

#### **SD BIOLINE**

### **HIV/SYPHILIS DUO**

#### PRODUCT DESCRIPTION

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

#### **KIT CONTENTS**

**06FK30:** 1 kit contains 25 test devices, 1 assay diluent and 1 instructions for use.

**06FK35:** 1 kit contains 25 test devices, 1 assay diluent and 1 instructions for use, 25 alcohol swabs, 25 lancets, 25 capillary pipettes.

#### **PERFORMANCE**

	HIV	SYPHILIS
Sensitivity	99.91%	99.67%
Specificity	99.67%	99.72%

 $<sup>^{\</sup>ast}$  Internal evaluation of SD BIOLINE HIV/Syphilis Duo test

#### **TYPE OF SPECIMEN**

Whole blood, serum, plasma

## RUNNING TIME FOR TEST RESULT INTERPRETATION

15-20 minutes

#### PACKAGING INFORMATION

- Dimensions: 152 x 125 x 71 mm (25 tests)
- Volume : 1,349 cm<sup>3</sup> (25 tests)
- Weight:
  - 250 g (06FK30)
  - 260 g (06FK35)

#### SHIPPING CARTON

- 25 tests per kit, 60 kits per carton
- Dimensions : 515 x 475 x 390 mm
- Volume: 95,404 cm<sup>3</sup>
  Weight: 60 kits
  - vveignt. 00 kits
  - 15.06 kgs (06FK30)
  - 15.77 kgs (06FK35)

#### STORAGE CONDITIONS

- Storage temperature : 1-30 °C.
- Keep away from extreme heat and humidity.
- Do not freeze test kits or reagent.
- Full effectiveness of expiry date is under ideal storage conditions.
- Stability of kit components is guaranteed until expiry date.
- DO NOT use any components after expiry date.

#### **SHELF LIFE**

24 months

#### **QUALITY CONTROL**

A procedural control is included in the test device as a control line. If the control line does not appear after 20 minutes, the test is invalid and the specimen should be tested with a new device.

# MATERIALS REQUIRED BUT NOT PROVIDED

- A pair of disposable gloves
- Timer
- Pen
- A biohazard box
- A non-sharps disposal bin



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- 1. Sensitivity and Specificity are extracted from the Instructions for use of each product.
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