



IMPORTANT

Ortho Clinical Diagnostics

September 2017

IMPORTANT PRODUCT CORRECTION NOTIFICATION Lower than Expected BENZ Results using VITROS® Chemistry Products DAT Performance Verifiers

Affected Product	Product Code (Unique ID No.)	Level	Lot No.	Expiry Date
VITROS® Chemistry Products DAT Performance Verifiers	6802327 (10758750002610)	Level I	H5616	27-JUN-2018
	6802328 (10758750002627)	Level II	J5617	
	6802329 (10758750002634)	Level III	K5618	
	6802330 (10758750002641)	Level IV	L5619	
	6802331 (10758750002658)	Level V	M5620	
<i>This issue only affects BENZ. No other assays in the VITROS DAT Performance Verifiers are affected.</i>				

Dear Customer,

This notification provides information regarding lower than expected Quality Control (QC) results obtained for VITROS BENZ Reagent using the specific lots of VITROS DAT Performance Verifier listed above.

If the issue occurs, QC results for BENZ may be at or below the Range of Means as defined in the Assay Sheets. This issue may lead to calibration verification failures or flagging of routine QC results.

Investigation Summary

VITROS DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS and 4600 Chemistry Systems and VITROS 5600 Integrated Systems. VITROS BENZ Reagent is used for the semi-quantitative or qualitative determination of benzodiazepines (BENZ) in human urine using a cut-off of either 200 or 300 ng/mL.

Ortho Clinical Diagnostics (Ortho) has performed an investigation and found that QC results for BENZ (only) were lower than expected when using the affected lots. The data confirmed that the concentration of lormetazepam (BENZ) in the affected lots of VITROS DAT PVs has shown a decrease with time. There are reduced levels of lormetazepam when the controls were tested on a confirmatory method (i.e., gas chromatography/mass spectrometry).

- No other assays in the VITROS DAT Performance Verifiers are affected by this issue.
- Our investigation confirmed that the VITROS BENZ Reagent is performing within acceptable limits.

Impact to Patient Results

Patient results are valid providing that QC results are within your established acceptance range.

REQUIRED ACTIONS

- If the QC results using VITROS DAT Performance Verifiers are within your established ranges for each assay, it is acceptable to use the affected lots until new VITROS product is available.
NOTE: If QC results for BENZ are below your established ranges, please use a control material from another supplier until you have new VITROS product.
- Post this notification by each system that processes VITROS BENZ Reagent.
- Complete the Confirmation of Receipt form and return by **September 29, 2017**.
- Forward this notification if you have distributed these products outside of your facility.

Resolution

Ortho is working in conjunction with our supplier to expedite the availability of new lots.

We anticipate that new lots (all 5 levels) will be available within 6 to 8 weeks. We will notify you when these are available.

In the interim, we will closely monitor the concentration of lormetazepam (BENZ) in the affected lots.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766

Sincerely,



Jon Wong, QA Manager

QUESTIONS AND ANSWERS

1. What actions should my laboratory perform regarding previously reported results?

Previously reported patient results are valid providing that quality control results are within your acceptance range.

2. Are other assays in the VITROS DAT Performance Verifier affected?

No, this issue only affects QC results obtained using VITROS BENZ Reagent. Our data indicates that no other assays are exhibiting lower than expected QC results.

3. Will my affected lots of VITROS DAT Performance Verifier be replaced or credited?

Upon availability of new lots, we will send a follow up notification in order for you to indicate how much of the affected product in your inventory needs to be credited. In the interim, if your QC results are within your established ranges, continue to use these lots.

4. When can I expect replacement product to be available?

Ortho is working in conjunction with our supplier to expedite new lots. At this time, we have no other unaffected lots in our inventory. We anticipate that new lots (all 5 levels) will be available within 6 to 8 weeks.

5. What if my QC is out of my established range?

Follow your routine troubleshooting procedures if your QC results are outside of your established range. If unresolved, obtain QC material from an alternate vendor.

6. What do I need to consider if using another vendor's control?

As stated in the "*Quality Control*" section of the VITROS BENZ Reagent Instructions for Use:

Evaluate the performance of other commercial control fluids for compatibility with this test before using for quality control.

Control materials other than VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV and V may show a difference when compared with other lormetazepam methods if they:

- Depart from a true human matrix.
- Contain high concentrations of preservatives, stabilizers, or other nonphysiological additives.
- Contain drugs or drug metabolites other than lormetazepam.