Accumetrics

Health Care Professional From Dealer

Urgent Field Safety Notice

Accumetrics VerifyNow IIb/IIIa 25-Test and 10-Test Kits
Product Codes: 85011 and 85310
Reference Number: IVD14.014; CAPA 13-014
Return of Medical Device to the Supplier

February 24, 2014

The purpose of this letter is to provide important information regarding the VerifyNow IIb/IIIa Test kit lots listed in the table provided with this notification. An essential part of Accumetrics' quality system is continuous product performance surveillance. During this surveillance, Accumetrics has determined that the affected VerifyNow IIb/IIIa Test kit lots may result in the reporting of an erroneous low platelet aggregation unit (PAU) result. An erroneous low PAU result may also cause a low % inhibition calculation due to a low baseline PAU. Lower than actual or expected PAU values may contribute to excess administration of IIb/IIIa antiplatelet agents, which has the potential to lead to an adverse event. Typically, higher doses of antiplatelet agents are associated with higher risk of bleeding. Corrective actions are being implemented to prevent these issues from affecting future lots of VerifyNow IIb/IIIa Test kits. Accumetrics has not received any reports of adverse events for these issues. Please contact Accumetrics Technical Support immediately if you become aware of an unreported adverse event related to the use of affected VerifyNow IIb/IIIa Test kits (Accumetrics Customer Support 800-643-1640 option 2 or e-mail at support@accumetrics.com).

NOTE: Only VerifyNow IIb/IIIa 10-Test and VerifyNow IIb/IIIa 25-Test kits listed on the attached table are affected by this condition; no other lots are affected.

Our records indicate that at least one kit box of this product has been shipped to your facility. Please take the following actions:

1. Forward this communication to all those within your organization who need to be aware of this matter. If any affected products have been forwarded to another facility, please forward a copy of this communication to them immediately.

2. Check your inventory to determine if you have any affected VerifyNow IIb/IIIa Test kits.
Unexpired lots: Discontinue use and remove from inventory for return to your Dealer.

Expired lots: Discard any expired lots. Contact your Laboratory Medical Director or attending physician and refer to your facility's Policy and Procedure Manual to determine the appropriate course of action regarding the need to review past results.

3. Complete the attached **Health Care Professional Account Tracking Form** and return it within 10 days to your Dealer. It is important that you complete the form whether or not you have remaining inventory of these lots. Your Dealer will provide you with credit for all unexpired, unused, returned product.

Accumetrics has notified the relevant National Competent Authorities of this Field Safety Corrective Action. The Authorized Representative is MDSS GmbH (Telephone: +49 511 6262 8630) or email info@MDSS.com. Any complaints and/or adverse events experienced with the use of the affected product should be promptly reported to Accumetrics Technical Support. We sincerely apologize for any inconvenience that this matter may cause.

Questions?	Please contact your Dealer.

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LIST OF AFFECTED LOTS

UNEXPIRED AFFECTED LOTS			
Item Number	**Description**	**Lot/Serial**	**Expiration Date**
85011	VerifyNow IIb/IIIa 25-Test	WC0182B	7/8/2014
85011	VerifyNow IIb/IIIa 25-Test	WC0182C	7/8/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0182A	7/8/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0182D	7/8/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0182E	7/8/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0182F	7/8/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0182G	7/8/2014

EXPIRED AFFECTED LOTS			
Item Number	**Description**	**Lot/Serial**	**Expiration Date**
85011	VerifyNow IIb/IIIa 25-Test	WC0180C	10/21/2013
85011	VerifyNow IIb/IIIa 25-Test	WC0180E	10/21/2013
85011	VerifyNow IIb/IIIa 25-Test	WC0180F	10/21/2013
85011	VerifyNow IIb/IIIa 25-Test	WC0181A	1/11/2014
85011	VerifyNow IIb/IIIa 25-Test	WC0181C	1/11/2014
85011	VerifyNow IIb/IIIa 25-Test	WC0181D	1/11/2014
85011	VerifyNow IIb/IIIa 25-Test	WC0181F	1/11/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0180A	10/21/2013
85310	VerifyNow IIb/IIIa 10-Test	WC0180B	10/21/2013
85310	VerifyNow IIb/IIIa 10-Test	WC0180D	10/21/2013
85310	VerifyNow IIb/IIIa 10-Test	WC0181B	1/11/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0181E	1/11/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0181G	1/11/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0181H	1/11/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0181J	1/11/2014
85310	VerifyNow IIb/IIIa 10-Test	WC0181K	1/11/2014

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Health Care Professional Account Tracking Form
VerifyNow® IIb/IIIa

Please complete and return this form.

Customer Name _____

Customer Address _____
Street

_____
City Country Postal Code

Contact Name _____

Contact Phone Number _____

Fax Number _____ E-Mail Address _____

Please select all that apply:

☐ I have read and understand the attached letter.
☐ I do not have any affected unexpired lots of VerifyNow IIb/IIIa
☐ I have the following amount of VerifyNow IIb/IIIa Lot Numbers

Item Number	Description	Lot Number	Number of Boxes
85011	VerifyNow IIb/IIIa 25-Test	WC0182B	
85011	VerifyNow IIb/IIIa 25-Test	WC0182C	
85310	VerifyNow IIb/IIIa 10-Test	WC0182A	
85310	VerifyNow IIb/IIIa 10-Test	WC0182D	
85310	VerifyNow IIb/IIIa 10-Test	WC0182E	
85310	VerifyNow IIb/IIIa 10-Test	WC0182F	
85310	VerifyNow IIb/IIIa 10-Test	WC0182G	

☐ I was not able to complete the actions provided in the letter because (please describe below):

_____

_____

Return this form to your Dealer.