7.0</b> mg/dL
		6.0 – <b>70.0</b> mg/L
	GENs 5 & Above	0.6 – <b>19.0</b> mg/dL
		6.0 – <b>190.0</b> mg/L

***OCD will replace your remaining inventory of VITROS® mALB Reagent, please do the following:***

- Inspect your current inventory of VITROS® mALB Reagent to determine the quantity of GENs 3 or 4 remaining in your inventory. **Note:** GEN 2 is expired.
- Complete the attached Confirmation of Receipt Form so that we can issue your replacement order. Please return this form no later than **September xx, 2010.**
- Once you have received your replacement product, discontinue using VITROS® mALB Reagent, GENs 3 or 4 and discard any remaining inventory.

**Note:** When GEN 5 or above is implemented in your laboratory, it will no longer be necessary to display the previous communication (Ref. CL10-219) near your VITROS® 5600 Integrated System or VITROS® 5,1 FS Chemistry System.

If you have additional questions, please contact Customer Technical Services at **insert number.**

Sincerely,

**Insert appropriate name**

**Insert appropriate number**

Enclosure: Copy of previously issued Urgent Field Safety Notice (Ref. CL10-219\_EU)

**Confirmation of Receipt - Response Required**

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**Upper Limit of the Measuring (Reportable) Range for Generation 5 & Above  
VITROS<sup>®</sup> Chemistry Products mALB Reagent**

So that we can complete our records, please return this form to us no later than **September xx, 2010.**

**FAX TO:** *Insert appropriate name*

**FAX:** *Insert appropriate number*

**Section I – Confirmation**

I received the *previous* Urgent Field Safety Notice (Ref. CL10-219\_EU) and this notification (Ref. CL10-263\_EU) and I understand the instructions provided by OCD. Upon receipt of my replacement order, I will discard my remaining inventory of VITROS<sup>®</sup> mALB Reagent, GENs 3 or 4. I received the notification (Ref. CL10-263\_EU) and I understand that upon receipt of my replacement order, I will discard my remaining inventory of VITROS<sup>®</sup> mALB Reagent, GENs 3 or 4.

**Please check the appropriate box below:**

- No replacement is required. I have no VITROS<sup>®</sup> mALB Reagent, GENs 3 or 4 remaining in my inventory.
- Replacement is required. I have the following affected lots in my inventory, which I agree to discard upon receipt of my replacement order.

**Note:** In order to provide product for all customers, we may need to allocate orders until additional product is available.

<b>Indicate the quantity of VITROS<sup>®</sup> mALB Reagent discarded:</b>	
<b>Lot Number</b>	<b>Quantity Discarded</b>

Your Name: \_\_\_\_\_ Job Title (optional): \_\_\_\_\_

Signed\*: \_\_\_\_\_ Date: \_\_\_\_\_

Fax Number: \_\_\_\_\_ Telephone Number: \_\_\_\_\_

*\*Your signature provides confirmation that you have received and understood this notification.*

*Your comments are always welcome:*

**Section II – Your Name and Address**

Verify your name and mailing address:

<b>Please complete this section if your name or mailing address has changed:</b>		
Institution Name: _____		
Contact Name: _____		
Address: _____		
City: _____	State/Province: _____	Zip/Postal Code: _____
Telephone: _____	FAX: _____	