



Standard Diagnostics, Inc.
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FIELD SAFETY NOTICE: SD BIOLINE Chikungunya IgM

Date: 19th March, 2019

- Product Name : SD BIOLINE Chikungunya IgM
- FSA number: FA18001
- Type of Action: Voluntary Recall (Device removal)
- Intended Audience: The affected customers

Details of affected IVD:

- Product code: 46FK10
- Affected Lot numbers:

Lot No.	Manufacturing Date	Expiry Date
46ADB005A	2016.12.12	2018.12.11
46ADB005B	2017.01.05	2019.01.04
46ADC001A	2017.02.23	2019.02.22
46ADC002A	2017.10.27	2019.10.26
46ADC002B	2018.01.04	2020.01.03
46ADC003A	2018.05.10	2020.05.09
46ADC003B	2018.06.27	2020.06.26

Description of the problem:

Standard Diagnostic, Inc. received a complaint that SD BIOLINE Chikungunya test exhibits a sensitivity that is less than described in the Instructions for Use (IFU). Upon receiving the complaint, Standard Diagnostic Inc. conducted a thorough investigation.

The results of the investigation confirm the SD BIOLINE Chikungunya test involving multiple lots (refer to the table above for affected lots) is performing at a sensitivity lower than outlined in the IFU. The root cause is under investigation.

A risk assessment and Health Hazard Evaluation has been performed. It identified that a lack of sensitivity can lead to a false negative result. If, contrary to the instructions for use, this result is used as the sole criterion for the diagnosis of Chikungunya, diagnosis and treatment can be delayed. Although the risk to the patient is estimated as none to negligible, in an abundance of caution, we are recalling affected lots referenced in the table above.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

- Examine your inventory immediately to determine if you have product on hand subject to this action. If so, quarantine the product.
- Remove the product subject to this voluntary recall. Perform this action according to local regulations or guidelines, and dispose or destroy the product.
- * If the product is in your stock and is to be discarded, ***Certificate of Destruction*** or ***photographs of destruction*** should be provided with the reconciliation form.
- Fill out the reconciliation status table.
- Send this reconciliation form with Certificate of Destruction or Photographs of Destruction to us by 19th March 2019.
- Compensation will be provided for the quantities of discarded products.

Transmission of this Field Safety Notice:

This notice needs to be provided to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred. Please maintain a record of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Should you have any questions please contact SD Technical Service Team:

Name: SD Technical Service Team


Organization: Standard Diagnostics, Inc.

Address: Yunmin Techno Town, 46, 15beon-gil, Borahagal-ro, Giheung-gu, Yongin-si, Kyonggi-do, Republic of Korea

E-mail address: krproductsupport@alere.com

We apologize for any inconvenience this recall may cause to you and your patients.

Sincerely,



Taesuk Kim
Sr. Director, Quality Assurance
Abbott Standard Diagnostics

Attachment 1. Reconciliation Form

• Affected Product information

Product name	Catalogue Number	Lot numbers
SD BIOLINE Chikungunya IgM	46FK10	Describe below table.

• Users information

*Lab or company Name	
*Name	
*Address	
*Email	
*Telephone	
Fax.(if available)	

** Information required to be filled out.*

• Quantities of Affected Products

Lot	Total Quantities Received	Quantities Consumed	Quantities Discarded
	_____Kits	_____Kits	_____Kits
	_____Kits	_____Kits	_____Kits
	_____Kits	_____Kits	_____Kits
	_____Kits	_____Kits	_____Kits
	_____Kits	_____Kits	_____Kits

* "Total Quantities received" shall be equal to sum of "Quantities consumed" and "Quantities discarded".

• **Required actions**

- 1) Examine your inventory immediately to determine if you have product on hand subject to this action. If so, quarantine the product.
- 2) Remove the product subject to this voluntary recall. Perform this action according to local regulations or guidelines, and dispose or destroy the product.

* If the product is in your stock and is to be discarded, ***Certificate of Destruction*** or ***photographs of destruction*** should be provided with the reconciliation form.

- 3) Fill out the above reconciliation status table.
- 4) Send this reconciliation form with Certificate of Destruction or Photographs of Destruction to us by 31th March 2019.
- 5) Compensation for the quantities of discarded products will be performed.

• **Please tick the box**

- I have read, understood and took the required actions.**
- I discarded all affected kits as per local guideline.**

Should you have any questions please contact SD Technical Service Team:

Name: SD Technical Service Team

Organization: Standard Diagnostics, Inc.

Address: Yunmin Techno Town, 46, 15beon-gil, Borahagal-ro, Giheung-gu, Yongin-si, Kyonggi-do, Republic of Korea

E-mail address: krproductsupport@alere.com

Date

Signature

Attachment 2. Product Identification Tool

This tool is to assist customers identify the lot and catalogue number of product subject to this action.

1. Following is an example of packaging:

Catalogue number 46FK10 is printed on the upper side of the package.

Lot number is printed on the left side of the package.

For *in vitro* diagnostic use only
Store at 1-30°C until expiration date

Chikungunya IgM

CE EC REP

Consulting GmbH
Postfach 80 D-66386
St. Ingbert Germany

LOT 46ADB005B

Sub : A
Diluent : 46ADB004
Mfg : 2017.01.05
2019.01.04
(YYYY.MM.DD)

10-30°C 25T




IVD

2. Following is an example of a foil pouch:

Lot number is printed on the back side of the foil pouch


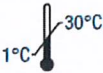

Front side


Immunochromatographic Assay **1 Test**





SD BIO LINE **Rapid Test**

For *in vitro* diagnostic use only
Store at 1 – 30 °C (34 – 86 °F) sealed

 **SD** STANDARD DIAGNOSTICS, INC.
www.standardia.com

Back side

 Item:	Chikungunya IgG
 Lot No.:	46ADB005B
 Mfg.date: (YYYY.MM.DD)	2017.01.05
 Exp.date: (YYYY.MM.DD)	2019.01.04

B104N

FKA-P-1

Lot Number