

Syphilis remains
a public
health threat
around the
world.

The Alere Determine™ Syphilis TP
Outstanding performance versus industry standards

Meter Kit Contents	Sample Type	Kit Size	Product Code
Alere Determine™ Syphilis TP	Serum Plasma *Whole Blood	100 Tests	7D2443
Alere Determine™ Syphilis TP (CE)	Serum Plasma *Whole Blood	100 Tests	7D2447

* For Whole Blood application please order Chase Buffer.

Accessories	Kit Size	Product Code
EDTA Capillary Tubes	100 Tests	7D2222
EDTA Capillary Tubes (CE)	100 Tests	7D2227
Chase Buffer	100 Tests	7D2243
Chase Buffer (CE)	100 Tests	7D2247

Alere: The leader in point-of-care testing

The Alere Determine™ TB LAM Ag

Rapid point-of-care diagnostic tool designed for HIV & TB co-infected individuals.

The Alere Pima™ Analyser

The only portable point-of-care device providing absolute CD4 count.

The Alere Determine™ HIV 1/2 Ag/Ab Combo

Detecting the HIV infection an average 5–7 days earlier than the 3rd generation rapid antibody tests.

Distributed by:

alere.com

Alere International Limited
Parkmore East Business Park
Ballybrit, Galway
Ireland
Tel: +353 91 429900
professionaldiagnostics@alere.com
Product availability varies by region

References

1. Hook EW, Peeling RW. Syphilis Control—A Continuing Challenge. *NEJM* 2004;351:122-124.
2. Peeling RW, Mabey DCW. Disease Watch: Focus Syphilis. *Nature Reviews* 2004;2:448-449.
3. Reproductive Tract Infections & Sexually Transmitted Infections including HIV/AIDS: Eliminating congenital syphilis. Geneva, World Health Organisation, 2005.
4. Centres for Disease Control and Prevention. Syphilis Fact Sheet. May, 2004. <http://www.cdc.gov/std/Syphilis/STDFact-Syphilis.htm>
5. Serum specimens from 325 cases of non-syphilis and 176 cases of syphilis from three clinical sites in Japan were tested by Determine Syphilis TP and two commercially available tests.
6. Whole blood specimens with paired serum and plasma from 47 cases of non-syphilis and 52 cases of syphilis from three clinical sites in Japan were tested by Determine Syphilis and two commercially available tests.

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Rapid Detection, Rapid Results



detect... diagnose... determine...

Actual size

00DET0805EVAL



Rapid diagnostic tests play a pivotal role in global efforts to control syphilis

Significant disease burden

- 12 million new cases of syphilis each year, mostly in developing countries¹
- Incidence rapidly increasing in Eastern Europe²
- Epidemiology shifting to homosexual men and illicit drug users in North America and Europe¹

Congenital syphilis a major cause of morbidity and mortality

- 500,000 infants are born each year with congenital syphilis³
- 500,000 stillbirths and miscarriages are caused by maternal syphilis annually³

Linked to HIV transmission

- 2 to 5 fold increased risk of acquiring HIV infection when syphilis is present⁴

Value of simple, reliable diagnostic tests

- Provide on-site testing of those with suspicious clinical lesions
- Screen pregnant women for congenital syphilis

The Aler Determine™ Syphilis Test

A rapid *in vitro* qualitative immunoassay for detection of antibodies to *Treponema pallidum*

Rapid

- Clear, dependable results in 15 minutes
- Patients can be tested and treated in the same visit

Flexible

- Can use whole blood or serum/plasma
- Collection can be by fingerstick or venipuncture

Easy to transport and store

- No refrigeration required
- Storage conditions 2-30°C
- No power or water source needed to run the test

Simple procedure

- **Step 1**, add 50µl of sample to pad. If using whole blood, add chase buffer.
- **Step 2**, wait 15 minutes, then read the result
Two red bars = positive. One red bar in the control window = negative. (No red bar in the control window means test is invalid.)
- Requires minimal training and no equipment
- So easy it can be used at the lowest levels of health care service

The Aler Determine™ Syphilis Test

Point-of-care diagnostics that provides accurate and reliable results in just 15 minutes.

Excellent sensitivity using serum⁵

Specificity	Population	Serum	Test A	Test B
Specificity	Non- syphilis	100%	100%	100%
Specificity	Non- syphilis	100%	97.73%	94.32%

Highly accurate using whole blood and paired serum and plasma⁶

Specificity	Population	Whole Blood	Plasma	Serum	Test A Serum	Test B Serum
Specificity	Non- syphilis	100%	100%	100%	100%	100%
Specificity	Non- syphilis	92.31%	100%	100%	98.08%	94.23%