

**SD****STANDARD DIAGNOSTICS, INC.**

156-68 Hagal-dong, Giheung-gu
Yongin-si, Kyonggi-do, Korea 446-930
Tel : 82-31-899-2800 Fax : 82-31-899-2840
<http://www.standardia.com>

Advisory Notice - Recall

Date ; November 21, 2011

Re; SD BIOLINE HIV 1/2 3.0, Cat No. 03FK10

Lot No. 023418, 023418B, 023419, 023424, 023424B, 023425B

Dear Valued Customer

The purpose of this letter and Advisory notice is to inform you that Standard Diagnostics is initiating a voluntary recall of the SD BIOLINE HIV 1/2 3.0, Cat No. 03FK10 Lot No. 023418, 023418B, 023419, 023424, 023424B, 023425B

Please discontinue use immediately and recall all kits with these lot numbers.

Our investigations have confirmed that the above lots have some defect. An invalid ratio is about 10~15% in lot. Sample pad for these lots has fast absorption than previous lots and partial of nozzle for bottle is bigger than specification, two types of defect made overflow. Individual defect rate is about 10% but it makes invalid from 10% to 50%. So we make a decision to recall. After finding quantity we will decide next procedure and let you know that.

CUSTOMER REQUIRED ACTION

- Discontinue use and/ or sale of the following product:
SD BIOLINE HIV 1/2 3.0, Cat No. 03FK10
Lot No. 023418, 023418B, 023419, 023424, 023424B, 023425B
- Discontinue use all kits of the above listed lot number. Send the Verification Faxback Form(Attachment 1) confirming quantity to Young-ah Chae, Manager of Quality Assurance +82-31-899-9758. Advisory Notice and Faxback Form send to all your customers to whom you distributed the product to.
- Upon receipt of all faxback forms from your customers please confirm that all lots you distributed were recalled by completion of the second faxback form(Attachment 2), Please send to Young-ah Chae, Manager of Quality Assurance +82-31-899-9758.
- Please complete and FAX the enclosed Verification Forms(Attachment 1 &2) within 10days to confirm your receipt of this notice, to indicate the number of kits quantity.

CONTACT INFORMATION

For additional product needs, please contact your Regional Manager or distributor.

For technical information, please any questions or concerns to your Regional Manager.

We sincerely regret any inconvenience regarding this product performance issue. We are working diligently to ensure that SD BIOLINE HIV 1/2 3.0 kits meet all specifications.

Thank you for your cooperation and support.

Sincerely,



Young-ah Chae

Quality Assurance Manager

Standard Diagnostics

Please complete this form even if you do not have any involved product and FAX back to Standard Diagnostics at Fax number +82-31-899-9758

Customer/Distributor Verification Form – Attachment 1

Advisory Notice - Recall

1. We acknowledge receipt of the Standard Diagnostics product Recall notice dated, November 21, 2011 for the following product.

SD BIOLINE HIV 1/2 3.0, Cat No. 03FK10

Lot No. 023418, 023418B, 023419, 023424, 023424B, 023425B

2. We confirm that all areas where the product could be located have been checked
3. We confirm that if product has been distributed to another facility that the facility has been notified of this recall

4. SELECT ONE OF THESE STATEMENTS, SIGN THIS FORM and FAX

We do not have any affected product

We recall the following product(s)- Please confirm the product, lot number(s) the quantity remained.

Product Name	Cat No.	Lot No.	Kit Quantity
SD BIOLINE HIV 1/2 3.0	03FK10	023418	
		023418B	
		023419	
		023424	
		023424B	
		023425B	

DATE _____

AUTHORIZED SIGNATURE _____

PRINT NAME _____

TITLE _____ DEPARTMENT _____

INSTITUTION _____

ADDRESS _____

EMAIL _____

PHONE _____

To satisfy requirements for regulatory reporting, please complete and return this form within 10 business days of receipt to Standard Diagnostics at FAX +82-31-899-9758.

Please complete this form even if you do not have any involved product and FAX back to Standard Diagnostics at Fax number +82-31-899-9758

Customer/Distributor Verification Form – Attachment 2

Advisory Notice - Recall

1. We acknowledge receipt of the Standard Diagnostics product Recall notice dated, November 21, 2011 for the following product.

SD BIOLINE HIV 1/2 3.0, Cat No. 03FK10

Lot No. 023418, 023418B, 023419, 023424, 023424B, 023425B

2. TICK THE FOLLOWING STATEMENT, SIGN THIS FORM and FAX

We confirm that we have received confirmation from all our customers that any remaining they hold of this lot number has been recalled.

DATE _____

AUTHORIZED SIGNATURE _____

PRINT NAME _____

TITLE _____ DEPARTMENT _____

INSTITUTION _____

ADDRESS _____

EMAIL _____

PHONE _____

To satisfy requirements for regulatory reporting, please complete and return this form within 10 business days of receipt to Standard Diagnostics at FAX +82-31-899-9758.