Standard Diagnostics, Inc.
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URGENT FIELD SAFETY NOTICE:
SD BIOLINE HIV Ag/Ab Combo

Date: 14th Apr, 2017

- Product Name : SD BIOLINE HIV Ag/Ab Combo
- FSCA-identifier: FA17001
- Type of action: Voluntary recall
- Attention: The affected customers
  cc Chairman Medical Board and Relevant Head of Departments

Details on affected IVD:

- Product code: 03FK30, 03FK35
- Affected Lot numbers:

No.	Lot No.	Manufacturing Date	Expiry Date
1	03BDA003A	2015.09.11	2017.03.10
2	03BDA004A	2015.10.20	2017.04.19
3	03BDA005A	2015.11.26	2017.05.25
4	03BDA006A	2015.12.09	2017.06.08
5	03BDA006B	2016.02.11	2017.08.10
6	03BDB001A	2016.04.13	2017.10.12
7	03BDB001B	2016.06.02	2017.12.01
8	03BDB001C	2016.07.05	2018.01.04
9	03BDB002A	2016.08.16	2018.02.15

Description of the problem:

Standard Diagnostics, Inc. (hereafter SD) has received two performance complaints of SD BIOLINE HIV Ag/Ab Combo in Feb, 2017 from Kyrgyzstan.

SD investigated the complaints and confirmed that the lots listed in the above table did not meet the performance claim for analytical sensitivity of p24 antigen (Claimed detection limit in the package insert: 2 IU/ml, however the lots listed above detect a concentration of 16 IU/ml.)

When performing as expected, the p24 component of the assay may enable the detection of infection about 7 days before the antibody results become positive. If a patient is in the very early diagnostic window period, the lower p24 sensitivity of the 9 lots above may reduce the detection period by one or two days, with the possibility of a false negative result.

If a false negative result occurs, it is possible that treatment of a patient that is HIV positive could be delayed and further transmission of the infection to sexual partners or through blood transfusion could occur.

Therefore, based on the investigation findings including health hazard evaluation, SD have decided to conduct voluntary recall for the list of lots from the market.

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The scope of this action involves only the lots listed in this notice. The cause of the failure has been identified and corrective actions applied. Lots manufactured before 03BDA003A and after 03BDB002A are not included in the scope of this voluntary recall.

This voluntary recall has been communicated to WHO (World Health Organization) and concerned national authorities.

Advice on action to be taken by the user:

- Examine your inventory immediately to determine if you have product on hand subject to this action. If so, quarantine such product(s).
- Remove the products subject to this voluntary recall. Perform this action according to local regulations or guidelines, and dispose or destroy the product.
- Fill out the attached reconciliation form.
- Send the reconciliation form to your distributor or sales representative.
- The compensation for the quantities of discarded products will be done by reimbursement of purchase price.
- For patients of which negative results on p24 antigen were obtained, conduct confirmatory assays.

Transmission of this Field Safety Notice:

This notice needs to be passed on 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,

[redacted]

Taesuk Kim
Sr. Director, Quality Assurance
Alere Standard Diagnostics