

## WHO Prequalification of In Vitro Diagnostics Programme PUBLIC REPORT

**Product: SD BIOLINE HIV/Syphilis Duo**  
**Number: PQDx 0179-012-00**

### Abstract

**SD BIOLINE HIV/Syphilis Duo** with product codes **06FK30** and **06FK35**, manufactured by Standard Diagnostics, Inc., **Rest-of-World regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 28 October 2015.

SD BIOLINE HIV/Syphilis Duo is a solid phase immunochromatographic assay for the qualitative detection of antibodies to all isotypes (IgG, IgM, IgA) specific to HIV-1/2 and/or *Treponema pallidum* (TP) simultaneously in human serum, plasma or whole blood.

SD BIOLINE HIV/Syphilis Duo contains a membrane strip, which is pre-coated with recombinant HIV-1 capture antigen (gp41), recombinant HIV-2 capture antigen (gp36) and Recombinant HIV-sub O antigen on test band 1 region and recombinant *Treponema pallidum* antigens (17KDa) on test band 2 region, respectively.

The recombinant HIV-1/2 antigen (gp41, gp36) - colloid gold conjugate, recombinant *Treponema pallidum* antigens colloid gold conjugate (17KDa), the specimen sample and sample diluent move along 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 a letter of HIV, SYP and C as Test Line HIV (HIV-1/2), Test Line SYP (Syphilis) and Control Line on the surface of the device. Both the Test Lines and Control Line in result window are not visible before applying any sample. The Control Line is used as a procedural control. The Control Line should always appear if the test procedure is performed properly and the test reagents of the Control Line are working.

The test kit contains:

	1x25 tests/kit Product code 06FK30	1x25 tests/kit Product code 06FK35
<b>Test devices</b> Individually foil pouched with a desiccant	25	25
<b>Assay diluent</b> Plastic bottle	1 vial of 4mL	1 vial of 4mL
<b>Specimen transfer devices (capillary pipettes)</b> Disposable, 20µl	N/A	25 units
<b>Lancets</b> Disposable, sterilized	N/A	25 units
<b>Alcohol swabs</b> Disposable	N/A	25 units
<b>Instructions for Use</b>	1 unit	1 unit

Storage:

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

Shelf-life:

24 months.

### Summary of prequalification status for SD BIOLINE HIV/Syphilis Duo

	Initial acceptance	
	Date	Outcome
<b>Status on PQ list</b>	28 October 2015	listed
<b>Dossier assessment</b>	14 July 2015	MR
<b>Inspection status</b>	24 July 2015	MR
<b>Laboratory evaluation</b>	16 September 2015	MR

MR: Meets Requirements

NA: Not Applicable

SD BIOLINE HIV/Syphilis Duo was accepted for the WHO list of prequalified in vitro diagnostics on the basis of data submitted and publicly available information.

## **Background information**

Standard Diagnostics, Inc. submitted an application for prequalification of SD BIOLINE HIV/Syphilis Duo. Based on the established prioritization criteria, SD BIOLINE HIV/Syphilis Duo was given priority for prequalification.

### **Product dossier assessment**

Standard Diagnostics, Inc. submitted a product dossier for SD BIOLINE HIV/Syphilis Duo 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 in accordance with the internal report on the screening and assessment of a product dossier (PQDx\_009 v2). Based on the product dossier screening and assessment findings, a recommendation was made to accept the product dossier for SD BIOLINE HIV/Syphilis Duo for prequalification.

Commitments for prequalification:

N/A

### **Manufacturing site inspection**

A comprehensive inspection was performed at the site of manufacture (Production: 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea 446-930 and Warehouse: 19-22, Dongtansandan 3-gil, Dongtan-myeon, Hwaseong-si, Gyeonggi-do, Republic of Korea) of SD BIOLINE HIV/Syphilis Duo in May 2015 as per the Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics (PQDx\_014 v1). The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality. The manufacturer's responses to the nonconformities found at the time of the inspection were accepted 24 July 2015.

Commitments for prequalification:

N/A

### **Laboratory evaluation**

SD Bioline HIV/Syphilis Duo was evaluated by WHO in the last quarter of 2014/first quarter of 2015 using serum/plasma specimens. From this evaluation, we drew the following conclusions:

SD Bioline HIV/Syphilis Duo is an immunochromatographic assay for the detection of HIV-1/2 and syphilis antibodies in human serum/plasma, fingerstick/venous whole blood specimens. A volume of 10 µL of serum/plasma is needed 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 done visually i.e. subjectively read.

In this limited evaluation a panel of 400 clinically-derived specimens was used. For antibodies to HIV, we observed an initial sensitivity (95% CI) of 100% (98.2% - 100%) and an initial specificity (95% CI) of 99.5% (97.2% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 100% (98.2% - 100%) and the final specificity (95% CI) was 99.5% (97.2% - 100%) compared to the reference assays. Lot to lot variation was acceptable.

For the case of antibodies to *Treponema pallidum*, we observed an initial sensitivity (95% CI) of 86.5% (81.0% - 90.9%) and an initial specificity (95% CI) of 99.5% (97.2% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 87.0% (81.5% - 91.3%) and the final specificity (95% CI) was 99.5% (97.2% - 100%) compared to the reference assays. Lot to lot variation was acceptable.

For HIV eight seroconversion panels were evaluated. SD Bioline HIV/Syphilis Duo detected on average 0.125 specimens earlier than the benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics) [EIA].

For syphilis one seroconversion panel was evaluated. SD Bioline HIV/Syphilis Duo detected on average 2 specimens earlier than the benchmark assay; Vitros Syphilis (Ortho Clinical Diagnostics) [treponemal EIA] .

For the HIV mixed titer panel, SD Bioline HIV/Syphilis Duo correctly identified all specimens compared to the reference result.

For the syphilis mixed titer panel, SD Bioline HIV/Syphilis Duo correctly identified all specimens compared to the reference result.

For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210] SD Bioline HIV/Syphilis Duo gave an indeterminate result for the HIV-1 group O specimen. SD Bioline HIV/Syphilis Duo correctly identified all HIV-1 group M subtypes and HIV-2 specimens.

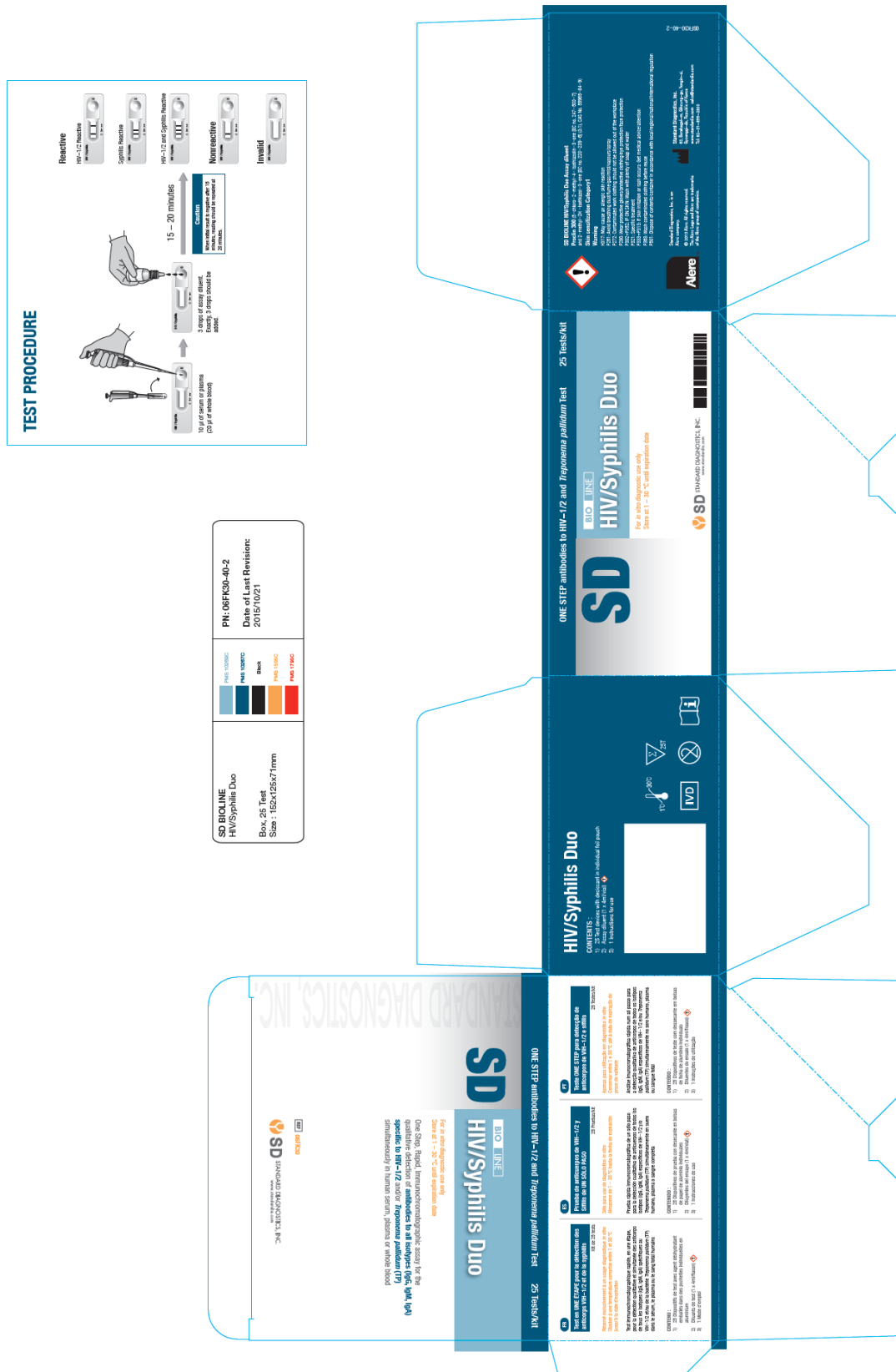
For the 1st International Reference Panel for anti-treponemal [NIBSC code 05/132], SD Bioline HIV/Syphilis Duo correctly identified all specimens.

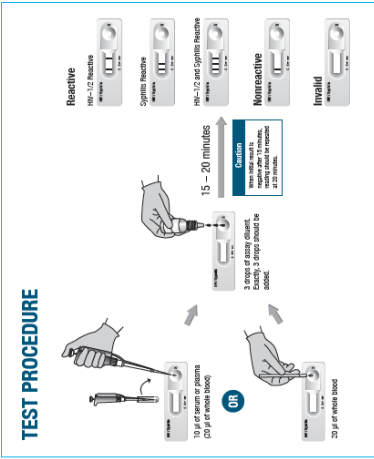
In this study, 2.5% of the results for syphilis were recorded as indeterminate, 0% for HIV. Results were interpreted independently by three technicians; the inter-reader variability was 0% for HIV and 4% for syphilis. The invalid rate was 0%.

## **Labelling**

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

## 1. Labels





**SD BIOLINE**  
**HIV/Syphilis Duo**  
Box, 25 Test, Full set  
Size: 15x125x71 mm

**PK: 06FK35-40-2**  
Date of Last Revision:  
2015/10/21

**Read Results:**  
HIV: **Blue**  
Syphilis: **Black**  
HIV & Syphilis: **Orange**  
HIV & Syphilis: **Red**

**SD BIOLINE**  
**HIV/Syphilis Duo**

ONE STEP antibodies to HIV-1/2 and *Treponema pallidum* Test 25 Tests/kit

For in vitro diagnostic use only  
Store at 1 – 35 °C until expiration date

One Step, Rapid, Immunochromatographic assay for the qualitative detection of antibodies to HIV-1/2 (HIV, gp141) and *Treponema pallidum* (TP, TPP) in human serum, plasma or whole blood.

**SD BIOLINE**  
DIAGNOSTICS, INC.  
25 Tests/kit

**CONTENTS:**

- 25 Test devices with desiccant in individual foil pouch
- 25 Test device pouches
- 25 Test device pouches
- 1 Instruction leaflet

**WARNING:**

- Do not use if the pouch is damaged or if the pouch is not sealed.
- Do not use if the pouch is not sealed.
- Do not use if the pouch is not sealed.
- Do not use if the pouch is not sealed.

**CAUTION:**

- Do not use if the pouch is damaged or if the pouch is not sealed.
- Do not use if the pouch is not sealed.
- Do not use if the pouch is not sealed.
- Do not use if the pouch is not sealed.

**REACTIVE:**

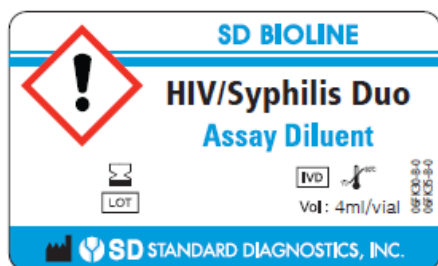
- Blue line in the HIV window and black line in the Syphilis window.
- Blue line in the HIV window and orange line in the Syphilis window.
- Blue line in the HIV window and red line in the Syphilis window.

**NON-REACTIVE:**

- No line in the HIV window and no line in the Syphilis window.
- No line in the HIV window and orange line in the Syphilis window.
- No line in the HIV window and red line in the Syphilis window.

**INVALID:**

- No line in the HIV window and no line in the Syphilis window.
- No line in the HIV window and orange line in the Syphilis window.
- No line in the HIV window and red line in the Syphilis window.





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**Alerte**

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