

## Customer Notification

HC17-01.A.OUS CA

November 2016

### ADVIA® 120/2120/2120i Sheath/Rinse (10L, 20L)

#### Sheath/Rinse Missing Linear Barcode

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

**Table 1. ADVIA® 120/2120/2120i Sheath/Rinse (10L, 20L) Affected Product:**

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date	Manufacturing Date
Sheath/Rinse (10L)	N/A	02337140	10316869	71323	2018-01-31	2016-07-24
				71325	2018-02-28	2016-08-10
				71327	2018-02-28	2016-08-10
				85703	2018-03-31	2016-09-02
				85705	2018-03-31	2016-09-02
				02805	2018-03-31	2016-09-14
Sheath/Rinse (20L)	N/A	01554628	10312272	53040	2018-01-31	2016-07-18
				53162	2018-01-31	2016-07-19
				53164	2018-01-31	2016-07-20
				71167	2018-01-31	2016-07-25
				71169	2018-01-31	2016-08-01
				71171	2018-01-31	2016-08-01
				71173	2018-02-28	2016-08-04
				71175	2018-02-28	2016-08-05
				71177	2018-02-28	2016-08-15
				71179	2018-02-28	2016-08-16
				71321	2018-02-28	2016-08-22
				85603	2018-02-28	2016-08-23
				85605	2018-02-28	2016-08-23
				85607	2018-02-28	2016-08-26

### Reason for Customer Notification

Siemens Healthcare Diagnostics has confirmed the linear barcode is missing from the label of the ADVIA®120/ ADVIA®2120/ ADVIA®2120i Sheath/Rinse cubitainers for the lots listed in Table 1.

There are two barcodes required on each cubitainer. The barcode required for automatic entry of the lot number and expiration date was not placed on the cubitainer during manufacturing of these lots.

Both the 20L (SMN 10312272/REF 01554628) and 10L (SMN 10316869 /REF: 02337140) configurations are impacted.

### Risk to Health

The potential exists for a minimal delay in testing during manual entry of lot and expiration date information. The risk to health is negligible.

### Actions to be taken by the Customer

For the products listed in Table 1, you may continue to use these products by performing the following steps:

Refer to the instructions in the Operator Guide (Section "Replacing the Sheath/Rinse") on how to manually enter this information into the system.

- At the **Logs** menu, select the **Reagent tab**
- Select **Reagent Installation**
- For each new reagent lot number enter in the **Expiration Date** and **Lot #**

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.

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