

Siemens Healthcare Diagnostics Inc.

Customer Notification

VC-18-06.A.OUS July 2018

Dimension Vista[®] System Dimension Vista[®] LOCI[®] Reaction Vessels Vessel Pickup Errors

Our records indicate that your facility may have received the following product:

Table 1. Dimension Vista® Affected Product:

Product	Catalog Number	Siemens Material Number	Lot Number	First Shipment Date
Dimension Vista® LOCI® Reaction Vessels	KS855	10445212	All lots prior to lot NH3912618	2018-05-10

Reason for Notification

Siemens Healthcare Diagnostics has received customer complaints regarding Dimension Vista[®] LOCI[®] Reaction Vessels causing Vessel Pickup errors. Supplier internal investigation has identified the potential for a LOCI Reaction vessel to contain a small hole or indent on the top of the vessel. This may result in the Vista system generating a "Vessel Pickup error" when the defective vessel is not successfully picked up by the vacuum system. The error is resolved when the defective vessel is removed from the system.

Not all vessels are impacted. The frequency of defective vessels is low. Any LOCI Reaction Vessel lot manufactured prior to lot NH3912618 may be impacted.

Siemens continues to manage inventory as we work with the supplier to resolve this quality issue.

Actions to be Taken by the Customer

• Due to the low frequency of vessels causing errors, Siemens is recommending continued use of all lots.

To identify the Dimension Vista LOCI Reaction Vessel lot number your laboratory is currently using; the last five (5) digits of the vessel lot number contain the manufacturing date: The first three (3) digits represent the Julian date with the last two (2) digits representing the year of manufacture. For example, lot NH3912618

126 = Manufacturing Julian date

18 = Manufacturing year 2018

Therefore, any Vista LOCI Reaction vessel lot number with a Julian date lower than 126 and manufactured in 2018 or earlier may be impacted.

• If you should encounter a "Vessel Pickup error", please refer to the Vista Operator's Guide or online Vista iGuide (Chapter 8; Troubleshooting section) for guidance to clear the error.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

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