

August xx, 2010

URGENT PRODUCT CORRECTION

**Temporary Decrease to the Upper Limit of the Measuring (Reportable) Range
VITROS® Chemistry Products mALB Reagent, Generations 2, 3, and 4
(CAT No. 6801740)**

Dear Customer,

This notification is to inform you of an Urgent Product Correction for VITROS® Chemistry Products mALB Reagent, Generations (GENs) 2, 3, and 4. Ortho Clinical Diagnostics (OCD) has received several customer complaints 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).

Our investigation determined that urine samples with albumin levels between 300 - 800 mg/dL (3000 - 8000 mg/L) may be negatively biased and give values within the reportable range without an initial dilution. As a result of our findings, OCD has *temporarily* decreased the upper limit of the Reportable Range as defined in the table below.

Product Name	GENs Affected	Current Reportable Range (Conventional/SI Units)	Decrease in Reportable Range (Conventional/SI Units)
VITROS® Chemistry Products mALB Reagent	GENs 2, 3, 4	0.6 – 19.0 mg/dL	0.6 – 7.0 mg/dL
		6.0 – 190.0 mg/L	6.0 – 70.0 mg/L

The decrease in the upper limit is reflected in the enclosed Assay Data Diskette (ADD) Data Release Version (DRV) 5593. A recalibration of these GENs is not required. VITROS Performance Verifier ranges for VITROS® mALB Reagent have not changed.

Please do the following:

1. Load the enclosed Assay Data Diskette DRV 5593 which contains the decreased upper limit of the Reportable Range for VITROS® mALB Reagent, GENs 2, 3, and 4.
NOTE: Refer to the table on page 3 for specific directions.
2. Since the change to the Reportable Range is short-term, the VITROS® Chemistry Products mALB Reagent Instructions for Use will NOT be revised. Please store this notification with your appropriate user documentation while continuing to use GENs 2, 3, or 4.
3. Display this communication near the system to ensure compliance by all operators of the VITROS® 5600 Integrated System or VITROS® 5,1 FS Chemistry System.
4. Complete and return the attached Confirmation of Receipt Form by August XX, 2010.
5. Forward this information if you have distributed this product outside of your facility.

We are working diligently to identify root cause of this issue and to implement corrective actions as appropriate. We anticipate that the Reportable Range for mALB will revert back to 0.6 – 19.0 mg/dL (6.0 – 190.0 mg/L) beginning with GEN 5 which is expected to be available in the near future.

We apologize for any inconvenience this may cause your laboratory and appreciate your continued support of Ortho Clinical Diagnostics products. We have anticipated some questions you may have in the following Question and Answer section. If you have any additional questions, please contact Customer Technical Services at *insert appropriate number*.

Sincerely,

insert appropriate name

insert appropriate title

Enclosure:

Assay Data Diskette DRV 5593

Questions and Answers

1. Is there any effect on my previously reported albumin results?

Our internal testing indicated that some samples with urine albumin concentrations **above 300 mg/dL (3000.0 mg/L)** had predicted results in the reportable range between 0.6– 19.0 mg/dL (6.0 – 190.0 mg/L) without an initial dilution of the sample. Our data indicates that this is a small percentage of samples being tested in most circumstances, since these levels of urine albumin occur infrequently.

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

2. How are my patient, quality control, and proficiency samples affected?

Patient, Quality Control & Proficiency samples greater than 7.0 mg/dL (70 mg/L) should be handled according to your normal laboratory protocol. For example, report the result as greater than 7.0 mg/dL (70 mg/L) or dilute the sample and reanalyze.

NOTE: Some Quality Control samples may be greater than 7.0 mg/dL (70.0 mg/L). If this should occur, a dilution may be required.

If dilutions are performed, follow your normal laboratory protocol using VITROS® Chemistry Products FS Diluent Pack 2 (BSA/saline). Do not manually dilute samples. Refer to your system’s user documentation for information using the On-Analyzer Dilution procedure.

3. How do I update the Reportable Range for mALB?

The decrease in the reportable range is contained on the enclosed ADD DRV 5593. Before the ADD is loaded, an Assay Configuration dialog box will prompt you to select either ‘*Restore Defaults*’ (Option 1) or ‘*Retain Configuration*’ (Option 2).

Please choose from the following options based upon if your system contains user –modified parameters that are flagged with an “M1” code.

IMPORTANT TO NOTE: If you configured reflex dilutions, reflex reductions or made Reportable (Measuring Range) changes to any assay, use the ‘*Retain Configuration*’ (Option 2) to save your configuration changes.

	<i>Restore Defaults</i> Option 1	<i>Retain Configuration</i> Option 2
1. Determine if any assays are user-modified on your system(s)	Follow directions for option 1 if mALB or <i>other</i> assays have <u>not</u> been previously user-modified.	Follow directions for option 2 if mALB or <i>other</i> assays <u>have been user-modified</u> .
2. Select the appropriate option when loading ADD DRV 5593	Load ADD DRV 5593, select ‘ <i>Restore Defaults</i> ’ when prompted by the Assay Configuration dialog box.	Load ADD DRV 5593, select ‘ <i>Retain Configuration</i> ’ when prompted by the Assay Configuration dialog box.
3. Actions Required	Reportable range for mALB will be revised upon the loading of the ADD DRV 5593. No further action is required.	Verify that the reportable range for mALB has been revised, if not, you will need to <i>manually</i> enter the decreased reportable range following the directions on page 4.

Questions and Answers (Continued)

4. Upon loading ADD DRV 5593, how can I determine if mALB Measuring (Reportable) Range was revised if I selected 'Retain Configuration' (Option 2)?

To determine if the upper limit for mALB has been revised to 7.0mg/dL (70 mg/L):

- ✓ From the main menu, Select *Options*
- ✓ Select *Review/Edit Calibrations*
- ✓ Select *Urine*
- ✓ Select *mALB*
- ✓ Select *Review Assay Data*
- ✓ Select *GEN 2*
- ✓ Repeat this procedure for GENs 3 & 4

5. What action is required if the Measuring (Reportable) Range was not automatically revised upon loading ADD DRV 5593 if I selected 'Retain Configuration' (Option 2)?

If the Reportable Range was not automatically revised, you will need to manually enter the decreased upper reportable range:

- ✓ From the main menu, Select *Options*
- ✓ Select *Review/Edit Calibrations*
- ✓ Select *Urine*
- ✓ Select *mALB*
- ✓ Select *Review Assay Data*
- ✓ Select *GEN 2*
- ✓ Touch the box that displays the 'Upper Reportable Range'
- ✓ Using the keyboard Select *Delete*
- ✓ Using the keyboard, enter the value to 7.0 mg/dL (70 mg/L).
- ✓ Select *Save*
- ✓ Select *Yes*
- ✓ Repeat this procedure for GENs 3 & 4.

Note: The User Modified center box will then display 'M1'

To make a back up diskette to save these changes:

- ✓ From the main menu, select *Options*
- ✓ Select *Perform Backup*
- ✓ Select *Full Backup* (follow the screen prompts)

Questions and Answers (Continued)

6. How can I identify the GEN number on the carton or the reagent pack?

The GEN number (**highlighted in red**) and can be identified in the following examples:

Product carton will display as: **02**-XXXXXXXX-XX-XX

Reagent pack will display as: XXXX **02** XXXX

7. When will this issue be resolved?

We are working diligently to identify root cause of this issue and to implement preventative and corrective actions as appropriate. We anticipate that the Reportable Range will revert back to 0.6 – 19.0 mg/dL (6.0 – 190.0 mg/L) beginning with GEN 5. We will issue a follow up notification upon its availability.

Since the change to the Reportable Range is short-term, the VITROS[®] Chemistry Products mALB Reagent Instructions for Use will NOT be revised. Please store this notification with your appropriate user documentation while continuing to use GENs 2, 3, or 4.

8. Will I receive product credit for costs associated with any additional testing?

It is likely that due to this interim action, there may be additional consumption of VITROS[®] mALB Reagent. OCD is currently developing a process by which compensation will be provided (i.e., credit or replacement) when GEN 5 becomes available.

Confirmation of Receipt

URGENT PRODUCT CORRECTION

Temporary Decrease to the Upper Limit of the Measuring (Reportable) Range VITROS® Chemistry Products mALB Reagent, Generations 2, 3, and 4 (CAT No. 6801740)

So that we can complete our records, please return this form to us by **August XX, 2010.**

FAX TO: *insert appropriate title*

FAX: *insert appropriate number*

Section I – Confirmation

I received the Urgent Product Correction Notification (Ref. CL10-219a) regarding negatively biased results using VITROS® Chemistry Products mALB Reagent, GENs 2, 3, and 4. I understand that I must load ADD DRV 5593, which contains the decreased upper limit for the Reportable Range.

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:

Please complete this section if your name or mailing address has changed:

Institution Name: _____

Contact Name: _____

Address: _____

City: _____ State/Province: _____ Zip/Postal Code: _____

Telephone: _____ FAX: _____