Abbott

For the use of registered medical practitioners or hospitals or a laboratory.

ABON™ Syphilis Antibody Test Product Training

Agenda

1. Syphilis Overview
2. Syphilis Diagnostic Method
3. ABON Syphilis Test

Syphilis Overview

Syphilis Overview

- Infectious, sexually transmitted disease
- Caused by Spirochete Treponema pallidum
- Enters through broken skin or mucous membrane
- Major cause of morbidity and mortality in the pre-antibiotic era

Data adapted from:
1. The rapid syphilis test toolkit management 3, developing syphilis testing and treatment algorithms using rapid tests, Global Health Laboratories, https://globalhealthlaboratories.tghn.org/site_media/media/articles/MANAGEMENT_3.pdf
2. http://www.antimicrobe.org/b242.asp

Syphilis Overview

Transmission mainly by

Sex

Mother to Child

- **Perinatal transmission:**
  - - at any time during pregnancy
  - - at any stage of the disease

- **Syphilis can infect unborn baby if a mother has untreated during pregnancy:**
  - 80% chance - infect the unborn baby
  - 25% chance – the infected baby will die either shortly before or after birth
  - 25% chance – Infected baby who survive may have low birth weight or serious infection, which may lead to perinatal death.

Data adapted from:
3. The global elimination of congenital syphilis: rationale and strategy for action, World Health Organization 2007, ISBN 978 92 4 159585 8, http://whqliboc.who.int/publications/2007/9789241595858_eng.pdf

Syphilis Overview

Syphilis in Adult

- **Primary : Chancre**
- **Secondary : Generalized skin and mucous membrane eruption**
- **Latent :**
  - Early latent Symptomatic (relapse) < 2yr
  - Late latent Asymptomatic >2yr
- **Tertiary : May be divided into three different forms**
  - Gummatous syphilis
  - Late neurosyphilis
  - Cardiovascular syphilis

Data sourced from:
4. AMEETA E. SINGH AND BARBARA ROMANOWSKI, Syphilis: Review with Emphasis on Clinical, Epidemiologic, and some biologic features, Clinical Microbiology Reviews, Apr. 1999, p.187-209.

Syphilis Overview

Congenital Syphilis

- Prenatal syphilis acquired in utero
- Most women with syphilis of less than one year's duration will transmit the infection to their unborn child.
- Transmission usually takes place between the 16th and 28th week of pregnancy

Data adapted from:
5. The global elimination of congenital syphilis: rationale and strategy for action, World Health Organization 2007, ISBN 978 92 4 159585 8

Syphilis Overview

Syphilis-HIV Interactions

- Enhances risk of transmission of HIV, how?
  - Reducing physical barriers
  - Increasing the number of receptor cells
  - Increasing HIV viral load in genital lesions, semen or both
- Genital ulcers caused by syphilis make it easier to transmit and acquire HIV infection sexually. It is an estimated 2- to 5- fold increased risk of acquiring HIV if exposed to that infection when syphilis is present
- Increased relapse of neurosyphilis

Data adapted from:

6. https://blog.aids.gov/2012/12/syphilis-and-hiv-a-dangerous-duo-affecting-gay-and-bisexual-men.html

Syphilis Overview

Screening Recommendations

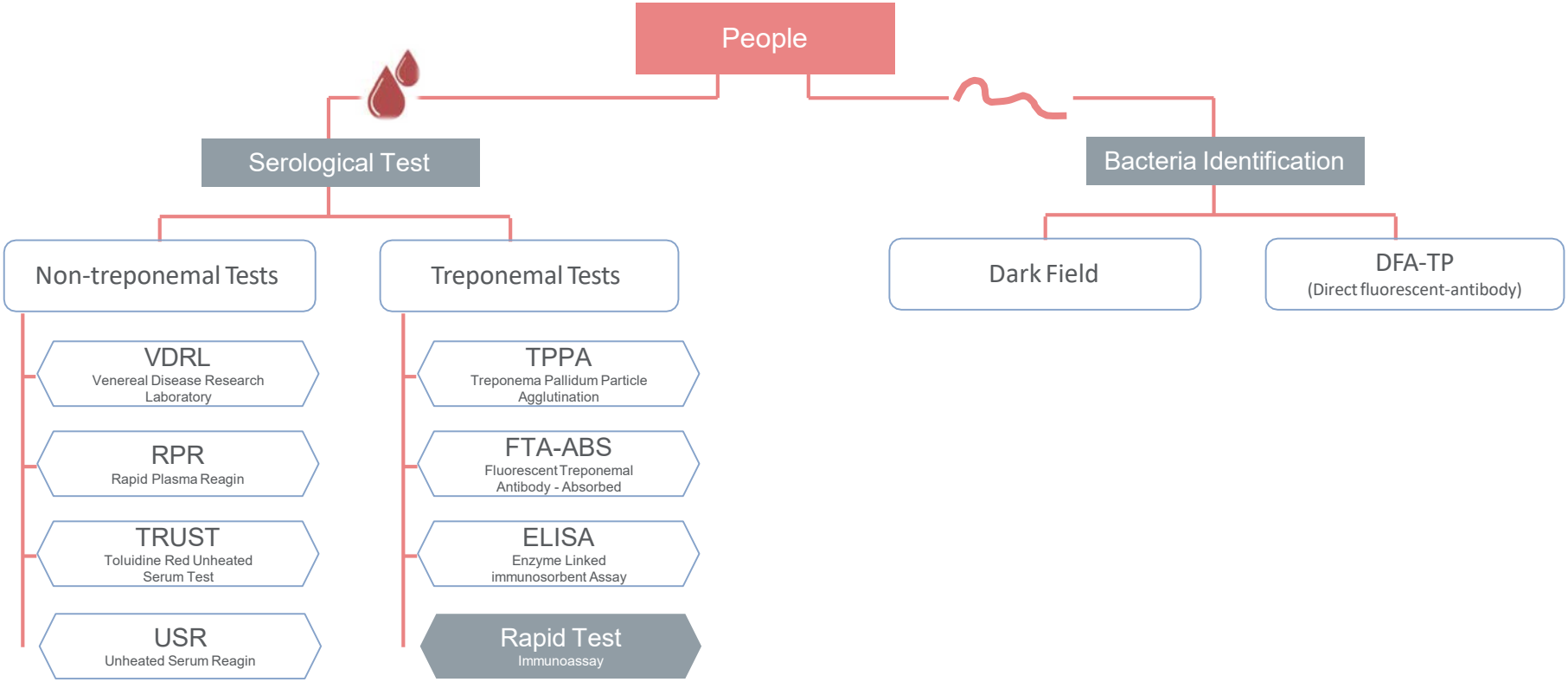
- Screen pregnant women at least at first prenatal visit.
- In high prevalence communities, or patients at risk
- Test twice during the third trimester, at 28 weeks, and at delivery, in addition to routine early screening
- Any woman who delivers a stillborn infant after 20 weeks gestation should be tested for syphilis.
- Screen other populations based on local prevalence and the patient's risk behaviors

Check your local Screening guideline

Data adapted from:
7. http://www.cdc.gov/std/tg2015/syphilis-pregnancy.htm

Syphilis Diagnostic Method

Syphilis Diagnosis



Data adapted from:

8. AMEETA E. SINGH AND BARBARA ROMANOWSKI, Syphilis: Review with Emphasis on Clinical, Epidemiologic, and some biologic features, Clinical Microbiology Reviews, Apr. 1999, p.187-209s http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2095002/

Why use Syphilis rapid test？

Features	RPR	VDRL	TRUST	TPHA	FTA-ABS	ELISA	LF Rapid Test
1. Fast, 10 Min. Results	✓	✗	✓	✗	✗	✗	✓
2. Utilizes Antigens for Improved Specificity	✗	✗	✗	✓	✓	✓	✓
3. Easy Visual Interpretation	✗	✗	✗	✗	✓	✗	✓
4. Easy Test Procedure	✓	✓	✓	✗	✗	✗	✓
5. Individually Packaged Single Tests Available	✗	✗	✗	✗	✗	✗	✓
6. Suitable for Use in Physician's Office	✗	✓	✗	✗	✗	✗	✓

Data adapted from:
9. AMEETA E. SINGH AND BARBARA ROMANOWSKI, Syphilis: Review with Emphasis on Clinical, Epidemiologic, and some biologic features, Clinical Microbiology Reviews, Apr. 1999, p.187-209s

Why use Syphilis rapid test?

- Cost-effective
- No equipment needed
- Easy to operate
- Results available soon
- Can be transported and stored at temperatures below 30°C

Data adapted from:
10. The use of rapid syphilis tests, World Health Organization, TDR/SDI/06.1, WHO/TDR, 2006, http://www.who.int/tdr/publications/tdr-research- publications/use-rapid-syphilis-tests/en/

ABON Syphilis Ultra Rapid Test (Whole Blood/Serum/Plasma)

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Product Description	Syphilis Ultra Rapid Test (Whole Blood/Serum/Plasma)	
Product type	Rapid immunochromatographic assay	
Intend Use	Qualitative detection of antibodies (IgG and IgM) to *Treponema Pallidum(TP)*	
Specimen	Serum / Plasma / Whole Blood	
Sensitivity	99.5%(98.1%-99.9%)	
Specificity	99.8%(98.9%-100.0%)	
Time to result	10 minutes	
Storage	4~30 °C	
Shelf Life:	24 months	
Test Type	**Strip**	**Device**
Cat. No	ISY-U401	ISY-U402
Kit size	50 Tests	40 Tests
Kit contents	• Test Devices • Droppers • Package Insert • Buffer (Phosphate buffer 0.05M; pH7.4)	• Test Devices • Droppers • Package Insert • Buffer (Phosphate buffer 0.05M; pH7.4) for whole blood only
Language	Multi Language (En/Fr/Es/Po)	

Data adapted from: Package Insert

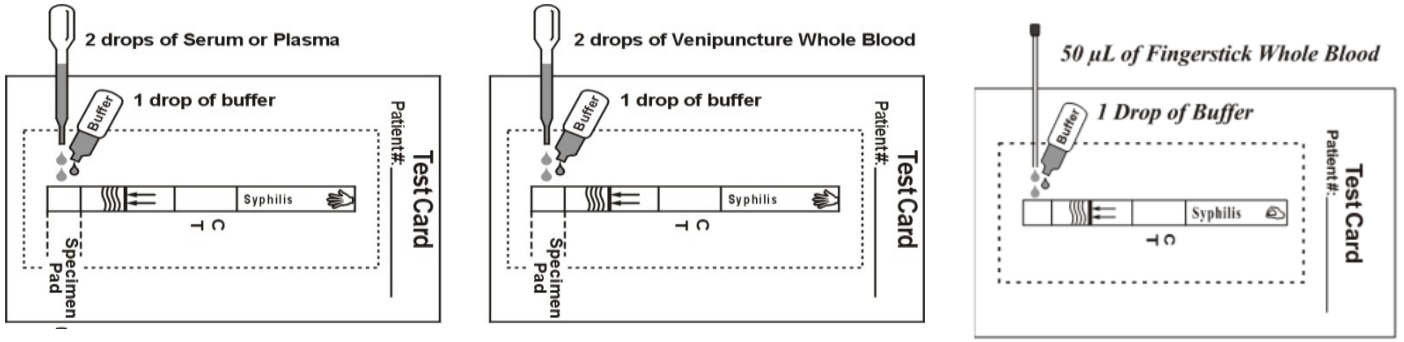
ABON Syphilis Ultra Rapid Test (Whole Blood/Serum/Plasma)

- Simple test format
- No equipment needed
- Easy to use
- Fast result read time at 10 min
- 2 years shelf life and store as packaged in the sealed pouch either at room temperature or refrigerated (2-30° C)

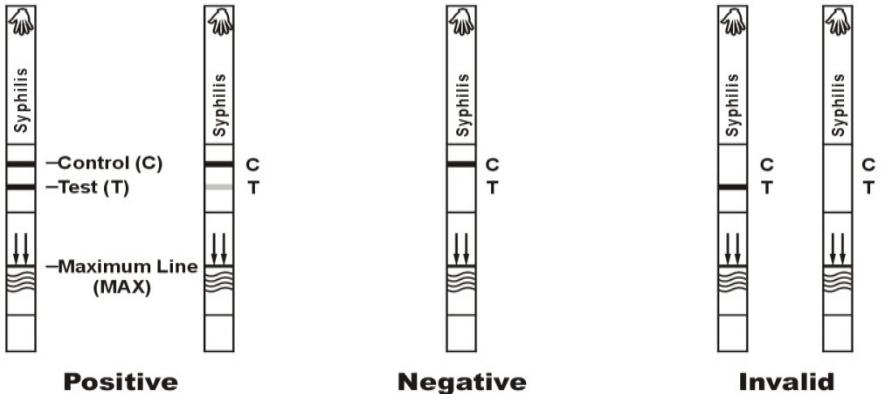
Data adapted from:
10. The use of rapid syphilis tests, World Health Organization, TDR/SDI/06.1, WHO/TDR, 2006, http://www.who.int/tdr/publications/tdr-research- publications/use-rapid-syphilis-tests/en/

ABON Syphilis Ultra Rapid Test (Whole Blood/Serum/Plasma)

Strip



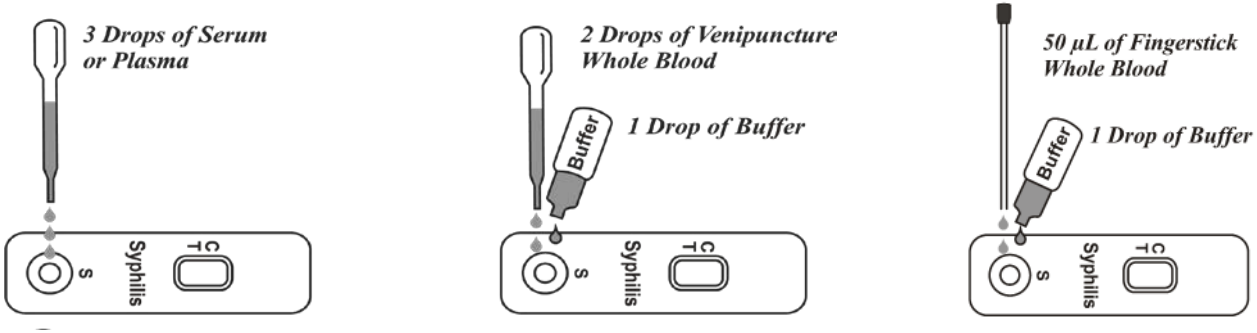
Wait 10 minutes, then read the result. Do not read the result after 30 minutes.



Data adapted from: Package Insert

ABON Syphilis Ultra Rapid Test (Whole Blood/Serum/Plasma)

Device



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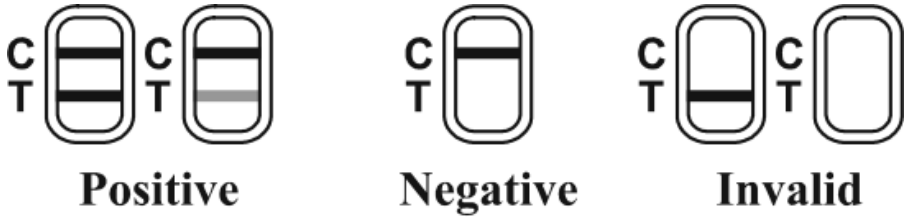

Data adapted from: Package Insert

ABON Syphilis Ultra Rapid Test (Whole Blood/Serum/Plasma)

Performance

Method		TPHA		Total Results
Syphilis	Results	Positive	Negative	
	Positive	382	1	383
	Negative	2	485	487
Total Results		384	486	870

Relative sensitivity: 99.5% (98.1%-99.9%)*
Relative specificity: 99.8% (98.9%-100.0%)*
Accuracy: 99.7% (99.0%-99.9%)*

*95% Confidence Intervals

Data adapted from: Package Insert

References

1. The rapid syphilis test toolkit management 3, developing syphilis testing and treatment algorithms using rapid tests, Global Health Laboratories, https://globalhealthlaboratories.tghn.org/site_media/media/articles/MANAGEMENT_3.pdf
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