

SD BIOLINE

SYPHILIS 3.0

PRODUCT DESCRIPTION

SD BIOLINE Syphilis 3.0 is a rapid, qualitative test for the detection of antibodies to all isotypes (IgG, IgM, IgA) specific to Syphilis (*Treponema pallidum*) in human serum, plasma or whole blood.

KIT CONTENTS

06FK10: 1 Kit contains 30 test devices, assay diluent (1 x 4 ml/vial) and 1 instructions for use.
Optional: alcohol swab, lancet, capillary pipette

PERFORMANCE

- Sensitivity : 99.3% (vs. TPHA)
- Specificity : 99.5% (vs. TPHA)

*Sensitivity and Specificity are extracted from the Instructions for use.

TYPE OF SPECIMEN

Whole blood, serum, plasma

RUNNING TIME FOR TEST RESULT INTERPRETATION

5-20 minutes

PACKAGING INFORMATION

- Dimensions: 182 x 125 x 71 mm
- Volume: 1615.25 cm³
- Weight: 283 g

SHIPPING CARTON

- 30 tests per kit, 45 kits per carton
- Dimensions: 560 x 390 x 385 mm
 - Volume: 84,084 cm³
 - Weight: 14.24 kg

STORAGE CONDITIONS

- Storage temperature : 2-30 °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.

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

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

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

