

January xx, 2014

URGENT FIELD SAFETY NOTICE

VITROS[®] Chemistry Products White Correction Factor Slides Incorrect Assay Value for Lot 9052-0045-6358 Part No. J02315 (Expiry 01-August-2015)

Dear Customer,

As part of a Field Safety Corrective Action, this is to inform you of an urgent field safety notice involving an incorrect assay value listed on the *specific* lot of VITROS[®] Chemistry Products White Correction Factor Slides listed below:

Product Name	Part Number	Affected Lot Number	Expiry Date
White Correction Factor Slides	J02315	9052-0045-6358	01-August-2015

This urgent field safety notice has been initiated due to an incorrect assay value printed on the product carton for the 460 nm wavelength (filter) that may cause a delay in the ability to obtain and report TBIL, Bu, Bc, and derived tests results (listed on page four).

NOTE: *The only slides that utilize 460 nm wavelength measurements are VITROS[®] Chemistry Products TBIL Slides and VITROS[®] Chemistry Products BuBc Slides.*

Background Information

VITROS[®] White Correction Factor Slides are used when performing the Reflectometer Correction Factor adjustment for the VITROS[®] Systems listed below:

- **VITROS[®] 250/350 Chemistry Systems (Product Codes 6802153/6801759)**
- **VITROS[®] 4600 Chemistry Systems (Product Code 6802445)**
- **VITROS[®] 5600 Integrated Systems (Product Code 6802413)**
- **VITROS[®] 5,1 FS Chemistry Systems (Product Codes 6801375/6801890)**

The Reflectometer Correction Factor adjustment procedure optimizes the calibration of the reflectometer. Performing Quality Control (QC) testing is required following the Reflectometer Correction Factor adjustment procedure if any White Correction Factor (WCF) update is required.

Investigation Summary

Ortho Clinical Diagnostics, Inc. (OCD) determined that an incorrect assay value was listed on the product package (outer carton) for the 460 nm wavelength (filter). All other assay values listed for Lot 9052-0045-6358 are correct. The 460 nm wavelength is only used to determine the predicted concentration when processing VITROS[®] TBIL Slides or VITROS[®] BuBc Slides.

Correct Assay Value	Incorrect Assay Value
0.8658	0.3785

Impact to Results

If the incorrect assay value of **0.3785** was entered for the 460 nm wavelength while performing the Reflectometer Correction Factor adjustment procedure, the following would occur:

- The respective VITROS[®] System would flag the output to indicate that the *new* value for the 460 nm wavelength White Correction Factor (WCF) differs from the *current* 460 nm wavelength by more than 15%:
 - VITROS[®] 250 or 350 Systems would have three *asterisks* (*) on the system screen.
 - VITROS[®] 4600, 5600 or 5,1 FS Systems would have a “Repeat” status on the system screen.
 - NOTE:** Following the procedure defined in the User’s Guide, if the correction factors are updated, Quality Control fluid testing is required.
 - If the correction factors were updated using the incorrect assay value, Quality Control results will NOT pass the acceptance criteria:
 - For Bu - A “No Result” is obtained and PI flag (Potential Interferent) is generated.
 - For Bc – The predicted value will be < Measuring Range for the assay.
 - For TBIL–Quality Control results will be negatively biased by > 2 Standard Deviations (SD).
 - If calibration was performed after obtaining unacceptable Quality Control results, the following would occur:
 - Bu & Bc calibrations will fail.
 - TBIL will successfully calibrate and Quality Control results will be acceptable.
- NOTE:** Patient results using VITROS[®] TBIL slides will be acceptable.

We have no complaints of misreported results due to an incorrect assay value as this issue has been detected by the operator.

Resolution

OCD will replace your remaining inventory of VITROS[®] White Correction Factor Slides, Lot 9052-0045-6358. It is acceptable to use your current inventory of Lot 9052-0045-6358 providing that you input **0.8658** as the assay value for the 460nm wavelength. If you have previously used this lot to update the Reflectometer Correction Factor on your VITROS[®] System(s), please repeat the procedure using the correct assay value.

Required Actions

- Inspect your inventory to determine if you have any VITROS[®] White Correction Factor Slides from Lot 9052-0045-6358.
- Complete and return the Confirmation of Receipt form by **January xx, 2014**. Indicate on the form if you have any inventory of the affected lot that will require replacement.
- If you do not have an alternate lot in your inventory, it is acceptable to use Lot 9052-0045-6358 providing that you input **0.8658** as the assay value for the 460 nm wavelength during the Reflectometer Correction Factor Adjustment procedure.
- If you have previously used this lot to update the Reflectometer Correction Factor, please repeat the procedure using the correct assay value.
- If product replacement is required, discard your remaining inventory of Lot 9052-0045-6358 when your replacement order arrives.
- Forward this information if you have distributed this product outside of your facility.

We have anticipated some questions you may have in the following Questions and Answers section. If you have any questions or need additional information, please call Customer Technical Services at *Insert appropriate number.*

Sincerely,

Insert appropriate name

Insert appropriate title

Questions and Answers

1. Are all VITROS® White Correction Factor Slides affected by this issue?

No, this issue only affects Lot 9052-0045-6358. Our investigation confirmed that an incorrect value was listed on the product package for the 460 nm wavelength (filter) *only*. All other assay values listed for Lot 9052-0045-6358 are correct.

2. Which VITROS® Slides use the 460 nm wavelength (filter)?

The 460 nm wavelength is used to determine the predicted concentration when processing VITROS® TBIL Slides or VITROS® BuBc Slides. The results may also be used in the following derived tests:

Derived Test Name	Acronym	Calculated Calculation	Additional Information
Direct Bilirubin	DBIL	DBIL = TBIL–Bu	Conjugated bilirubin & delta bilirubin
Delta Bilirubin	DELB	DELB = TBIL – (Bu + Bc)	Bilirubin covalently bound to albumin
Neonatal Bilirubin	NBIL	NBIL = Bu + Bc	Unconjugated bilirubin & Conjugated bilirubin

3. What is the impact to results if I used an incorrect assay value?

If the incorrect assay value of **0.3785** was entered for the 460 nm wavelength while performing the Reflectometer Correction Factor adjustment procedure, the following would occur:

- The respective VITROS® System would flag the output to indicate that the *new* value for the 460 nm wavelength White Correction Factor (WCF) differs from the *current* 460 nm wavelength by more than 15%:
 - VITROS® 250 or 350 Systems would have three *asterisks* (*) on the screen.
 - VITROS® 4600, 5600 or 5,1 FS Systems would have a “Repeat” status on the screen.
- NOTE:** Following the procedure defined in the User’s Guide, if the correction factors are updated, Quality Control testing is required.

- If the correction factors were updated using the incorrect assay value, Quality Control results will NOT pass the acceptance criteria:

- For Bu - A “No Result” is obtained and PI Flag (Potential Interferent) is generated.
- For Bc – The predicted value will be < Measuring Range for the assay.
- For TBIL – Quality Control results will be negatively biased as shown in the example:

Control Fluid Type	Expected QC Result for TBIL	QC Result using Incorrect Assay Value
Performance Verifier Level I	1.86 mg/dL	0.37 mg/dL
	31.81 µmol/L	6.33 µmol/L
Performance Verifier Level II	14.44 mg/dL	12.93 mg/dL
	246.92 µmol/L	221.10 µmol/L

The magnitude of bias observed is greater than 2 within laboratory Standard Deviations (SD) as specified in the Performance Verifier Assay Sheets.

Patient samples should **not** be processed until the Quality Control results issue is resolved and acceptable Quality Control results are obtained.

- If calibration was performed after obtaining unacceptable Quality Control results, the following would occur:
 - Bu & Bc calibrations will fail.
 - TBIL will successfully calibrate and Quality Control results will be acceptable.
- NOTE:** Patient results using VITROS® TBIL Slides will be acceptable.

Questions and Answers

4. Where is the assay value listed?

Assay values for all wavelengths are located on the outer carton of the VITROS® White Correction Factor Slides (as shown below). Assay values are individually assigned for each lot of slides released.



5. How can I determine if I used Lot 9052-0045-6358 on my VITROS® System?

Inspect your inventory to determine if you have VITROS® White Correction Factor Slides from Lot 9052-0045-6358.

To determine if you have used the incorrect assay value (**0.3785**) for 460 nm wavelength on your VITROS® System, select the appropriate steps for your system.

For VITROS® 250/350 Systems	For VITROS® 4600/5600/5,1 FS Systems
From the Options Menu: <ul style="list-style-type: none"> • Select <i>Subsystem Control</i> • Select <i>WCF Manual Entry</i> • Review entry for 460 nm* 	From the Diagnostics Menu: <ul style="list-style-type: none"> • Select <i>Adjustments</i> • From the bottom of the screen, select <i>Adjustment Values</i> or <i>View/Edit CF</i> • Review entry for 460 nm*
*WCF value for the 460 nm should be 0.8000 to 1.000, otherwise the Correction Factor procedure should be repeated.	

6. What action should I take if I used Lot 9052-0045-6358 to perform the Reflectometer Correction Factor adjustment procedure?

If you have previously used this lot to perform the Reflectometer Correction Factor adjustment procedure on your VITROS® System(s), please repeat the procedure using the correct assay value (**0.8658**) or an alternate lot of slides.

7. Can I continue to use my inventory of Lot 9052-0045-6358 until replacement arrives?

Yes, it is acceptable to use VITROS® White Correction Factor Slides, Lot 9052-0045-6358 providing that you input the correct assay value (**0.8658**) while performing the reflectometer correction factor adjustment procedure.

Confirmation of Receipt - Important Response Required

URGENT FIELD SAFETY NOTICE

**VITROS[®] Chemistry Products White Correction Factor Slides
Incorrect Assay Value for Lot 9052-0045-6358
Part No. J02315 (Expiry 01-August-2015)**

*So that we can complete our records, please return this form to us no later than **January xx, 2014.***

FAX TO: *Insert appropriate name*

FAX: *Insert appropriate number*

Section I: Confirmation

I received the Urgent Field Safety Notice (Ref. CL2014-001_EU) and understand that there is an incorrect assay value listed for VITROS[®] White Correction Factor Slides, Lot 9052-0045-6358. **Please choose from the following options:**

- My laboratory does not have any inventory of Lot 9052-0045-6358 and is not affected.
- My laboratory has the following inventory of Lot 9052-0045-6358 that will require replacement.
I have NOT used this lot to update the WCF on my VITROS System.
- My laboratory has the following inventory of Lot 9052-0045-6358 that will require replacement. I used this lot to update the WCF on my VITROS System and I will need to repeat the procedure using the correct assay value or an alternate lot of slides.

If product replacement is required, please indicate the quantity of sales units in your inventory:

Product Name	Part No.	Affected Lot Number	No. of Sales Units to be Discarded*
White Correction Factor Slides	J02315	9052-0045-6358	

Indicate Quantity To Replace Here: *NOTE: One sales unit = 1 box of 25 slides. We will send you replacement product upon receipt of this Confirmation of Receipt form.

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

Your Name: _____ Job Title (optional): _____

Signed*: _____ Date: _____

Fax Number: _____ Telephone Number: _____

J Number: _____ Institution: _____

Your comments are welcome:

Section II – Verification of your Name and Address

Verify your name and mailing address:

Please complete this section if your name and/or mailing address have changed:

Institution / Contact Name: _____

Address: _____

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

Telephone: _____ FAX: _____