

Dimension Vista® Intelligent Lab Systems

Dimension Vista® Elevated Triglyceride Results after Millipore Progard Pretreatment Pack Replacement

Our records indicate that your laboratory has either a Dimension Vista® 500 Intelligent Lab System or Dimension Vista® 1500 Intelligent Lab System using a Progard Pretreatment Pack on the onboard Millipore Water Purification Module (WPM).

Table 1: Dimension Vista® Affected Products

Product	Siemens Material Number (SMN)	Lot Numbers
Millipore Progard Pretreatment Pack	10450564	F7MA56608, F7MA50339, F7NA62488, F8AA93567, F8HA64477, F8AA13966, F8HA79819, F8BA20457, F8BA35774, F8DA59251, F8HA91305, F8JA97876, F8MA06374

Reason for Correction

Siemens Healthcare Diagnostics has identified an issue with Millipore Water Purification Module (WPM) Progard Pretreatment Packs when used with the Dimension Vista® Triglyceride assay. An investigation by Siemens identified the potential for patient and quality control (QC) triglyceride results to be erroneously elevated as a result of contamination introduced by the Millipore Progard Pretreatment Pack’s filter fibers. A positive bias of up to 122 mg/dL (1.38 mmol/L) has been observed. The potential for falsely elevated results could occur when processing the triglyceride assay immediately following the change of the Progard Pretreatment Pack in the Millipore WPM.

Not all Progard Pretreatment Packs are impacted. If you have received a Progard Pretreatment Pack with a Millipore lot number listed in Table 1, please refer to the “Actions to be Taken by the Customer” section in this letter.

Risk to Health

When this issue occurs, the potential exists for misinterpretation of falsely elevated triglyceride levels, which may affect consideration of intervention. Clinical impact would be mitigated by correlation to clinical history and presentation as well as by correlation to other lipid testing. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

If you have received a Progard Pretreatment Pack with a lot number listed in Table 1 and shown in Figures 1 and 2, please follow the steps below upon Progard Pretreatment Pack installation with use of the lots indicated in Table 1.

1. Verify your water tank level is 85% or less on the WPM Maintenance screen (press Setup > Supplies > Maintain Water Supply > Maintenance). If your tank level exceeds 85%, use the Advanced->Diagnostics->Prime Pumps routine to lower the tank volume.
2. Replace the Progard filter and perform any other required maintenance as instructed in Section 7 of the Dimension Vista System Operator's Guide.
3. After the Progard procedure completes, pause the instrument (Operation > Pause), and return to the WPM Maintenance screen (press Setup > Supplies > Maintain Water Supply > Maintenance)
4. Select the "Refill Tank" button. The process will take approximately 40 minutes to complete. An estimated time remaining is shown in the graphical user interface (GUI), and the white Status boxes in the top right indicate the steps of the process.
5. When complete, exit the WPM GUI by pressing "Hide Window." An instrument reset is automatically performed as part of the process.
6. Process triglyceride QC and ensure all levels are in range. If QC is out of range, do not recalibrate triglyceride; contact your Siemens Technical Support Representative.

Figure 1: Lot Number on Progard Pretreatment Pack

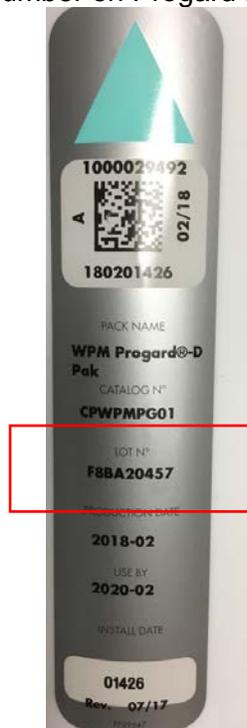


Figure 2: Lot Number on Shipping Label



If your instrument is currently using a Progard Pretreatment Pack from one of the affected lots listed in Table 1, process triglyceride QC to ensure that any contaminants have been purged from the system. If QC is out of range, do not recalibrate the triglyceride assay; contact your Siemens Technical Support Representative.

If you have received a Progard Pretreatment Pack with a lot number that is not listed in Table 1, please continue to use the Progard Pretreatment Pack as instructed in your Dimension Vista System Operator's Guide.

In addition, please perform the following:

- Review this letter with your Medical Director
- Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.
- Return the completed Field Correction Effectiveness Form to Siemens Healthcare Diagnostics as instructed in the last page of this letter.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local technical support provider.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens Technical Support Representative.

Dimension Vista is a trademark of Siemens Healthcare Diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

Dimension Vista® Elevated Triglyceride Results After Millipore Progard Pretreatment Pack Replacement

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated December 2018 regarding Dimension Vista® Elevated Triglyceride Results After Millipore Progard Pretreatment Pack Replacement.

Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Instrument Serial Number(s): _____

Customer Sold To #: _____

Customer Ship To #: _____

To fax this completed form please send it to the Customer Care Center – Technical Solutions at xxxxxx or please send a scanned copy of the completed form via email to xxxxxxxx.