Dirección Nacional de Medicamentos

República de El Salvador, América Central

UNIDAD DE INSPECCIÓN Y FISCALIZACIÓN

COMUNICACIÓN DE ALERTA

Santa Tecla, 30 de noviembre de 2017

LA DIRECCIÓN NACIONAL DE MEDICAMENTOS (DNM) ALERTA SOBRE *PRODUCTO:* **Dispositivo Médico SD BIOLINE HIV – ½ 3.0**

Nivel de alerta: I
Nombre del producto: **SD BIOLINE HIV – ½ 3.0**
Presentación: Caja por 30 pruebas
Número de registro sanitario: IM109504092014
Laboratorio Fabricante: Standar Diagnostics Inc.
Lote: 03ADC025A, código 03FK10
Fecha de vencimiento: 04/2019

Indicación: Para la detección cualitativa de antígenos y anticuerpos de todos los isotipos (IgG, IgM e IgA) especifico de VIH – ½ y/o treponema pallidium (TP), HIV-1 incluyendo subtipo-0 y/o HIV-2 simultáneamente en suero humano, plasma o sangre completa.

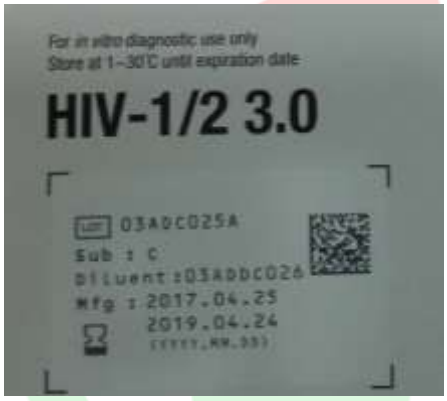
Descripción del problema encontrado:
Posible falso negativo o falso positivo en los resultados para la infección de VIH obtenidos con la utilización de la prueba.

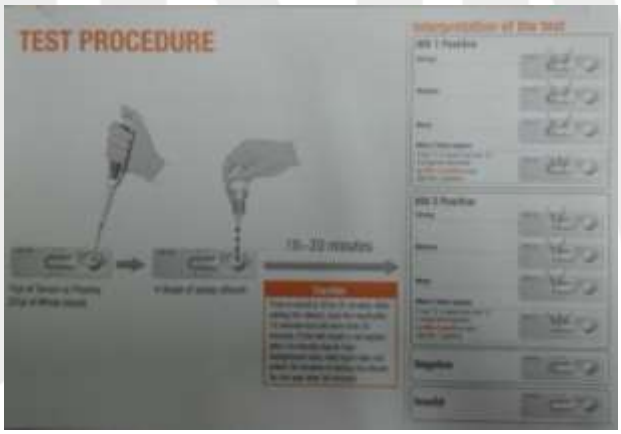
La DNM alerta a toda la población a abstenerse de adquirir y/o utilizar éste producto, en virtud de que su uso representa un riesgo para la salud de la persona que lo utilice. En razón de que es posible que el tratamiento de un paciente que es VIH positivo se retrase y se reproduzca una transmisión posterior de la infección, por lo que no existe certeza de su seguridad, calidad y eficacia.

La DNM recomienda no adquirir este tipo de producto ya que pueden generar un riesgo a la salud. Cualquier duda puede recurrir a ésta Dirección llamando al teléfono gratuito 136.

Se informa que la DNM continuará las acciones de vigilancia, como el aseguramiento de productos, para evitar la venta de los mismos porque representan un riesgo a la población.

ANEXOS





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Abbott

Standard Diagnostics, Inc.
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Giheung-gu, Yongin-si,
Gyeonggi-do, Republic of Korea (17099)
T: +82.31.899.2800 / 899.2805
fax +82.31.899.2842

FIELD SAFETY NOTICE: SD BIOLINE HIV -1/2 3.0

Date: 24th Nov, 2017

- Product Name : SD BIOLINE HIV -1/2 3.0
- FSCA-identifier: FA17002
- Type of action: Voluntary recall (Device removal)
- Attention: The affected customers

Details of affected IVD:

- Product code: 03FK10
- Affected Lot numbers:

Lot No.	Manufacturing Date	Expiry Date
03ADC025A Sub C	2017.04.25	2019.04.24

Description of the problem:

Standard Diagnostics, Inc. (hereafter SD) has received one complaint of SD BIOLINE HIV-1/2 3.0 in Oct, 2017 from Colombia. The description of the complaint is that two SD BIOLINE HIV-1/2 3.0 pouches contain HBsAg tests. (Cassette and strip are both HBsAg.)

Figure. Picture of mix up from the customer in Colombia

Distribution quantity for the affected lot is 93,870 tests.

SD investigated the process and determined that the maximum quantity of incorrect devices distributed is probably 11, including the two reported devices. While there is low probability of receipt and use of the erroneous product, we have decided to recall this lot as there is a risk to patients.

If the user doesn't recognize the wrong label and performs a test for HIV 1/2 with an HBsAg device, the possible outcomes include:
1. False negative result reported for HIV infection, when the patient truly has HIV but the negative result is for HBsAg. Based on the defect rate and HIV incidence rate, the estimated increased false negative percentage is 0.000014% – 0.000019%.
2. False positive result reported for HIV infection, when the positive result is really for HBsAg. Based on the defect rate and HBsAg incidence rate, the estimated increased false positive percentage is 0.000732% ~ 0.000084%

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

The scope of this action involves only the sub lot ("c") listed in this notice. The cause of the failure has been identified and corrective actions has been applied.
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.
- 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 status table.
- Send this reconciliation form to us by 28th Feb, 2018.
  * Refer to the detailed process in Attachment 1 and 2, Reconciliation form.
- The compensation for the quantities of discarded products will be done by replacement.

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.

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Attachment 1. Product Identification Tool for SD BIOLINE HIV-1/2 3.0

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

1. Following is an example of packaging:

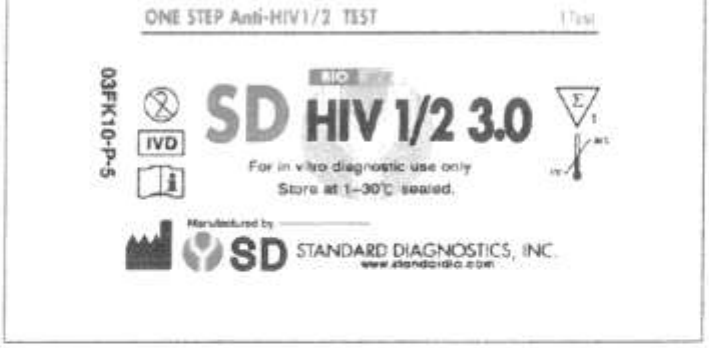
Product code 03FK10 is printed on the upper side of the package.

Lot number and sub code are printed on the left side of the package.

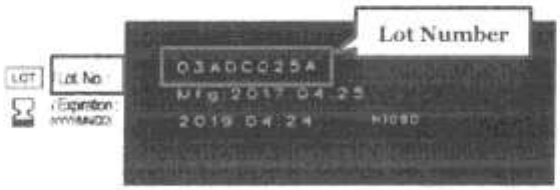
2. Following is an example of a foil pouch:

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

Front side



Back side



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