WHO Prequalification of In Vitro Diagnostics Programme
PUBLIC REPORT

Product: SD BIOLINE HIV-1/2 3.0
Number: PQDx 0027-012-00

Abstract

SD BIOLINE HIV-1/2 3.0 with product codes **03FK10** and **03FK16**, manufactured by **Standard Diagnostics, Inc.**, **"rest of the world"** regulatory version was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 20 May 2013. This public report was amended on 24 May 2017 to reflect addition of a new product code **03FK17**.

Intended use:
SD BIOLINE HIV 1/2 3.0 kit is a rapid, qualitative test for the detection of antibodies to certain isotypes (IgG, IgM, IgA) specific to HIV-1 including subtype-O and HIV-2 simultaneously in human serum, plasma or whole blood.

Assay description:
SD BIOLINE HIV-1/2 3.0 contains a membrane strip, which is pre-coated with recombinant HIV-1 capture antigen (gp41, p24) on test line "1" region and with recombinant HIV-2 capture antigen (gp36) on test line "2" region, respectively. The mixture (recombinant HIV-1/2 antigen (gp41, p24 and gp36) - colloid gold conjugate and the specimen moves upward on the membrane chromatographically to the test region (T) and form a visible line as the antigen antibody-antigen gold particle complex forms with high degree of sensitivity and specificity. This test device has the letter of 1, 2 and C as Test Line 1 (HIV-1), Test Line 2 (HIV-2) and Control Line on the surface of the device. All test lines and the control line in the result window should not be visible before applying any sample. The control line is used as a procedural control for the addition of reagents and may still appear if no specimen is added to the test device.

SD BIOLINE HIV-1/2 3.0 is intended as an aid in the diagnosis of infection with HIV-1/2.

Test kit contents:

	30T/kit (product code 03FK10)	**25T/kit (product code 03FK16)**	**25T/kit (product code 03FK17)**
Test cassettes individually packed in foil pouch with a desiccant	30 test devices	25 test devices	25 test devices

Assay diluent dispensed in plastic bottle	1 x 4ml/bottle	1 x 4ml/bottle	1 x 4ml/bottle
Specimen transfer devices Disposable (20µl)	N/A	25 units of 20 µl	25 units of 20 µl
Lancets Disposable, sterilized	N/A	25 units	25 units **(safety lancet)**
Alcohol swabs Disposable	N/A	25 units	25 units
Instructions for use	1 copy	1 copy	1 copy

Storage:
The test kit should be stored at 1 - 30 °C.

Shelf-life:
24 months.

Warnings/limitations:

1. The reading time for this product was changed, the revised instructions for use now state: "Time to result is 10 to 20 minutes. After adding the diluent, read the result after 10 minutes but not more than 20 minutes."
2. If the test result is not legible after 10 minutes due to high background colour, read again later but within 20 minutes of adding the diluent. Do not read after 20 minutes.
3. Dual infection of HIV-1 and HIV-2 within one individual is quite rare. Dual reactivity observed in SD BIOLINE HIV-1/2 3.0, i.e. HIV-1 line and HIV-2 line both reactive, is more likely to be caused by cross-reactivity given certain homology in the amino acid sequences of HIV-1 and HIV-2. To determine the virus type or diagnose a co-infection, confirmatory testing must be performed.

Summary of prequalification status for SD BIOLINE HIV-1/2 3.0

	Initial acceptance	
	Date	**Outcome**
PQ status amended	24 May 2017	
Status on PQ list	20 May 2013	listed
Dossier assessment	11 August 2011	MR
Inspection status	19 February 2013	MR
Laboratory evaluation	05 April 2013	MR

MR: Meets Requirements
NA: Not Applicable

Prioritization for prequalification

Based the established prioritization criteria, SD BIOLINE HIV-1/2 3.0 was given priority for prequalification.

Product dossier assessment

Standard Diagnostics, Inc. submitted a product dossier for SD BIOLINE HIV-1/2 3.0 as per the "Instructions for compilation of a product dossier" (PQDx_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors) appointed by WHO.

The manufacturer's response to the nonconformities found during the dossier assessment were accepted on 23 November 2011.

Commitments for prequalification:

1. Analytical performance studies
2. Clinical performance studies
3. Stability studies
4. A new version of the labels and instructions for use.

Based on the product dossier assessment findings, the product dossier for SD BIOLINE HIV-1/2 3.0 meets WHO prequalification requirements.

Manufacturing site inspection

A comprehensive second re-inspection was performed at the sites of the legal manufacturer of SD BIOLINE HIV 1/2 3.0 at 156-68 Hagal-dong Giheung-gu, Yongin-si, Kyonggi-do 446-930, Republic of Korea and 473-4 Bora-dong Giheung-gu, Yongin-si, Kyonggi-do, 446-904, Republic of Korea in November 2012[1], as per "Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics." (PQDx_014 v1).

Note: the inspection team were not able to review the batch manufacturing records of the lots submitted for the repeat WHO laboratory evaluation for the SD BIOLINE HIV 1/2 3.0. The lots for retesting had not been requested at the time of the inspection (November 2012) and were submitted subsequent to the inspection.

The manufacturer's responses to the nonconformities found at the time of the inspection were accepted 19 February 2013.

Commitments for prequalification:

[1] A subsequent inspection took place at Production: 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099 Republic of Korea and 46, Hagalro 15 beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do 17099 Republic of Korea and Warehouse: 19-22, Dongtansandan 3-gil, Dongtan-myeon, Hwaseong-si, Gyeonggi-do 18487, Republic of Korea on 6 to 8 May 2015.

1. The manufacturer has committed to continuing improvements in the quality management system particularly in the areas of clear lines of authority, identification and traceability, warehousing and clarity of work instructions and batch manufacturing records.
2. The manufacturer has committed to continuing close supervision of the lot release procedures together with ongoing communication over time to finalize any outstanding issues noted in the WHO responses to the inspection findings.

Based on the site inspection and corrective action plan review, the quality management system for SD BIOLINE HIV-1/2 3.0 meets WHO prequalification requirements

Laboratory evaluation

SD BIOLINE HIV-1/2 3.0 was evaluated by WHO in the last quarter of 2012 using serum/plasma specimens. From this evaluation, we drew the following conclusions:

SD BIOLINE HIV-1/2 3.0 is a lateral flow immunochromatographic assay for the discriminatory detection HIV-1 and HIV-2 antibodies in human serum/plasma and whole blood. A volume of 10µL of serum/plasma or 20µl of whole blood is required to perform the assay. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results is performed visually i.e. subjectively read.

In this limited evaluation on a panel of 1118 clinically-derived specimens, we found an initial sensitivity (95% CI) of 99.8% (98.8% - 100%) and an initial specificity (95% CI) of 99.9% (99.2% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.2% - 100%) and the final specificity (95% CI) was 99.9% (99.2% - 100%) compared to the reference assays. Lot to lot variation observed was within the acceptance criteria.

SD BIOLINE HIV-1/2 3.0 was unable to discriminate between HIV-1 and HIV-2 for seven HIV-2 specimens, and 22 HIV-1 specimens (6.3% of 460 HIV positive specimens), as two test bands of equal intensity were observed.

For eight seroconversion panels, SD BIOLINE HIV-1/2 3.0 detected on average 0.125 specimens later than the benchmark assay (Enzygnost Anti-HIV 1/2 Plus [Siemens Healthcare Diagnostics]).

For the mixed titer panel, SD BIOLINE HIV-1/2 3.0 correctly classified all specimens. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], SD BIOLINE HIV-1/2 3.0 detected all HIV-1 subtypes tested (HIV-1 A, HIV-1 B, HIV-C, HIV-1 CRF01_AE, and HIV-2).

In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the overall inter-reader variability was 1.9% (0.2% for HIV-1 band, 1.8% for HIV-2 band). The invalid rate was 0%.

Change notification

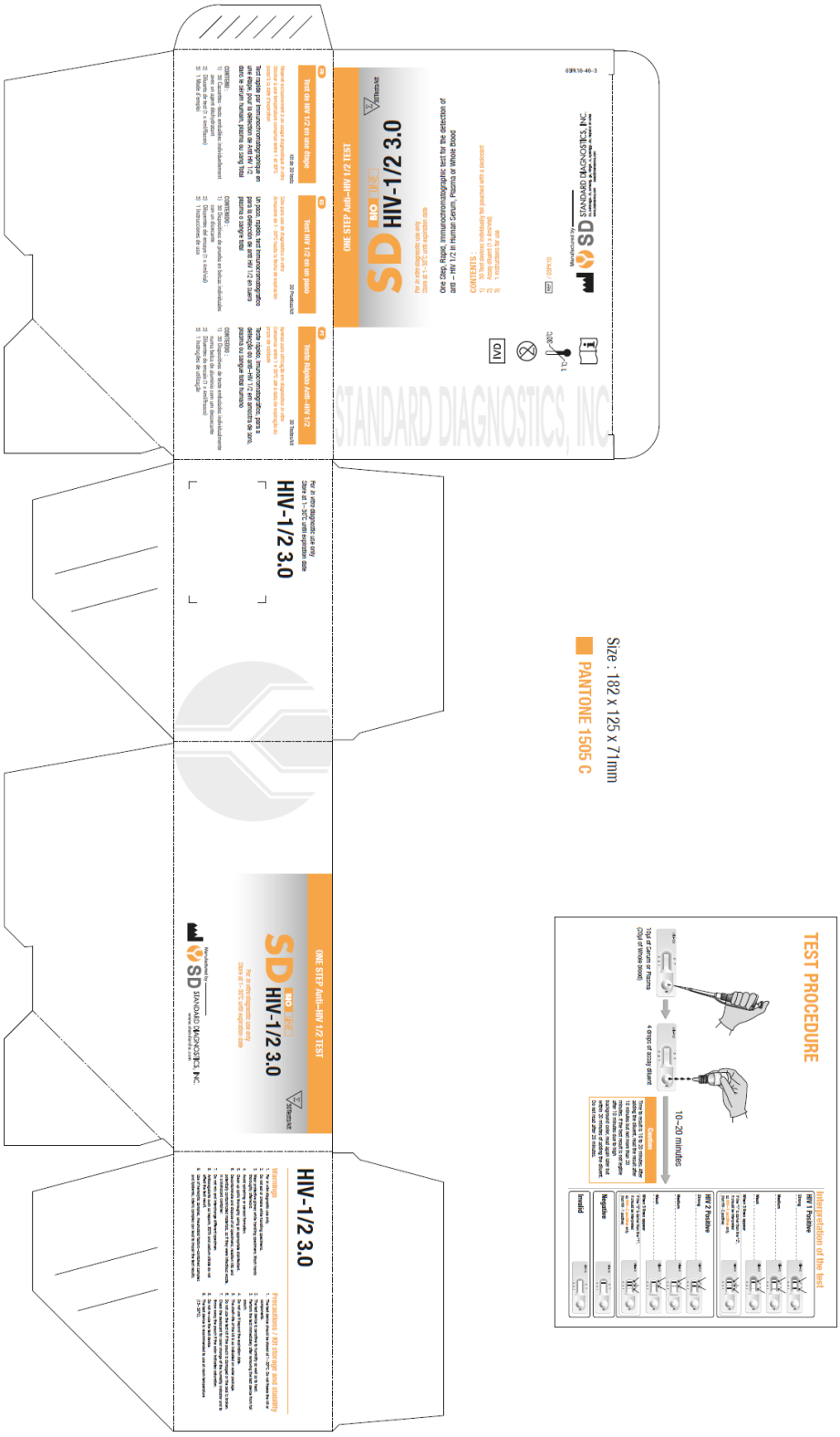
In 2016, Standard Diagnostics, Inc., submitted a change notifications related to addition of a new product code that includes safety lancets. This change notification was assessed and was found to meet WHO prequalification requirements.

Labelling

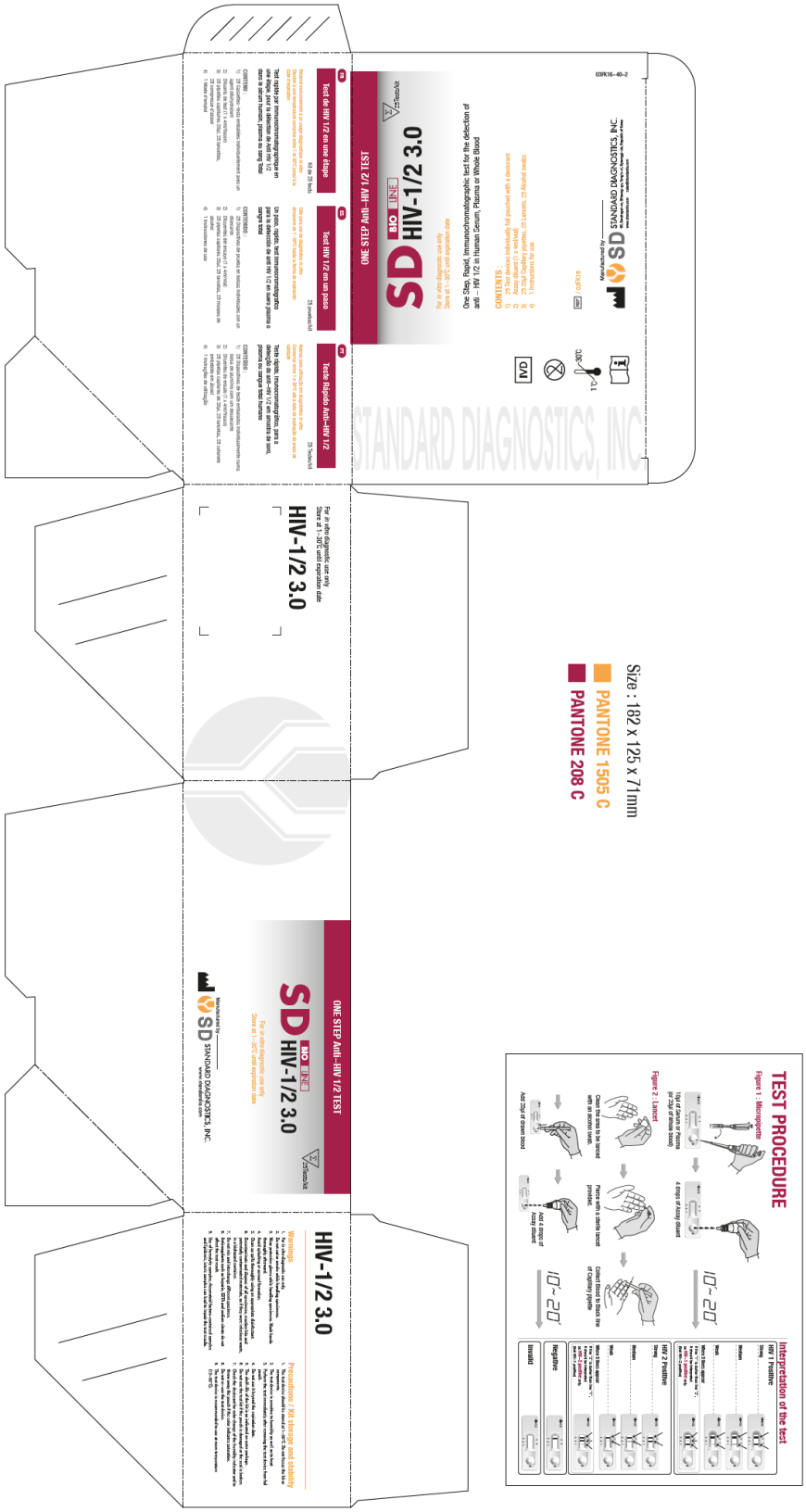
1. **Labels**
2. **Instructions for use**

1. Labels

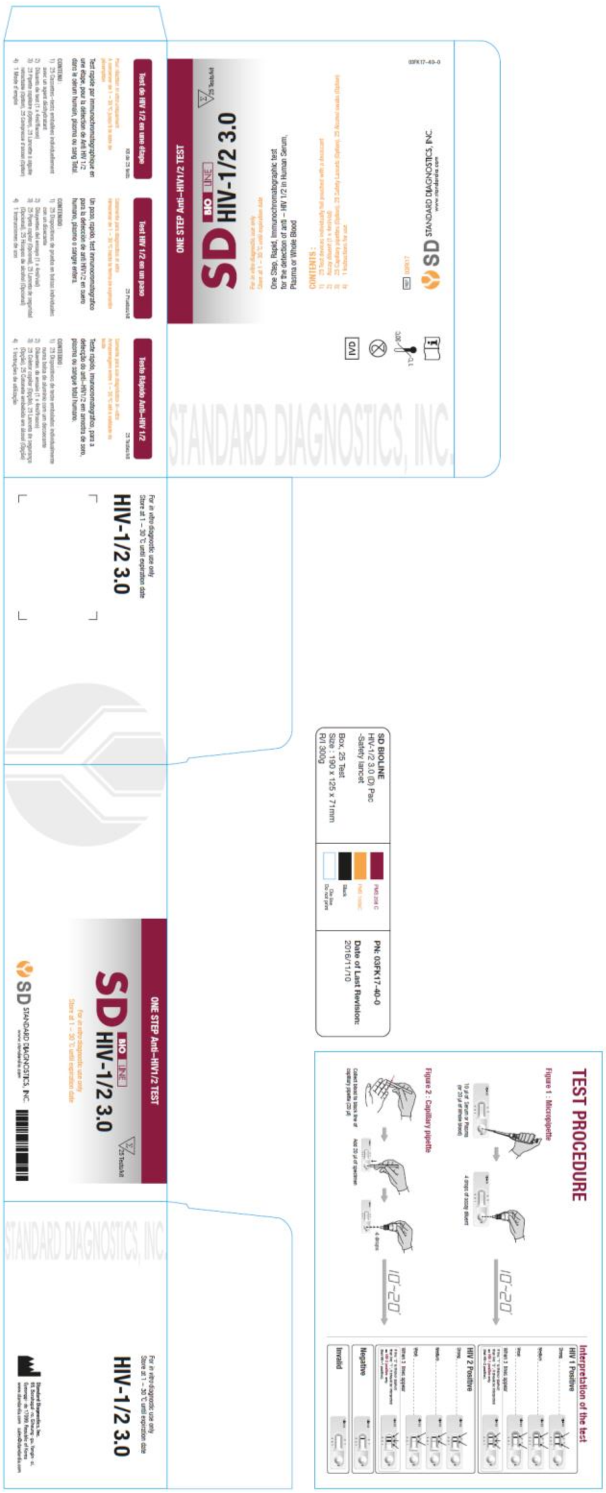
1.1 Package box for 03FK10



1.2 Package box for 03FK16



1.3 Package box for 03FK17



2. Instructions for use

2.1 IFU for 03FK10 and 03FK16


The 3rd Generation of ONE STEP antibodies to HIV-1/HIV-2 Test
SD BIOLINE HIV-1/2 3.0 (03FK10, 03FK16)
English
Français
Español
Português
STANDARD DIAGNOSTICS, INC.

The 3rd Generation of ONE STEP antibodies to HIV-1/HIV-2 Test

SD BIO LINE HIV-1/2 3.0 (03FK10, 03FK16)

Test Procedure
Procédure du test rapide
Procedimiento de Prueba Rápida
Procedimento do teste rápido

1

EN Now, open the package and look for the following:
1. Test devices individually foil pouched with a desiccant
2. Assay diluent
3. Instructions for use

FR Ouvrir le kit et vérifier les éléments suivants:
1. La plaque de test Dans son enveloppe Protectrice puis le déshumidificateur
2. Diluent
3. Notice d'utilisation

ES Ahora, abra el empaque y busque a continuación:
1. El dispositivo de prueba es empacado en una bolsa de aluminio con un desecante de forma individual
2. Diluyente del ensayo
3. Instrucciones de uso

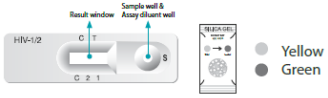
PT Abra a embalagem e observe abaixo:
1. Teste em card individualmente emsalado com dessecante
2. Diluente de ensaio
3. Instruções de utilização

EN Open the foil pouch and look for the following:
1. Result window
2. Sample well & Assay diluent well

FR Ouvrir l'enveloppe et vérifier les éléments suivants:
1. Fenêtre des résultats
2. Puits d'échantillon et diluent

ES Abra el empaque de aluminio y busque lo siguiente:
1. Ventana de Resultados
2. Pozo de muestra & diluyente del ensayo

PT Abra o envelope e observe:
1. Janela de resultado
2. Janela de amostra e diluente de amostra



Including only for Cat. No. 03FK16/Y compris seulement pour Cat. No. 03FK16./Inclusive sólo para No. Cat. 03FK16/Incluido apenas para o Nº deCatalogo. 03FK16

EN
1. 25 x capillary pipettes
2. 25 x Lancets
3. 25 x alcohol swabs

FR
1. 25 x Pipette capillaire de 20µl
2. 25 x Lancette
3. 25 x Tampon d'alcool

ES
1. 25 x Pipeta capilar 20µl
2. 25 x Lancetas
3. 25 x Algodón con alcohol

PT
1. 25 x Pipetas capilares de 20µl
2. 25 x Lancetas
3. 25 x Estrigão embebido em álcool

2

EN FIRST, read carefully the instruction on how to use the SD BIOLINE HIV-1/2 3.0 test kit.

FR Lire attentivement la notice du kit de SD BIOLINE HIV-1/2 3.0.

ES PRIMERO, Lea cuidadosamente las instrucciones sobre cómo usar el kit de prueba SD BIOLINE HIV -1/2 3.0.

PT Primeiramente leia cuidadosamente as instruções de como usar o teste SD BIOLINE HIV-1/2 3.0.

3

EN Next, look at the expiry date at the back of the foil pouch. Use another kit, if expiry date has passed.

FR Vérifier la date de péremption au verso de l'enveloppe protectrice. Utiliser un autre kit si la date de péremption est dépassée

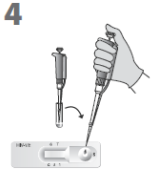
ES Luego, verifique la fecha de vencimiento en la parte posterior de la bolsa de aluminio. Use otro kit, si la fecha ha expirado.

PT Observe a data de validade atrás do envelope. Use outro kit caso a data de validade já tenha se passado.

[For example / Par exemple / Por ejemplo / Par exemple]

I. Blood (by venipuncture), Plasma or Serum specimen / Échantillon de sang (par ponction veineuse), de sérum, ou de plasma / Mues t ra de Sangre (por punc ión venosa), Plasma o suero / Sangue (por venipunção), plasma ou soro

4



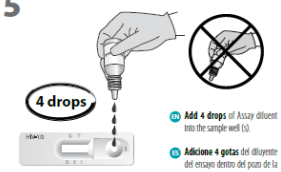
EN **Add 10µl of plasma or serum (20µl of blood)** into the sample well (s) using a micropipette.

FR Transférer **10µl de plasma, sérum, ou 20µl de sang** dans le puits d'échantillon (S) utilisant une micropipette.

ES Agregar **10µl de plasma o suero (20µl de sangre)** dentro del pozo de muestra usando micropipeta.

PT Adicione **10µl de plasma ou soro (20µl de sangue)** na janela de amostra usando uma micropipeta.

5



EN **Add 4 drops** of Assay diluent into the sample well (s).

FR **Ajouter 4 gouttes** de diluant dans le puits d'échantillon (S).

ES **Adicione 4 gotas** del diluyente del ensayo dentro del pozo de la muestra

PT **Adicione 4 gotas** de diluente de ensaio na janela de amostra.

II. Blood specimen (with a lancet) / Échantillon de sang (avec la lancette) / Muestra de sangre (con una lanceta) / Amostra sangue total (com lanceta)

4

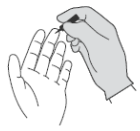
EN Clean the area to be lanced with an alcohol swab.

FR Nettoyer la surface à prélever à l'aide d'un tampon imbibé d'alcool.

ES Limpie el área a ser pinchada con un copo de algodón humedecido con alcohol.

PT Limpe a área a ser lancetada com swab de álcool.

5



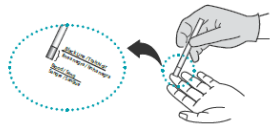
EN Pierce with a sterile lancet provided.

FR Piquer avec une lancette stérile fournie.

ES Pinchar con la lanceta estéril suministrada.

PT Fure com a lanceta estéril contida no kit.

6



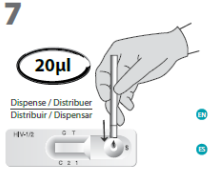
EN Take a **20µl** capillary pipette provided, immerse the open end in the blood drop and then release the pressure to draw blood into the capillary pipette to **black line.**

FR Saisir la pipette capillaire de **20µl** fournie, immerger l'orifice de la pipette dans la goutte de sang, puis relâcher la pression pour que le sang pénètre dans le tube capillaire. Prélever jusqu'au **trait noir** indiqué sur la tube.

ES Tome la pipeta capilar de **20µl** suministrada, inmersa la punta abierta en la gota de sangre y luego retire la presión para colectar la sangre dentro de la pipeta capilar hasta la **línea negra.**

PT Pegue a pipeta capilar de **20µl** contida no kit, coloque a abertura na gota de sangue e então aperte para que o sangue alcance a marca dos 20µl

7



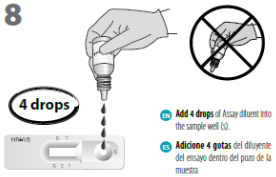
EN Add **20µl** of drawn blood into the sample well (s).

FR Transférer **20µl** de sang dans le puits d'échantillon (S).

ES Agregar **20µl** de la sangre recolectada dentro del pozo de muestra (S).

PT Adicione **20µl** de sangue na janela de amostra.

8



EN **Add 4 drops** of Assay diluent into the sample well (s).

FR **Ajouter 4 gouttes** de diluant dans le puits.

ES **Adicione 4 gotas** del diluyente del ensayo dentro del pozo de la muestra

PT **Adicione 4 gotas** de diluente de ensaio na janela de amostra.

Interpretation / Interprétation / Interpretación / Interpretação

EN Time to result is 10 to 20 minutes. After adding the diluents, read the result after 10 minutes but not more than 20 minutes. If the test result is not legible after 10 minutes due to high background color, read again later but within 20 minutes of adding the diluents. Do not read after 20 minutes.

FR Le délai d'obtention du résultat est compris entre 10 et 20 minutes. Après l'ajout du diluant, lire le résultat au bout de 10 minutes mais pas après 20 minutes. Si le résultat du test n'est pas lisible au bout de 10 minutes en raison de la couleur foncée de l'arrière plan, essayer une nouvelle fois de lire le résultat dans un délai maximum de 20 minutes. Ne pas lire le résultat au-delà de ce délai.

ES El tiempo de obtención de los resultados oscila entre 10 y 20 minutos. Tras añadir el diluyente del ensaye, lea el resultado después de 10 minutos (pero no espere más de 20 minutos). Si no puede leer el resultado del ensayo después de 10 minutos porque no se distingue del color de fondo, consulte el resultado de nuevo 20 minutos después de añadir el diluyente. No consulte el resultado una vez pasados 20 minutos.

PT O tempo para obter o resultado é de 10 a 20 minutos. Leia o resultado 10 minutos (e no máximo 20 minutos) depois de adicionar o diluente. Se não conseguir ler o resultado do teste após 10 minutos porque a cor de fundo não permite distinguir, volte a consultar o resultado no período de 20 minutos depois de ter adicionado o diluente. Uma vez passados os 20 minutos, não consulte o resultado.

How to interpret test results / Comment interpréter les résultats du test / Cómo interpretar los resultados / Forma de interpretar os resultados dos testes

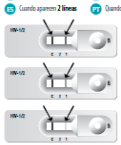
Negative / Negatif / Negativo

Positive / Positif / Postivo

HIV-1 Positive / Positif / Postivo

2 LINES / 2 BANDES / 2 LINEAS / 2 LINHAS

EN When **2 lines** appear **FR** Apparition de **2 bandes**
ES Cuando aparecen **2 líneas** **PT** Quando aparecem **2 linhas**



3 LINES / 3 BANDES / 3 LINEAS / 3 LINHAS

EN When **3 lines** appear "C," "T" and faint "T" Line
FR Apparition de **3 bandes** Bande "C", Bande "T", et Bande "T" Floue
ES Cuando aparecen **3 líneas** Líneas "C," "T" y "T" débil
PT Quando aparecem **3 linhas** Linha controle Linha "T", e Linha "T" fraca

EN If line **"T"** is darker than line **"2"**, it should be interpreted as HIV-1 positive only **(Not HIV-2 positive).**
Faint line : By homology in the amino acid sequence of HIV Type-1 and HIV Type-2.

ES Cuando la línea **"T"** es más oscura que la línea **"2"**, debe ser interpretado como HIV-1 positivo únicamente: **(No HIV-2 positivo)**
Por similitud en la secuencia de aminoácidos de HIV Tipo-1 y HIV Tipo-2.

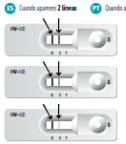
FR Bande **"T"** plus foncée que Bande **"2"**, doit être interprété comme VIH-1 positif. **(Non positif au VIH-2).**
Bande floue : par homologie des séquences d'acides aminés des types VIH-1 et VIH-2.

PT Quando a linha **"T"** apresenta-se mais escura que a linha **"2"**, a teste deve ser interpretado como HIV-1 positivo **(HIV-2 não positivo).**
Por similaridade na sequência de aminoácidos do HIV tipo 1 e HIV tipo 2.

HIV-2 Positive / Positif / Postivo

2 LINES / 2 BANDES / 2 LINEAS / 2 LINHAS

EN When **2 lines** appear **FR** Apparition de **2 bandes**
ES Cuando aparecen **2 líneas** **PT** Quando aparecem **2 linhas**



3 LINES / 3 BANDES / 3 LINEAS / 3 LINHAS

EN When **3 lines** appear "C," "2" and faint "T" Line
FR Apparition de **3 bandes** Bande "C", Bande "2", et Bande "T" floue
ES Cuando aparecen **3 líneas** Líneas "C," "2" y "T" débil
PT Quando aparecem **3 linhas** Linha controle Linha "2", e Linha "T" fraca

EN If line **"2"** is darker than line **"T"**, it should be interpreted as HIV-2 positive only **(Not HIV-1 positive).**
Faint line : By homology in the amino acid sequence of HIV Type-1 and HIV Type-2.

ES Cuando la línea **"2"** es más oscura que la línea **"T"**, debe ser interpretado como HIV-2 positivo únicamente: **(No HIV-1 positivo).**
Por similitud en la secuencia de aminoácidos de HIV Tipo-1 y HIV Tipo-2.

FR Bande **"2"** plus foncée que Bande **"T"**, doit être interprété comme VIH-2 positif. **(Non positif VIH-1).**
Bande floue : par homologie des séquences d'acides aminés des types VIH-1 et VIH-2.

PT Quando a linha **"2"** apresenta-se mais escura que a linha **"T"**, a teste deve ser interpretado como HIV-2 positivo **(HIV-1 não positivo).**
Por similaridade na sequência de aminoácidos do HIV tipo 1 e HIV tipo 2.

Remark / Remarque / Comentario / Nota

EN **[Both HIV 1 and HIV 2 Positive]**
If the band intensity between line 1 and line 2 is so similar to each other , even very sure , it can be both positive for HIV-1 and HIV- 2. In this case, confirm test using Western Blot is recommended to know exact virus type.

ES **[HIV 1 y HIV 2 Positivo]**
Si la intensidad de la banda entre la línea 1 y la línea 2 es tan similar a las otras, aunque es muy rara, puede ser tanto positiva para VIH-1 y VIH-2. En este caso, confirmar la prueba usando Western Blot es recomendable para conocer el exacto tipo de virus.

FR **[VIH-1 et VIH-2 positif]**
Si la densité de la bande des ligne 1 et la ligne 2 sont similaire, malgré que cela est très rare, il peut être positif pour le VIH-1 et le VIH-2. En ce cas, le test Western Blot est recommandé pour confirmer le type du virus.

PT **[HIV-1 e HIV-2 ambos positivos]**
Se a intensidade da banda entre a linha1 e a linha 2 é muito semelhante a outra, mesmo muito rara, pode ser tanto positivo para VIH-1 e VIH-2. Neste caso, confirmar utilizando o teste Western Blot que é recomendado para saber exactamente qual é o tipo de vírus.

Invalid / Invalide / No valido / Inválido

EN No "C" line or/and pink/purple smear

FR Absence de ligne "C" et/ou le tmoit de fond rose/violet

ES Sin la línea "C" y / o el color rosa / púrpura

PT Na linha "C" a presença da cor rosa ou roxa pode indicar uma mancha ou um borrão.

2.2 IFU for 03FK17

The 3rd Generation of ONE STEP antibodies to HIV-1/HIV-2 Test

SD BIO LINE HIV-1/2 3.0 (03FK17)

Test Procedure
Procédure du test rapide
Procedimiento de Prueba Rápida
Procedimento do teste rápido

1

EN Now, open the package and look for the following:
1. Test devices individually foil pouched with a desiccant
2. Assay diluent
3. Instructions for use

ES Ahora, abra el empaque y busque a continuación:
1. Dispositivos de prueba en bolsas individuales con un desecante
2. Diluyente del ensayo
3. Instrucciones de uso

FR Ouvrir le kit et vérifier les éléments suivants:
1. Cassettes-tests emballées individuellement avec un agent déshydratant
2. Diluant de test
3. Mode d'emploi

PT Abra a embalagem e observe abaixo:
1. Dispositivos de teste embalados individualmente numa bolsa de alumínio com um dessecante
2. Diluente do ensaio
3. Instruções de utilização

Options / Opcional / Opções

EN
1. 20µl capillary Pipette
2. Safety Lancet
3. Alcohol swab

FR
1. Pipette capillaire de 20µl
2. Lancette à aiguille retractable
3. Tampon d'alcool

ES
1. Pipeta capilar 20µl
2. Lanceta de seguridad
3. Algodón con alcohol

PT
1. Pipeta capilares de 20µl
2. Lanceta de Segurança
3. Esfregão embebido em álcool

2

EN FIRST, read carefully the instruction on how to use the SD BIOLINE HIV-1/2 3.0 test kit.

FR Lire attentivement la notice du kit de SD BIOLINE HIV-1/2 3.0.

ES PRIMERO, Lea cuidadosamente las instrucciones sobre cómo usar el kit de prueba SD BIOLINE HIV -1/2 3.0.

PT Primeiramente leia cuidadosamente as instruções de como usar o teste SD BIOLINE HIV 1/2 3.0.

3

EN Next, look at the expiry date at the back of the foil pouch. Use another kit, if expiry date has passed.

FR Vérifier la date de péremption au verso de l'enveloppe protectrice. Utiliser un autre kit si la date de péremption est dépassée.

ES Luego, verifique la fecha de vencimiento en la parte posterior de la bolsa de aluminio. Use otro kit, si la fecha ha expirado.

PT Observe a data de validade atrás do envelope. Use outro kit caso a data de validade já tenha se passado.

[For example / Par exemple / Por ejemplo / Par exemple]

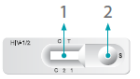
4

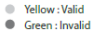
EN Open the foil pouch and look for the following:
1. Result window
2. Sample well & Assay diluent well

FR Ouvrir l'enveloppe et vérifier les élément suivants:
1. Fenêtre des résultats
2. Puits d'échantillon et diluant

ES Abra el empaque de aluminio y busque lo siguiente:
1. Ventana de Resultados.
2. Pozo de muestra & diluyente del ensayo

PT Abra o envelope e observe:
1. Janela de resultado
2. Janela de amostra e diluente de amostra

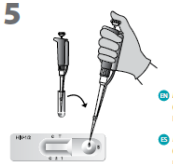




● Yellow : Valid
● Green : Invalid

I. Blood (by venipuncture), Plasma or Serum specimen / Échantillon de sang (par ponction veineuse), de sérum, ou de plasma / Muestra de Sangre (por punc ión venosa), Plasma o suero / Sangue (por venipunção), plasma ou soro

5



10µl (Plasma or Serum)
Or 20µl (Blood)

EN **Add 10µl of plasma or serum (20µl of blood)** into the sample well (s) using a micropipette.

ES Agregar **10µl de plasma o suero (20µl de sangre)** dentro del pozo de muestra (s) usando micropipeta.

FR Transférer **10µl de plasma, sérum, ou 20µl de sang** dans le puits d'échantillon (s) utilisant une micropipette.

PT Adicione **10µl de plasma ou soro (20µl de sangue)** na janela de amostra (s) usando uma micropipeta.

6

EN **Add 4 drops** of assay diluent into the sample well (s).

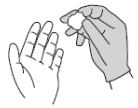
ES **Adicione 4 gotas** del diluyente del ensayo dentro del pozo de la muestra (s).

FR **Ajouter 4 gouttes** de diluant dans le puits d'échantillon (s).

PT **Adicione 4 gotas** de diluente de ensaio na janela de amostra (s).

II. Blood specimen (with a Safety lancet) / Échantillon de sang (avec la lancette à aiguille retractable) / Muestra de sangre (con una lanceta de seguridad) / Amostra sangue total (com lanceta de segurança)

5



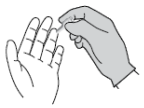
EN Clean the area to be lanced with an alcohol swab.

ES Limpie el área a ser pinchada con un copo de algodón humedecido con alcohol.

FR Nettoyer la surface à prélever à l'aide d'un tampon imbibé d'alcool.

PT Limpe a área a ser lancetada com swab de álcool.

6



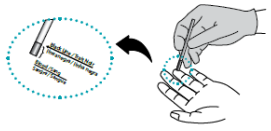
EN Pierce with a safety lancet provided.

ES Pinchar con la lanceta de seguridad suministrada.

FR Piquer avec une lancette à aiguille retractable fournie.

PT Fure com a Lanceta de segurança contida no kit.

7



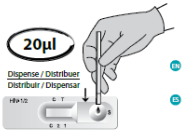
EN Take a **20µl** capillary pipette provided, immerse the open end in the blood drop and then release the pressure to draw blood into the capillary pipette to **black line.**

ES Tome la pipeta capilar de **20µl** suministrada, inmersa la punta abierta en la gota de sangre y luego retire la presión para colectar la sangre dentro de la pipeta capilar hasta la **línea negra**.

FR Saisir la pipette capillaire de **20µl** fournie, immerger l'orifice de la pipette dans la goutte de sang, puis relâcher la pression pour que le sang pénètre dans le tube capillaire. Prélever jusqu'au **trait noir** indiqué sur la tube.

PT Pegue a pipeta capilar de **20µl** contida no kit, coloque a abertura na gota de sangue e então aperte para que o sangue **alcance a marca** dos 20µl.

8



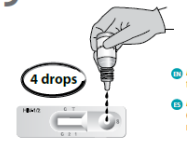
EN Add **20µl** of drawn blood into the sample well (s).

ES Agregar **20µl** de la sangre recolectada dentro del pozo de muestra (s).

FR Transférer **20µl** de sang dans le puits d'échantillon (s).

PT Adicione **20µl** de sangue na janela de amostra (s).

9



EN **Add 4 drops** of assay diluent into the sample well (s).

ES **Adicione 4 gotas** del diluyente del ensayo dentro del pozo de la muestra (s).

FR **Ajouter 4 gouttes** de diluant dans le puits (s).

PT **Adicione 4 gotas** de diluente de ensaio na janela de amostra (s).

Interpretation / Interprétation / Interpretación / Interpretação

EN Time to result is 10 to 20 minutes. After adding the diluents, read the result after 10 minutes but not more than 20 minutes. If the test result is not legible after 10 minutes due to high background color, read again later but within 20 minutes of adding the diluents. Do not read after 20 minutes.

FR Le délai d'obtention du résultat est compris entre 10 et 20 minutes. Après l'ajout du diluant, lire le résultat au bout de 10 minutes mais pas après 20 minutes. Si le résultat du test n'est pas lisible au bout de 10 minutes en raison de la couleur foncée de l'arrière plan, essayer une nouvelle fois de lire le résultat dans un délai maximum de 20 minutes. Ne pas lire le résultat au-delà de ce délai.

ES El tiempo de obtención de los resultados oscila entre 10 y 20 minutos. Tras añadir el diluyente del ensayo, lea el resultado después de 10 minutos (pero no espere más de 20 minutos). Si no puede leer el resultado del ensayo después de 10 minutos porque no se distingue del color de fondo, consulte el resultado de nuevo 20 minutos después de añadir el diluyente. No consulte el resultado una vez pasados 20 minutos.

PT O tempo para obter o resultado é de 10 a 20 minutos. Leia o resultado 10 minutos (e no máximo 20 minutos) depois de adicionar o diluente. Se não conseguir ler o resultado do teste após 10 minutos porque a cor de fundo não permite distinguir, volte a consultar o resultado no período de 20 minutos depois de ter adicionado o diluente. Uma vez passados os 20 minutos, não consulte o resultado.

How to interpret test results / Comment interpréter les résultats du test / Cómo interpretar los resultados / Forma de interpretar os resultados dos testes

Negative / Negatif / Negativo

Positive / Positif / Postivo

HIV-1 Positive / Positif / Postivo

2 LINES / 2 BANDES / 2 LÍNEAS / 2 LINHAS

EN When **2 lines** appear
ES Cuando aparecen **2 líneas**
FR Apparition de **2 bandes**
PT Quando aparecem **2 linhas**

3 LINES / 3 BANDES / 3 LÍNEAS / 3 LINHAS

EN When **3 lines** appear "C", "T" and faint "Z" line
FR Apparition de **3 bandes** Bande "C", Bande "T", et Bande "Z" floue
ES Cuando aparecen **3 líneas** Línea "C," "T" y "Z" débil
PT Quando aparecem **3 linhas** Linha controle Linha "T", e linha "Z" fraca

EN If line **"T"** is darker than line **"Z"**, it should be interpreted as HIV-1 positive only. **(Not HIV-2 positive).**
Saint line : By homology in the amino acid sequence of HIV Type-T and HIV Type-2.

ES Cuando la línea **"T"** es más oscura que la línea **"Z"**, debe ser interpretado como HIV-1 positivo únicamente **(No HIV- 2 positivo)**
Por similitud en la secuencia de aminoácidos de HIV Tipo- T y HIV Tipo-2.

FR Bande **"T"** plus foncée que Bande **"Z"**, doit être interprété comme VIH-1 positif. **(Non positif au VIH-2).**
Bande floue : par homologie des séquences d'acides aminés des types VIH- T et VIH-2.

PT Quando a linha **"T"** aparenta ser mais escura que a linha **"Z"**, o teste deve ser interpretado como HIV-1 positivo **(HIV-2 não positivo).**
Por similaridade na sequência de aminoácidos do HIV tipo T e HIV tipo 2.

HIV-2 Positive / Positif / Postivo

2 LINES / 2 BANDES / 2 LÍNEAS / 2 LINHAS

EN When **2 lines** appear
ES Cuando aparecen **2 líneas**
FR Apparition de **2 bandes**
PT Quando aparecem **2 linhas**

3 LINES / 3 BANDES / 3 LÍNEAS / 3 LINHAS

EN When **3 lines** appear "C", "T" and faint "T" Line
FR Apparition de **3 bandes** Bande "C", Bande "T", et Bande "T" floue
ES Cuando aparecen **3 líneas** Línea "C," "T" y "T" débil
PT Quando aparecem **3 linhas** Linha controle Linha "T", e linha "T" fraca

EN If line **"T"** is darker than line **"T"**, it should be interpreted as HIV-2 positive only. **(Not HIV- 1 positive).**
Saint line : By homology in the amino acid sequence of HIV Type- 1and HIV Type-2.

ES Cuando la línea **"T"** es más oscura que la línea **"T"**, debe ser interpretado como HIV-2 positivo únicamente **(No HIV- 1 positivo).**
Por similitud en la secuencia de aminoácidos de HIV Tipo- 1y HIV Tipo-2.

FR Bande **"T"** plus foncée que Bande **"T"**, doit être interprété comme VIH-2 positif. **(Non positif VIH-1).**
Bande floue : par homologie des séquences d'acides aminés des types VIH- 1 et VIH-2.

PT Quando a linha **"T"** aparenta ser mais escura que a linha **"T"**, o teste deve ser interpretado como HIV-2 positivo **(HIV-1 não positivo).**
Por similaridade na sequência de aminoácidos do HIV tipo 1 e HIV tipo 2.

Remark / Remarque / Comentario / Nota

EN **[Both HIV-1 and HIV-2 Positive]**
If the band thickness between line 1 and line 2 is so similar to each other, even very rare , it can be both positive for HIV-1 and HIV- 2. In this case, confirm test using Western Blot is recommended to know exact virus type.

ES **[HIV-1 y HIV-2 Positivo]**
Si el grosor de la banda de la línea 1 y línea 2 son similares entre sí, siendo poco común, puede ser positivo para ambos VIH-1 y VIH- 2. En este caso, confirmar la prueba usando Western Blot, se recomienda conocer el tipo exacto de virus.

FR **[VIH-1 et VIH-2 positif]**
S'il y a similitude entre l'épaisseur des bandes 1 et 2, on peut considérer, même si le cas est rare, le test positif pour VIH-1 et VIH-2. Dans ce cas il est recommandé d'effectuer un test Western Blot pour confirmer le résultat.

PT **[HIV-1 e HIV-2 ambos positivos]**
Quando as linhas 1 e 2 aparentam-se similares, mesmo que muito raro, pode ser um caso de HIV-1 e HIV-2 ambos positivos. Neste caso, é recomendado o uso do teste Western Blot para investigação exata do tipo do vírus.

Invalid / Invalide / No valido / Inválido

EN No "C" line
FR Absence de la Bande "C"
ES Sin la línea "C"
PT Sem a linha "C"