

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 Eze-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 Eze-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 Ezee-Nest cup	1mL	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 Eze-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>	
+BD Microtainer with Microgard Closure	
+Ezee-Nest13	yes

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.

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- 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 local Siemens technical support representative.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostic.

It is important that your organisation takes the actions detailed in the UFSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this UFSN. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the UFSN. Without your reply Siemens Healthcare cannot verify the completeness of the UFSN and the MHRA may need to issue a Medical Device Alert.

Fax: 0845 605 6800

Email: robert.davies@siemens.com

FIELD CORRECTION EFFECTIVENESS CHECK

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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 <input type="checkbox"/>	No <input type="checkbox"/>
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Name of person completing questionnaire:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Email:
Signed:	Date:

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