



October 2018

IMPORTANT PRODUCT CORRECTION NOTIFICATION
Biased Results using VITROS® Chemistry Products dLDL Reagent

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Department

This notification provides information regarding the potential for biased results when using VITROS dLDL Reagent, Generations (GENs) 26 and 27.

Affected Product	Product Code (Unique Device Identifier No.)	Affected Generations (GENs)	Expiry Dates
VITROS® Chemistry Products dLDL Reagent	6801728 (10758750006793)	GENs 26 & 27	6-NOV-2018 through 7-MAY-2019

Investigation

Due to complaints received for GENs 26 and 27 and internal testing of a new lot, Ortho has confirmed the potential for biased results. Our investigation has determined that GENs 26 and 27 are negatively biased by approximately 15 to 20 mg/dL (0.38 to 0.51 mmol/L) across the measuring range.

Impact to Results

The approximate shift in dLDL results that may be observed when using VITROS dLDL Reagent GENs 26 and 27 compared to GENs 28 and above is shown on page three.

REQUIRED ACTIONS

- **For GEN 26:** Discontinue using GEN 26 and switch to an alternate GEN of product as soon as possible. Please specify full or partial sales units remaining on your Confirmation of Receipt form.
- **For GEN 27:** Install ADD DRV 6003 on your VITROS System upon receipt. Following a successful recalibration, resume using VITROS dLDL Reagent, GEN 27 remaining in your inventory.
- Complete the Confirmation of Receipt form and return by **October 22, 2018**.
- Post this notification by each system that processes VITROS dLDL Reagent.
- Forward this notification if the product was distributed outside of your facility.

Traceability of Calibration

Values assigned to the VITROS Chemistry Products Calibrator Kit 19 and VITROS Chemistry Products FS Calibrator 1 for low-density lipoprotein cholesterol are traceable to the CDC LDL-C Reference Measurement Procedure.

Resolution

GEN 26: Ortho will credit your account for your remaining inventory of VITROS dLDL Reagent, GEN 26. In the interim, you may continue to use GEN 26 until you can switch to an alternate GEN.

GEN 27: The calibrator values for VITROS dLDL Reagent, GEN 27 have been adjusted to align with our reference method.

- Assay Data Diskette (ADD) Data Release Version (DRV) 6003 and above will contain the *revised* calibrators values.
- ADD DRV 6003 will be sent to your facility with a follow up notification. It will also be available for systems that are e-connected on or about 15 October 2018.
- It is acceptable to continue using GEN 27 until the ADD is installed on your system. Although it is acceptable to use GEN 27, product credit is available upon request using the Confirmation of Receipt form.

IMPORTANT TO NOTE: After loading ADD DRV 6003 (or above) for the first time, VITROS dLDL Reagent, GEN 27 will become uncalibrated and **will require recalibration**.

GEN 28 & above: VITROS dLDL Reagent, GEN 28 and above is set to align with our reference method (i.e., a Beta-Quantification method).

In order to provide product for all customers, allocation may be necessary.

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 1800-5646-766.

Questions and Answers

1. What is the impact to VITROS dLDL results?

If you are currently using GEN 26 and change to GEN 28 or above, you will observe a positive shift in results as shown below*.

VITROS dLDL Reagent GENs 28 & Above versus GEN 26					
Concentration (mg/dL)	Shift (mg/dL)	Concentration (mmol/L)	Shift (mmol/L)	Concentration (g/L)	Shift (g/L)
< 100	+15	< 2.59	+0.39	< 1.00	+0.15
100 to 129	+18	2.59 to 3.34	+0.47	1.00 to 1.29	+0.18
130 to 159	+20	3.36 to 4.11	+0.52	1.30 to 1.59	+0.20
160 - 189	+19	4.14 to 4.89	+0.49	1.60 – 1.89	+0.19
>/=190	+22	>/=4.91	+0.57	>/=1.90	+0.22

If you are currently using GEN 27, following the recalibration with ADD DRV 6003, you will observe a positive shift in results as shown below*.

VITROS dLDL Reagent GEN 27 (<u>Recalibrated</u>) versus GEN 27 (Current Performance)					
Concentration (mg/dL)	Shift (mg/dL)	Concentration (mmol/L)	Shift (mmol/L)	Concentration (g/L)	Shift (g/L)
< 100	+13	< 2.59	+0.34	< 1.00	+0.13
100 to 129	+8	2.59 to 3.34	+0.21	1.00 to 1.29	+0.08
130 to 159	+6	3.36 to 4.11	+0.16	1.30 to 1.59	+0.06
160 - 189	+3	4.14 to 4.89	+0.08	1.60 – 1.89	+0.03
>/=190	+4	>/=4.91	+0.10	>/=1.90	+0.04

**These are average results; your results may vary slightly depending upon your current system performance.*

The current reference interval and method correlation data in the Instructions for Use are not impacted by this change.

2. Should I take any action on previously reported results generated using VITROS dLDL Reagent, GENs 26 & 27?

Although a review of previous results is not required, discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director or with the requesting physician. The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.

3. What should I do with my current inventory of VITROS dLDL Reagent, GENs 26 & 27?

If you are using GEN 26, Ortho will credit your account for your remaining inventory.

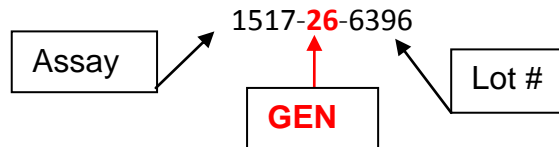
The calibration data for GEN 27 has been adjusted to align with our reference method. Assay Data Diskette DRV 6003 and above will contain *revised* calibration data for GEN 27. Following a successful recalibration, you may resume using VITROS dLDL Reagent, GEN 27 remaining in your inventory.

In the interim, you may continue to use your current inventory until the resolution is implemented in your laboratory.

Questions and Answers (continued)

4. How can I determine the GEN Number for the VITROS dLDL Reagent in my inventory?

Use the example below to determine the GEN on the product packaging:



5. What is Ortho doing to prevent this issue?

Our investigation into the root cause is pending. We will implement corrective and preventative actions as appropriate.