Alere Technologies GmbH
Loebstedter Str. 103-105
D-07749 Jena
Germany

URGENT FIELD SAFETY NOTICE

Product name: Pima™ Analyser

FSCA-identifier: ATJ_FCA-0001

Type of action: IVD modification a d advice given by manufacturer regarding use of the I VD

Date: 07/12/2015

Attention: All customers of Pima™ Analysers with device serial numbers listed below

Details on affected IVD:

Pima™ Analyser catalogue numbers: 260300003, 260300004, 260300006

Pima™ Analyser serial numbers: PIMA-D-006353 to PIMA-D-009382

Description of the problem:

As part of our post-market surveillance activities we have identified an increase in reports of mechanica failure and prolonged test runtime leading to increased rates of invalid tests or other failures with the Pima™ Analysers where no result is reported. In addition there has been an increase in incidences of misaligned optics potentially leading to underquantification of CD4 counts.

The mechanical and timing failures do not impact the test result of the assay or patient safety, but can lead to a delay in result reporting. The likelihood of the mechanical failures may increase with extended use of the device. The optical failures may, in some circumstances, impact the results achieved with the analyser leading to underquantification of CD4 count.

An independent medical assessment of these events has established that there is low likellihood of patient impact due to underquantification of CD4 count and potential for temporary patient impact due to delay in result reporting.

Based on these post-market observations, Alere is informing customers who have received Pima™ Analyser with aforementioned serial numbers of these issues and actions that need to be taken.

Our records indicate that you may have received one of the affected instruments.

Advice on action to be taken by the user:

- Review the serial number of your device against the information given in section "**Details on affected IVD**" above.
- If you have one of the listed devices, test it with the Pima™ Bead Standard according to the Instructions for Use (IFU) that accompanied the device. If you do not have a Pima™ Bea Standard at hand or require a copy of the IFU, please contact Technical Support for your region and we will supply you with a set of Pima Bead Standards free of charge (contact information can be found below).
- Compare the results of the Pima™ Bead Standard tests to the manufactur ng range printed on the product label inside the protective cartridge case. If the results fall outside of the manufacturing range as sho n on the product label, you should immedi tely stop using the Pima™ Analyser and contact Technical Support for further instructions. If the results fall within the manufacturing range, you may continue using your Pima™ Analyser.
- In line with good laboratory practice, you should perform daily Pima™ Bead Standard testing as required by the IFU as part of the routine instrument quality control activiies.

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- In case of any malfunction of the device, immediately contact Technical Support for your region to arrange an appropriate error assessment, repair or replacement. Should your instrum nt require repair or replacement, appropriate measures will be taken after assessing your indi idual situation and needs. Alere has allocated extra instruments designated for temporary replacement, with the aim of limiting disruption of service for our customers.
- Given the nature of this failure and the independent medical assessment performed for Alere, we have concluded that patient risk is low. Decisions for patient follow up should be made by the individual's attending healthcare provider.
- All customers operating devices that fall within the range listed in section "**Details on affected IVD**" should complete the confirmation form attached and return it to Alere as describe in the form by January 11, 2016.

The above action(s) are to be taken by all recipients of this FS .

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred or sold to. Please maintain aw reness of this notice and resulting action for at least 3 months to ensure effectiveness of the corrective action.

Contact person for further information:

Contact your regional Technical Support in case you have any further questions:

Africa:	+27 21 5315 999	Afrisupport@ale e.com
Asia Pacific:	+61 7 3363 7166	au.techsupport@alere.com
China:	+86 400 889 1117	TechSupport.ASHS@alere.com
Europe:	+44 161 483 5884	EME.techsupport@alere.com
India:	+91 11 45089400	technical.service@alere.com
Latin America:	+57 2 6618916,	la.techsupport@alere.com
	+57 2 6618797	
Russia & CIS:	+972 8 9429 683	Tsupport@orgenics.co.il

We confirm that this notice has been or will be notified to the appropriat National Regulatory Authorities as needed.

Signature:

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Head of Quality Management, Alere Technologies GmbH

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Urgent Field Safety Notice
Reply Form

I confirm that I have been informed of the mechanical and opti al issues related to the Pima Analyser and have performed the following actions:

Please tick the appropriate boxes:

☐ According to my records, I did not get this product and will consequently take no further action.

☐ I have made myself familiar with the contents of the letter and will follow the recommended precautions and other measures. I have performed Pima™ Bead Standard tests and implemented appropriate egular quality control measures on the following Pima™ Analyser(s) [if more space is required, please add pages to your reply]:

PIMA-D-00 _ _ _ _ PIMA-D-00 _ _ _ _ PIMA-D-00 _ _ _ _ PIMA-D-00 _ _ _ _

☐ I have forwarded this notification to all customers / consi nees to whom we have transferred or sold the product.

Please complete the following details as appropriate:

Date	Name (printed)	Signature
Title	Department	
Institution		
Address		
Post/Zip Code	City	
Telephone	FAX	E-mail

Send by FAX to **……..** OR e-mail to **regulato ……** OR send by mail to **Alere Technologies GmbH, c/o ……., Loebstedter Str. 103- 105, D-07749 Jena, Germany**

To meet the global requirements for reporting, please fill out this form after receipt and send it back to us by January 11, 2016.