

Siemens Capillary Caps for RAPIDLyte[®] Multicap and Multicap[®]-S Blood Collection Capillaries

Material Change Impacting Use of Capillary Caps

Our records indicate that you have purchased the following Siemens Capillary Cap products for use with our blood collection Multicap[®] glass and Multicap[®]-S plastic capillaries:

Table 1. Capillary Caps

SMN	Description	Package Count	Legacy Part Number
10311053	Caps for capillary 100 µL	200	478601
10311054	Caps for capillary 140/175 µL	100	478605
10328655	Caps for capillary 50/60 µL	200	478527

Reason for the Urgent Field Safety Notice

This notification is to advise you of a potential issue with Siemens Capillary Caps used with Siemens blood collection Multicap glass and Multicap-S plastic capillaries.

Following receipt of several customer complaints, an investigation identified that a material change made by the supplier has resulted in capillary caps that are more difficult to apply to the capillaries.

Attempting to apply these capillary caps to the capillaries could result in spillage of the sample or possible breakage of the glass capillary.

Risk to Health

The inherent risk for capillary glass tube breakage is slightly increased due to this issue. These risks include potential exposure to infectious agents in the blood and/or a delay of testing.

Actions to be Taken by the Customer

Siemens recommends the following actions be taken by the customer:

1. Siemens advises that you use caution when applying the Capillary Caps with Siemens Multicap glass and Multicap-S plastic capillaries to minimize the potential for breakage or bending.
2. Please contact Siemens if you have any issues when applying these Capillary Caps to Siemens Multicap glass and Multicap-S plastic capillaries.

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3. Complete and return the Field Correction Effectiveness Check form attached to this letter.
4. Please retain this letter with your laboratory records, and forward it to those who may have received this product.

Siemens is taking action to quickly resolve the issue and provide new Capillary Caps for our capillary blood collection products. Timing to resolve the issue and have the new Capillary Caps available is expected within the next one to two weeks.

We regret any inconvenience that this may cause you and thank you for your continued support of Siemens Healthcare Diagnostics blood gas testing products. If you have any questions on the content of this bulletin, please contact your Customer Care Center.

Trademark Information

RAPIDLyte and Multicap are trademarks of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Material Change Impacting Use of Capillary Caps

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 32320 Rev. A dated January 2015 regarding the Material Change Impacting Use of Capillary Caps. Please read the 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.

Ref: POC 15-103

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:	
Street:	
City:	Post Code:
Phone:	Email:

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

Please return this completed FC Effectiveness form within 14 days to:

FAX: 016297401

EMAIL: CruinnFSNGroup@cruinn.ie