

Microbial Contamination of ADVIA 360 Control Set (L-N-H) Lot B1122, Normal Level



Customer Notification

HC 23-03.A.OUS

December 2022

ADVIA® 360 Hematology System

Microbial Contamination of ADVIA 360 Control Set (L-N-H) Lot B1122, Normal Level

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

Table 1. ADVIA 360 Hematology System Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing Date (YYYY-MM-DD)
ADVIA 360 Control Set (L-N-H)	11170853	00630414600833B112220230205	B1122	2023-02-05	2022-10-07

Reason for Customer Notification

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed through investigation that the ADVIA 360 Control Set Normal level control for Lot B1122 may exhibit hemolysis or deterioration due to a microbial contamination which may result in one or more parameters recovering high out of package insert ranges. The Low and High controls for Lot B1122 do not show signs of contamination and are recovering within range. Patient results are not affected.

A new lot of ADVIA 360 Control Set (L-N-H) will be available as a replacement lot by January 13, 2023.

Actions to be Taken by the Customer

- For the product listed in Table 1, please perform the following steps:
 - Inspect the Normal Level control for signs of hemolysis or deterioration. Signs of hemolysis or deterioration include observing an unclear separation between the blood cells and the supernatant, a very dark red supernatant or obtaining unacceptable results when the control is run on the hematology analyzer.
 - If signs of hemolysis or deterioration are noted, discard the tube per the Instructions for Use. Do not use the product if hemolysis or deterioration is suspected.
 - If Quality Controls are passing package insert claims, then results can be reported.

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- If Quality Control results are failing, follow your laboratory practices to manage reporting the parameters.
- If you experience this issue, you may request no-charge replacement product from your local Siemens Healthineers or distributor office. Please review your inventory of these products and assess your laboratory's replacement needs.
- Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product(s).

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 Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers technical support representative.

Additional Information

ADVIA is a trademark of Siemens Healthcare Diagnostics Inc.

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PRODUCT REPLACEMENT FORM

Microbial Contamination of ADVIA 360 Control Set (L-N-H) Lot B1122, Normal Level

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification HC 23-03.A.OUS dated December 2022 regarding Microbial Contamination of ADVIA 360 Control Set (L-N-H) Lot B1122, Normal Level.

Return this completed form to Siemens Healthcare Sdn Bhd as per the instructions provided at the bottom of this page.

Do you now have any of the noted product(s) on hand? Please check Yes No
inventories before answering.

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required

Product Description Product Catalog #/SMN #/Lot #	Quantity Return/ Replacement Quantity Required
ADVIA 360 Control Set (L-N-H), SMN 11170853, Lot B1122	

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Customer Sold To #: _____

Customer Ship To #: _____

Please send a scanned copy of the completed form via email to fscareportingunit.my@siemens-healthineers.com

If you have any questions, contact your local Siemens Healthineers technical support representative.