

Urgent Field Safety Notice

CI-16-03.A.OUS

March, 2016

ADVIA Centaur® CP

Sample processing using EZee-Nest Insert Cups

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

Table 1. ADVIA Centaur CP Affected Product

Product	Siemens Material Number (SMN)
ADVIA Centaur CP System	10309710

Reason for Correction:

Siemens Healthcare Diagnostics has identified an issue with use of the EZee-Nest Insert Cups (SMN 10313057) due to two inaccuracies that exist in the ADVIA Centaur CP Operator's Guide, Appendix D, Pre-Set Tube Types.

- The first inaccuracy refers to the sample volume supported by the system when using the Ezee-Nest insert cup to process samples. The Operator's Guide states that sample volumes greater than 50 µL can be used however volumes greater than 150 µL cannot be used when using an Ezee-Nest insert cup.

Supported Tubes or Manufacturer	Geometry in mm	Tube Setting	Sample Volume	Tip Prime Volume	Unusable Volume
<i>For use with 65-mm sample rack</i>					
+EZee-Nest	1mL Ezee-Nest cup	65 mm-Ezee-Nest13	≤ 50 µL	10 µL	≤ 50 µL
			> 50 µL	20 µL	≤ 50 µL

Actual >50 µL up to 150 µL

The ADVIA Centaur CP accepts the use of EZee-Nest insert cups with primary tubes that have a dimension of 13X65 mm OR 13X75 mm with a 65mm sample rack. The system will generate errors when attempting to aspirate sample volumes greater than 150 µL from Ezee-Nest insert cup(s).

The following errors will post in the event log when sample volumes greater than 150 µL are run. The system will then cancel the test, discard the sample and cuvette, and flag the result as 'Failed'.

Table 2. ADVIA Centaur CP System Errors

Error Number	Severity	Description
007 016 071 058	Warning	Results: Job 123456 XXXXX (1) failed. Cause - there is a sample probe aspiration integrity error.
007 000 072 043	Problem	Patient Samples: Integrity Error detected for 123456/XXXXX (replicate 1). Reason 1.

- The second inaccuracy refers to the use of the Universal Cup Adapter (SMN 10282127) with an EZee-Nest insert cup in 65-mm sample racks. Siemens has determined that the height of an EZee-Nest insert cup with Universal Cup Adapter fitted on a 65-mm sample rack, will not fit into the sample compartment. No samples will be processed.

<i>Supported Tubes or Manufacturer</i>	<i>Universal Cup Adapter</i>
<i>For use with 65-mm sample racks</i>	
<i>+BD Microtainer with Microgard Closure</i>	
<i>+Ezee-Nest13</i>	<i>yes</i>

Risk to Health

There is no impact to health as results are not generated with this failure mode. There is the potential for loss of aspirated sample (up to 250 µL including the dead volume in the insert cup).

Actions to be Taken by the Customer

- Do not use EZee-Nest Insert Cups with assays that require sample volumes greater than 150 µL.
- Do not use the Universal Cup Adapter with Ezee-Nest insert cups in the 65-mm sample racks.
- Ezee-Nest Insert cups must be used in 65mm sample racks with primary tubes that have a dimension of 13 x 65mm OR 13X75 mm.

Sample processing using EZee-Nest Cups

- Siemens recommends using the Siemens Sample Cup (SMN 10309545) along with the required 100-mm sample rack and '100 mm-Siemens Cup' Tube Setting for assays that require sample volumes greater than 150 µL.

Note: The Siemens Sample Cup requires an unusable/dead volume of 150 µL, in contrast to the EZee-Nest Insert Cup which requires 50 µL.

In addition, please perform the following:

- Complete and return the Field Correction Effectiveness Check form attached to this letter within 30 days.
- Please 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.

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.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostic.

FIELD CORRECTION EFFECTIVENESS CHECK

Sample processing using EZee-Nest Cups

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CI-16-03.A.OUS dated March, 2016 regarding Sample processing using EZee-Nest Cups. Please read each 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: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Please fax this completed form to the Customer Care Center at (xxx) xxx-xxxx. If you have any questions, contact your local Siemens technical support representative.