



December 2018

URGENT PRODUCT CORRECTION NOTIFICATION
Biased Results using VITROS® Chemistry Products VALP Reagent

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Departments

This notification provides information regarding VITROS VALP Reagent, Generation (GEN) 25.

Our records indicate you were shipped an affected lot.

Product Name (Unique Identifier No.)	Product Code	Affected Generation (GEN)	Affected Lots	Expiry
VITROS® Chemistry Products VALP Reagent Pack (10758750006748)	6801710	GEN 25	25-5263	2017-09-09
			25-5503	2018-01-06
			25-5727	2018-04-30
			25-5974	2018-08-14
			25-6067	2018-11-05
			25-6393*	2019-04-05

Description of Issue

Ortho has confirmed customer complaints of negatively biased results when using VITROS VALP Reagent, GEN 25.

Impact to Results

Our investigation has determined that results generated using GEN 25 are negatively biased across the measuring range as shown on page two.

As per standard practice, physicians monitoring patients' drug level will often review previous results. Due to the wide therapeutic range for VALP, the drug dose is more likely to be determined by disease control and the symptoms indicating side effects of the drug, rather than blood concentration.

If drug toxicity occurs, it would be an acute episode, and once resolved, VALP results obtained at that time would have no long term affect.

A review of previous results is not necessary and probably would reveal little actionable information. However, we do recommend that you discuss any concerns with your laboratory medical director or physicians.

Resolution

A root cause analysis is ongoing; however, our preliminary investigation has found that undetected variability in the release process caused a negative bias. We have implemented interim corrective actions to help prevent future occurrences. Further actions will be implemented as appropriate.

Alternate VALP reagent has demonstrated acceptable accuracy during our investigation.

If you have any GEN 25 (Lot 25-6393) remaining in your inventory, Ortho will credit your account.

REQUIRED ACTIONS

- Discontinue using Gen 25 (Lot 25-6393), discard any remaining inventory, and switch to GEN 26 or above.
- If you do NOT have GEN 26 or above at this time , place an urgent order for GEN 26 (or above) and consider the options below;
 - Use an alternate valproic acid method until your replacement order arrives OR...
 - Consult with your medical director to determine if the bias observed when using GEN 25 is acceptable for continued use, and if so, continue to use until your replacement arrives.
- Ortho will credit for your remaining inventory of Gen 25 (Lot 25-6393). Please specify full and/or partial sales units remaining on your Confirmation of Receipt form.
- In accordance with regulatory requirements, complete the Confirmation of Receipt form no later than **December 19, 2018**.
- Post this notification by your VITROS System or with your user documentation.
- Forward this notification if the product was distributed outside of your facility.

Contact Information

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

Questions and Answers

1. What is the impact to my results when using VITROS VALP Reagent, GEN 25?

Our internal investigation determined that results generated using GEN 25 are negatively biased across the measuring range. This data was generated using Lot 25-6067 (prior to its expiration) and Lot 25-6393; no other lots from GEN 25 were available for testing.

Conventional Units (µg/mL)		
Concentration Range (µg/mL)	Maximum Bias Observed (µg/mL)	Average Bias Observed (µg/mL)
<50	-5.2	-3.1
50-120	-14.5	-8.9
>120	-15.9	-7.8

SI Units (µmol/L)		
Concentration Range (µmol/L)	Maximum Bias Observed (µmol/L)	Average Bias Observed (µmol/L)
<346.5	-36	-21.5
346.5-831.6	-100.5	-61.7
>831.6	-110.2	-54.1

Alternate Units (mg/L)		
Concentration Range (mg/L)	Maximum Bias Observed (mg/L)	Average Bias Observed (mg/L)
<50	-5.2	-3.1
50-120	-14.5	-8.9
>120	-15.9	-7.8

Variables such as system maintenance, environment, reagent storage/handling, control material reconstitution and sample handling can affect the reproducibility of test results noted above.

2. Is this issue detectable?

VITROS Chemistry Products TDM Performance Verifiers I, II, and III will not detect this issue. If using another manufacturer's control or performing a patient correlation, the bias may be detected.

3. What should I do with my current inventory of VITROS VALP Reagent, GEN 25?

If you are using GEN 25, immediately discontinue using and discard your remaining inventory and switch to an alternate GEN. Ortho will credit your account as indicated on your Confirmation of Receipt form.

4. How can I determine the GEN number for the VITROS VALP Reagent in my inventory?

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

