Urgent Field Safety Notice

Alere HIV Combo

FSCA-identifier: FCA#AHC2017-01

Type of Action: Customer Notification

Date: July 14, 2017

Dear Valued Customer,
Alere HIV Combo is an *in vitro*, visually read, qualitative immunoassay for the detection of p24 antigen and antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood. As described in the "Limitation of Procedure" of the instructions for use (IFU), reactive results should be confirmed using another method and the results should be evaluated in light of the overall clinical evaluation before a diagnosis is made. Also, country-specific and other algorithms may apply and require retesting of initially reactive p24 antigen results.

If the instructions for use (IFU) and other algorithm testing requirements are not diligently followed and the initial reactive p24 Ag result is used to initiate clinical action, this could result in exposure to unnecessary medical treatment.

The purpose of this FSN is to both inform users of the increased frequency of p24 antigen reactive results in the below lots and to reinforce the instruction for use (IFU) advice that all initially reactive results (for antibody and/or p24 antigen) should be confirmed using another method.

Details on affected devices:
Alere Medical Co., Ltd. is issuing this Safety Notice to inform you of an issue with regard the following product:

Product Name	Device Lot Number	Catalog Number	Lot Number
Alere HIV Combo	**78169K100**	**7D2842** **7D2843** **7D2846** **7D2847** **7D2843SET** **7D2843SET**	**78169K100E** **78169K100A** **78169K100C** **78169K100B** **78169K100R** **78169K100S**
	79290K100	**7D2843SET**	**79290K100R**
	79291K100	**7D2843SET**	**79291K100R**
	79292K100	**7D2843SET**	**79292K100R**
	79293K100	**7D2842** **7D2843** **7D2843** **7D2843SET**	**79293K100C** **79293K100A** **79293K100B** **79293K100R**
	80671K100	**7D2843** **7D2846** **7D2847** **7D2843SET**	**80671K100B** **80671K100C** **80671K100A** **80671K100R**

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	81502K100	**7D2842** **7D2843** **7D2846**	**81502K100B** **81502K100A** **81502K100C**

Description of the problem:
Our internal investigations have identified that when testing with EDTA whole blood samples, the above lots may exhibit increased frequency of a red bar in the antigen (p24) result window, which could be interpreted as a false positive result. These bars may be faint. Antigen (p24) performance with other sample types continues to perform as per product specifications. Performance for HIV-1 and HIV-2 antibody performs as per product specifications.

Analysis of complaint data reported by users has identified no unacceptable trends of product performance. A health hazard investigation has been performed by an independent medical expert and has concluded there is no increased potential for adverse health consequence associated with the use of these lots when used strictly according to the instructions for use (IFU). These lots may continue to be used.

Manufacturing controls have been initiated; subsequent manufactured lots are performing in line with product specifications for sample types including EDTA whole blood.

Action to be taken by the user/distributor:

- Please forward this information to distributors and users of the kit.
- Review the instructions for use of the assay (and any other algorithm requirements applicable to your facility). Ensure that the requirement for retesting of initially reactive specimens is understood.
- Ensure that initially reactive p24 antigen and/or antibody results are retested using another method and the results are evaluated in consideration of the overall clinical evaluation before a diagnosis is made.
- Retain this notification as part of your laboratory Quality System documentation.
- To confirm your receipt of this notice, complete the enclosed Verification Form and return within 10 days.
  Please FAX or e-mail the completed Reply Form to:

Alere International Limited
Fax: +353-91-680102
E-mail: FSN.alere@alere.com

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Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please send this notice to any other organisations or customers on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the required action.

Contact reference:

Should you have any questions about the information contained in this notification, please contact:

Alere Product Support Care Centers

Region	Phone	E-Mail Address
Europe & Middle East	+44 (0) 161 483 9032	EMEproductsupport@alere.com
Asia Pacific	+ (61) 7 3363 7711	APproductsupport@alere.com
Africa, Russia & CIS	+ (972) 8 9429 683	ARCISproductsupport@alere.com
Latin America	+ (57) 2 661 8797	LAproductsupport@alere.com

Alere sincerely apologizes for the difficulty that this action may cause to you and your facility. We greatly value our relationship with you. We appreciate your attention and timely cooperation in this matter.

Sincerely,

Aki Asahina
Quality System Manager
Alere Medical Co., Ltd.

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Please complete this verification form even if you do not have any affected product and Fax Back to Technical Service at Fax Number +81-(0)47-311-5751 or email to QA.IMJ @alere.com

Customer/Distributor SAFETY NOTICE Verification Form

We acknowledge receipt of the Alere Medical Co., Ltd, SAFETY NOTICE dated July 14, 2017 for the following product:

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	79292K100	**7D2843SET**	**79292K100R**
	79293K100	**7D2842** **7D2843** **7D2843** **7D2843SET**	**79293K100C** **79293K100A** **79293K100B** **79293K100R**
	80671K100	**7D2843** **7D2846** **7D2847** **7D2843SET**	**80671K100B** **80671K100C** **80671K100A** **80671K100R**
	81502K100	**7D2842** **7D2843** **7D2846**	**81502K100B** **81502K100A** **81502K100C**

Please check the appropriate boxes:

☐ I have no record of receipt of this product and therefore will take no further actions.

☐ I have read and understand the letter and have followed the recommended actions.

☐ I have forwarded this notification to our customers/consignees to which we have provided product.

DATE*: _____

AUTHORIZED SIGNATURE*: _____

PRINT NAME*: _____

TITLE: _____ DEPARTMENT: _____

FACILITY*: _____

ADDRESS*: _____

CITY*: _____ STATE: _____ PHONE*: _____

POSTAL CODE*: _____ COUNTRY*: _____

EMAIL: _____

*** Mandatory field**

To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt to Technical Services at **+353-91-680102** or email to FSN.alere@alere.com

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