New Paradigm for Syphilis Diagnosis!

SD BIO LINE Syphilis 3.0

One Step
No need preprocessing
Whole blood available

Simple
No equipment required
Room temperature storage

Rapid
10 minutes
One step test

Accurate
Detecting all isotypes of Ab(IgG,IgM,IgA)
Evaluated by WHO with excellent performance

SD STANDARD DIAGNOSTICS, INC.
www.standardia.com

Treponemal Test.

- Sensitivity : 99.3%, Specificity : 99.5% (vs. TPHA)
- No “biological false positive(BFP)”

The 3rd Generation One Step Anti-TP Test.

- Direct sandwich method (Ag–Ab–Ag combination)
- Detecting all isotypes of antibodies, IgG, IgM, IgA
- Using recombinant antigen (17Kd, 15Kd) – Gold conjugate

High Sensitivity in Primary and Late Syphilis.

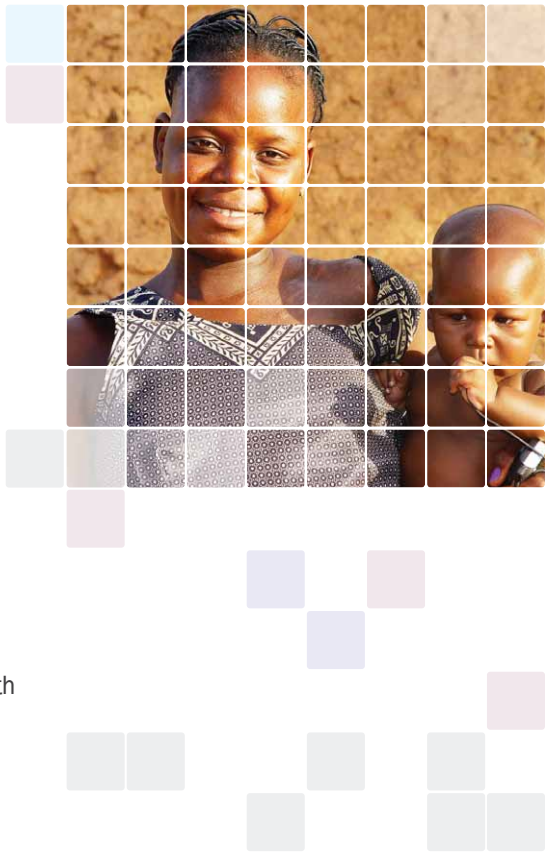
- Early diagnosis to detect IgM
- Excellent sensitivity in primary syphilis, even missed by TPHA

Simple & Easy Test Procedure.

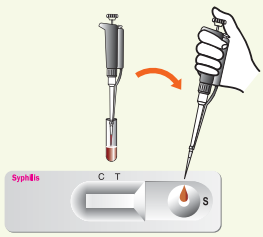
- Sample : Serum, Plasma or Whole blood
- No equipment or electrocity required
- Assay time : 5~20mins.

Evaluated By WHO, US CDC, PATH etc.

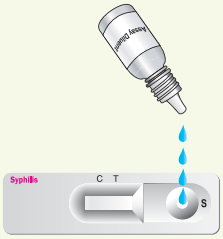
- Evaluated by WHO SDI(Sexually transmitted diseases Diagnostics Initiative) with excellent performance
- Procurement contracts with WHO and UNICEF



Test Procedure



Put whole blood (20ul) or serum, plasma (10ul) in the ’S’ hole.



Add 3~4 drops of assay diluent in the “S” hole.

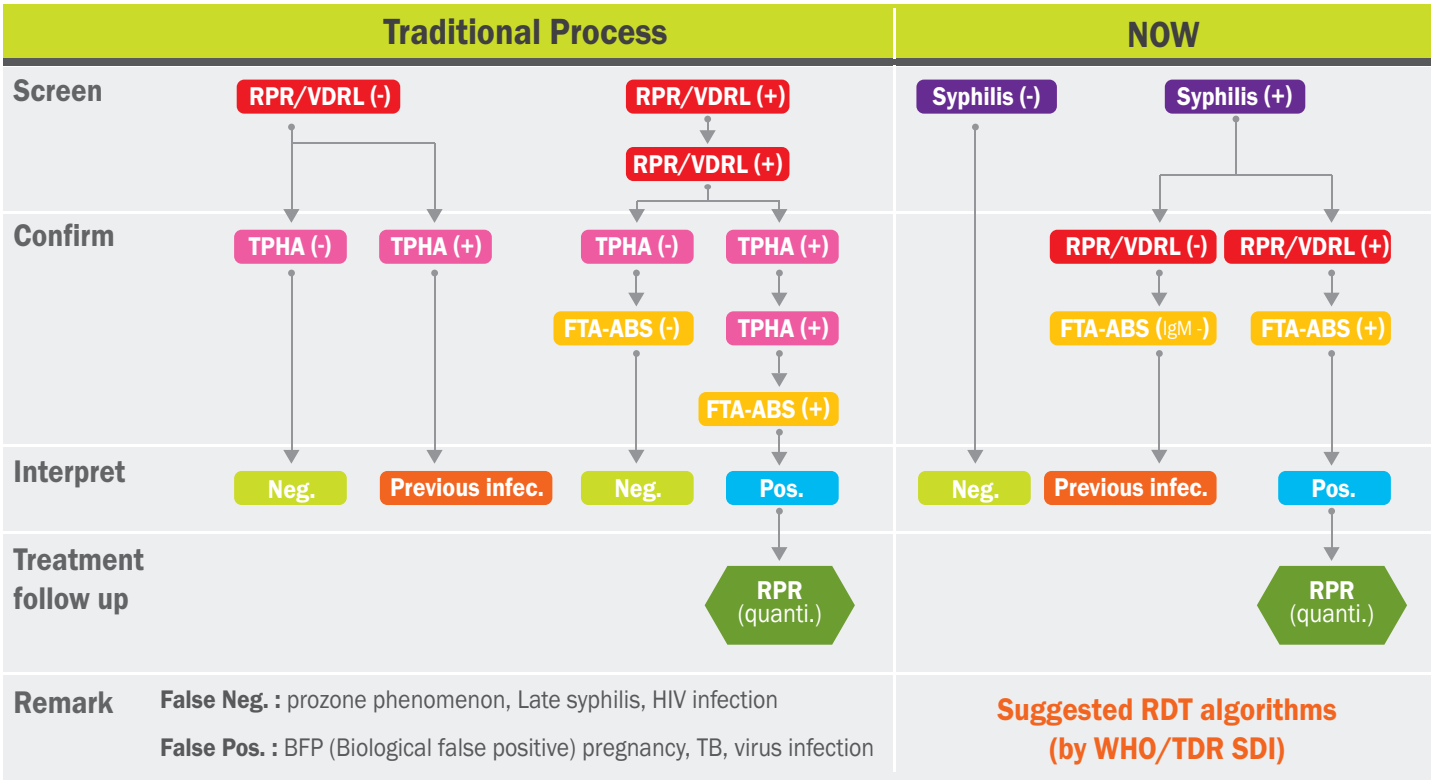
Interpret test result at 5~20minutes.

Comparison of Rapid test(ICA) vs Non-treponemal test

	Non-treponemal tests (RPR or VDRL)	Rapid test (ICA)
Advantages	- Simple to perform - Can distinguish between active and past treated infection	- Treponemal test - Simple to perform - Can be used with whole blood, serum or plasma - No equipment or electrocity required - Can be transported and stored at room temperature below 30˚C - No prozone effect - No biological false positive
Disadvantages	- Require electricity for refrigerator to store reagent, and for a rotator and centrifuge - Cannot be used with whole blood - False negative results can occur with excessive antibody (prozone effect)	- Give anti-TP informations about current and previous TP infection without differentiation

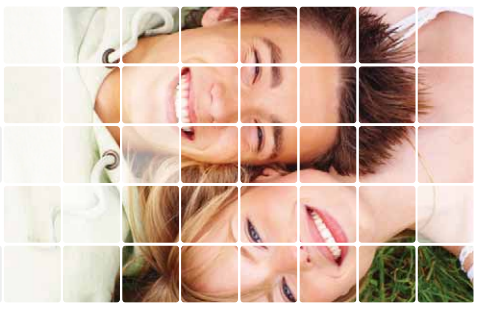
Rapid Test,
the optimal choice for mass screening program.

Suggested testing algorithms



Evaluation of six rapid tests for syphilis

Company	Sensitivity	Specificity
SD BIOLINE SYPHILIS 3.0, Korea	**100%**	**100%**
A company, USA	100%	97.90%
F company, JP	98% (100% after 1hr)	100% (100% after 1hr)
O company, UK	96%	100%
D company, Italy	94.5% (96.3% after 1hr)	94% (96% after 1hr)
Q company, India	94%	100%



Comparison of Diagnostic Method

Treponemal

Direct & Specific diagnostic methods of anti-treponema pallidum (TP) antibody

- **Rapid, EIA, TPHA, FTA-ABS**
- **Merit :** high specificity & sensitivity
- **Demerit :** detection of previous infection history

Non- Treponemal

Indirect & Non-specific diagnostic methods of anti-treponema pallidum (TP) antibody

- **RPR, VDRL**
- **Merit :** showing current infection
- **Demerit :** low sensitivity, low specificity

Method	RPR	TPHA	FTA-ABS	Syphilis Rapid
Assay Time	10~20mins.	2~24hrs.	6hrs.	5~20mins.
Sensitivity			Gold Standard	
Primary	40~50 %	80~90 %		99 %
Secondary	60~70 %	99 %		99 %
Latent & tertiary	10~20 %	99 %		99 %
Specificity	70~80 %	99.5 %		99.5 %
Strength	Current infection	High specificity	Differentiation between IgM/IgG	High sensitivity Early detection
Weakness	Low sensitivity Low specificity	Anti-TP detection of current & previous infection	Equipment needed	Anti-TP detection of current & previous infection
Use	Screen Treatment follow up	Screen/confirm	Confirm	Screen

Ordering Information

Product	Cat. No.	Component	Type	Tests/Kit	Specimen	Storage
SD BIOLINE Syphilis 3.0	06FK10	Test device, assay diluent	Device	1T x 30	Whole blood, serum, plasma	1~30˚C 24mons.
	06FK16	Test device, assay diluent, capillary	Device	1T x 30		
	06FK17	Test device, assay diluent, capillary, lancet	Device	1T x 50		
	06FK11	Test device, assay diluent	Multi-device	10T x 10		
	06FK12	Test strip, assay diluent	Strip	25T		

Logistic Information

Cat. No.	Pack Size	Kits per Carton	Carton Size(cm)	Carton G/Weight(kg)	CBM Weight(kg)
06FK10	1T x 30/kit	40 kits	53 x 48 x 40	14 kg	17 kg
06FK11	10T x 10/kit	40 kits	53 x 48 x 40	21.5 kg	17 kg
06FK12	25T/kit	387 kits	53 x 48 x 40	21 kg	17 kg

SD STANDARD DIAGNOSTICS, INC.
www.standardia.com
156-68 Hagal-dong, Giheung-ku, Yongin-si, Kyonggi-do, Korea 446-930
Tel : +82-31-899-9700 Fax : +82-31-899-9740 Mail : sales@standardia.com

SDC07-1114