

Sep 30, 2015

IMPORTANT PRODUCT CORRECTION NOTIFICATION

VITROS® Chemistry Products Calibrator Kit 9, Lot 0954

Immediate Action Required

Please distribute this information to the appropriate personnel at your facility

Dear Valued Customer,

This is to inform you of an Important Product Correction Notification involving the following:

Product Name	Product Code	Lot Number	Expiry Date	Unique Device Identifier No.
VITROS® Chemistry Products Calibrator Kit 9	8568040	0954	31-May-2016	10758750005031

The purpose of this notification is to inform you of a potential for an increase in U90-382 or 6LU condition codes (wash errors) when using VITROS® Calibrator Kit 9, Lot 0954 to calibrate VITROS® DGXN and PHYT Slides.

Summary of Anomaly

Ortho-Clinical Diagnostics, Inc. (OCD) observed an increase in the number of DGXN complaints associated with Magenta Wash Error generated condition codes. A breakdown of the complaints determined that the increase in VITROS DGXN complaints was driven by an increase in U90-382 condition codes (on VITROS 5,1FS systems and higher) and 6LU condition codes (on VITROS 250/350 systems). It was also noted that a significant number of the total U90-382/6LU complaints were generated while using non-VITROS BioRad control fluids.

A similar increase in the number of U90-382/6LU condition codes related complaints was also identified for VITROS PHYT. A large number of the U90-382/6LU complaints were generated using BioRad quality control fluids; however, for PHYT, a comparable number of complaints were noted that involved VITROS Therapeutic Drug Monitoring (TDM) quality control fluids.

An in-depth review of related complaints (U90-382/6LU wash errors) for both PHYT and DGXN identified a direct correlation with use of Calibrator Kit 9 lot 0954.

Impact to Patient Results

The increased wash error condition code associated with calibrator kit lot 0954 may make the kit unusable and need to be replaced, which may cause a test delay for up to 3 days. The affected tests include the VITROS DGXN and PHYT assays. Both assays are therapeutic drug monitoring assays for the quantitative measurement of circulating drug level to determine patient compliance and to establish optimal drug dose as well as to aid the diagnosis of drug overdose or toxicity. For patients whose optimal drug dose has not been established and conditions not stabilized or who experience drug overdose, the unavailability of the blood drug level in a timely fashion could potentially delay

optimal patient management. However, for both medicines, drug efficacy or toxicity is not always correlated with blood drug level and drug dose adjustment is largely based on patient's clinical response, signs and symptoms, and results of other tests (e.g. EKG for digoxin toxicity). So, it is unlikely a delay of the blood drug level results would lead to mismanagement of patient resulting in serious patient harm.

Actions Required from You

1. Discontinue using and discard all remaining inventory of VITROS® Calibrator Kit 9, Lot 0954 upon receipt of alternative product. OCD will credit your account.

NOTE: It is acceptable to use Lot 0954 until alternative product arrives.

2. Place an order for Cal Kit 9.
3. Recalibrate VITROS® DGXN and PHYT Slides using Cal Kit 9 in your facility with an alternative lot of calibrator upon availability.
4. Post this notification by the VITROS® System(s) or with the user documentation.
5. Complete and return the **Customer Acknowledgement Form** within **(2) two business days** to acknowledge your reading and understanding of this notice.

Rate of Occurrence

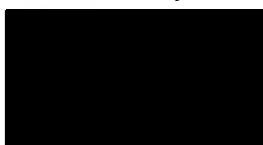
The error code associated with the calibrator kit lot 0954 happened 3-6% of the DGXIN or PHYT tests.

Resolution

Our investigation is ongoing. We will implement the appropriate corrective and/or preventative actions upon completion of the root cause analysis.

We apologize for the inconvenience this may cause your laboratory. 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 **1800 5646 766** at any time.

Yours sincerely,



Lee, Ching Hwee
Senior Regulatory Affairs Specialist

Questions and Answers

1. What products are affected by the increase in condition codes?

Our investigation determined that this issue is associated with VITROS® Calibrator Kit 9, Lot 0954. The increase in U90-382 and 6LU condition codes occurs when using VITROS® DGXN and PHYT Slides. VITROS® ACET and CRBM Slides are not affected by this issue.

2. What assays are supported by VITROS® Calibrator Kit 9?

VITROS® Calibrator Kit 9 is used to calibrate VITROS® 250, 350, 4600 and 5,1 FS Chemistry Systems and VITROS® 5600 Integrated Systems for the quantitative measurement of ACET, CRBM, DGXN, and PHYT.

3. What condition codes are posted on the system when the issue occurs?

VITROS® DGXN and PHYT Slides are classified as a multiple-point immuno-rate test type. The condition codes **U90-382** and **6LU** are listed below.

Type of System	Condition Displayed	Code	Flag with Result	Associated Suppressed
VITROS® 250, 350 Systems	6LU		Wash Error (WE)	
VITROS® 4600, 5600 and 5,1 FS Systems	U90-382			

4. What should I do with my current inventory of VITROS® Calibrator Kit 9, Lot 0954?

As a result of the increase in condition codes, your laboratory must discontinue using all remaining inventory of VITROS® Calibrator Kit 9, Lot 0954 and switch to an alternate lot. It is acceptable to use Lot 0954 until alternative product arrives.

OCD will credit your account. We have an adequate supply of alternate lots available. Please calibrate using the new lot as soon as possible to reduce the likelihood of condition codes.

5. What is the resolution?

Our investigation is ongoing. We will implement the appropriate corrective and/or preventative actions upon completion of the root cause analysis.