August 2013
241021/R6

Alere™ Determine™ Syphilis TP

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This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are deviations from the instructions in this package insert.

NAME AND INTENDED USE

Alere Determine™ Syphilis TP is an *In Vitro*, visually read, qualitative immunoassay for the detection of antibodies to *Treponema pallidum*, which is the bacteria that causes syphilis infection, in human serum, plasma or whole blood. The test is intended as an aid to detect antibodies to *Treponema pallidum* from infected individuals.

SUMMARY AND EXPLANATION OF THE TEST

Syphilis is caused by infection with the bacterium *Treponema pallidum*[1] which can be transmitted congenitally or by sexual contact. The disease can evolve into a latent phase in which syphilis is clinically inapparent. Serologic tests (nontreponemal specific and treponemal specific) are currently the primary method for syphilis diagnosis and management. Nontreponemal tests (VDRL, RPR, etc.) are generally used for screening, and treponemal tests (TPHA, FTA-ABS, etc.) are used as confirmatory tests.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

Alere Determine™ Syphilis TP is an immunochromatographic test for the qualitative detection of antibodies to *Treponema pallidum* antigens.

Sample is added to the sample pad. As the sample migrates through the conjugate pad, it reconstitutes and mixes with the *Treponema pallidum* antigen-selenium colloid conjugate. This mixture continues to migrate through the solid phase to the immobilized *Treponema pallidum* antigens at the patient window site.

If antibodies to *Treponema pallidum* are present in the sample, the antibodies bind to the *Treponema pallidum* antigen-selenium colloid and to the *Treponema pallidum* antigen at the patient window, forming a red line at the patient window site. If antibodies to *Treponema pallidum* are absent, the *Treponema pallidum* antigen-selenium colloid flows past the patient window, and no red line is formed at the patient window site.

To ensure assay validity, a procedural control bar is incorporated in the assay device.

CONTENTS

Alere Determine™ Syphilis TP, 30 Tests (7D2442) or 100 Tests (7D2443)

- **Alere** Determine™ Syphilis TP Test Card, 3 or 10 cards (10 tests/card), *Treponema pallidum* antigen coated.

ACCESSORIES (required but not provided)

For testing Whole Blood samples

- **CHASE BUFFER** 1 Bottle (2.5 mL) Chase Buffer (7D2243) prepared in phosphate buffer. Preservatives: Antimicrobial Agents.

Whole Blood (fingerstick assay)

- **EDTA CAPILLARY TUBES** (Mylar-coated) 7D2227
- EDTA Capillary Tubes (Non-Mylar-coated / Not available in CE countries) 7D2222

WARNINGS AND PRECAUTIONS

For professional use only.

CAUTION

This product contains human sourced infectious and/or potentially infectious components. Refer to the **CONTENTS** section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, it is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.[2,3]

STORAGE

Alere Determine™ Syphilis TP Test and the Chase Buffer must be stored at 2-30°C until expiration date. Kit components are stable until expiration date when handled and stored as directed. Do not use kit components beyond expiration date. Immediately reseal all unused tests in the foil pouch containing the desiccant by pressing seal from end to end to close. Do not use devices that have become wet or the packaging has become damaged.

SPECIMEN COLLECTION

Serum, Plasma, and Whole Blood Collection by Venipuncture

Human serum, plasma, and whole blood collected by venipuncture should be collected aseptically in such a way as to avoid hemolysis.

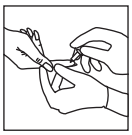
Specimens showing particulate matter or turbidity should be centrifuged before testing in order to avoid providing erroneous results.

NOTE: For whole blood specimens, EDTA collection tubes must be used.

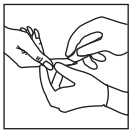
Whole Blood Collection by Fingerstick[4]

Before collecting a fingerstick specimen, place an EDTA capillary tube on a clean dry surface.

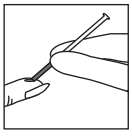
1. Choose the fingertip of the middle, ring, or index finger (whichever is the least callused) for adults and children older than one year. Warm the hand as needed with a warm, moist towel or warm water to increase blood flow.



2. Clean fingertip with alcohol; allow to air dry. Position the hand palm-side up.



3. Use a new lancet for each person. Place the lancet off-center on the fingertip. Firmly press the lancet against the finger and puncture the skin. Dispose of the lancet in an appropriate biohazard sharps container.



4. Wipe away the first drop of blood with a sterile gauze pad.
5. Hold the finger lower than the elbow and apply gentle, intermittent pressure to the base of the punctured finger several times. Touch the tip of the EDTA Capillary Tube to the drop of blood*. Avoid air bubbles.

* If EDTA Capillary Tubes will be used, fill the tube with blood between the 2 marked lines (50 µL).

SPECIMEN STORAGE

- Serum and plasma specimens should be stored at 2-8°C if the test is to be run within 7 days of collection. If testing is delayed more than 7 days, the specimen should be frozen (-20°C or colder).
- Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 7 days of collection. Do not freeze whole blood specimens.
- Whole blood collected by fingerstick should be tested immediately.

TEST PROCEDURE

The desired number of test units from the 10-test card can be removed by bending and tearing at the perforation.

NOTE:

- **Removal of the test units should start from the right side of the test card to preserve the lot number which appears on the left side of the test card.**
- **Assay should be initiated within 2 hours after removing the protective foil cover from each test.**

1. Remove the protective foil cover from each test.
2. For serum or plasma samples:
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait a minimum of 15 minutes (up to 24 hours) and read result.
3. For whole blood (venipuncture) samples:
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait one minute, then apply one drop of Chase Buffer to the sample pad.
   c. Wait a minimum of 15 minutes (up to 24 hours) and read result.
4. For whole blood (fingerstick) samples:
   a. Apply 50 µL of sample (by EDTA capillary tube) to the sample pad (marked by the arrow symbol).
   b. Wait until blood is absorbed into the sample pad, then apply one drop of Chase Buffer to the sample pad.
   c. Wait a minimum of 15 minutes (up to 24 hours) and read result.

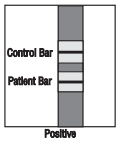
QUALITY CONTROL

To ensure assay validity, a procedural control is incorporated in the device and is labeled "Control". If the control bar does not turn red by assay completion, the test result is invalid and the sample should be retested.

INTERPRETATION OF RESULTS

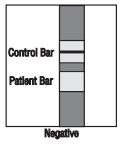
POSITIVE (Two Bars)

Red bars appear in both the control window (labeled "Control") and the patient window (labeled "Patient") of the strip. Any visible red bar in the patient window should be interpreted as positive.



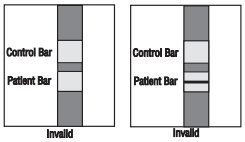
NEGATIVE (One Bar)

One red bar appears in the control window of the strip (labeled "Control"), and no red bar appears in the patient window of the strip (labeled "Patient").



INVALID (No Bar)

If there is no red bar in the control window of the strip, and even if a red bar appears in the patient window of the strip, the result is invalid and should be repeated.



NOTES:

- The test result is positive even if the patient bar appears lighter or darker than the control bar.
- If an invalid test result occurs repeatedly, or for technical assistance, contact your local distributor or call Technical Support.

LIMITATIONS OF THE PROCEDURE

- **Alere** Determine™ Syphilis TP is designed to detect antibodies to *Treponema pallidum* in human serum, plasma, and whole blood. Other body fluids or pooled specimens may not give accurate results.
- The intensity of the patient bar does not necessarily correlate to the titer of antibody in the specimen.
- No diagnostic test provides absolute assurance that a sample does not contain either low levels of antibodies to *Treponema pallidum*, such as those present at a very early stage of infection, or antibodies with low reactivity to the *Treponema pallidum* antigens. Therefore, a negative result at any time does not preclude the possibility of exposure to infection with syphilis. If the overall clinical evaluation suggests that either of the conditions described above is present, reading the test results after at least 30 minutes up to overnight as allowed in the instructions for use is recommended to maximize test sensitivity.
- Positive specimens should be evaluated in light of the overall clinical evaluation before a diagnosis is made.
- Whole blood or plasma specimens containing anticoagulants other than EDTA may give incorrect results.

PERFORMANCE CHARACTERISTICS

SPECIFICITY AND SENSITIVITY

Serum specimens from 325 cases of non-syphilis and 176 cases of syphilis from three clinical sites in Japan were tested by **Alere** Determine™ Syphilis TP and two commercially available tests (Table I).

Table I
Specificity and Sensitivity of Alere Determine™ Syphilis TP for Detection of Syphilis

	Population	Number of Specimens Tested	Alere Determine™ Syphilis TP	Commercially Available Test A	Commercially Available Test B
Specificity	Non-syphilis	325	100.00% (325/325)	100.00% (325/325)	100.00% (325/325)
Sensitivity	Syphilis	176	100.00% (176/176)	97.73% (172/176)	94.32% (166/176)

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 with **Alere** Determine™ Syphilis TP and two commercially available tests (Table II).

Table II
Specificity and Sensitivity of Alere Determine™ Syphilis TP in Whole Blood and Paired Serum and Plasma Specimens

	Population	Number of Specimens Tested	Alere Determine™ Syphilis TP			Commercially Available Test A	Commercially Available Test B
			Whole Blood	Plasma	Serum	Serum	Serum
Specificity	Non-syphilis	47	100.00% (47/47)	100.00% (47/47)	100.00% (47/47)	100.00% (47/47)	100.00% (47/47)
Sensitivity	Syphilis	52	92.31% (48/52)	100.00% (52/52)	100.00% (52/52)	98.08% (51/52)	94.23% (49/52)

BIBLIOGRAPHY (See back page)

Advice Line (See back page)

The manufacturing process produces different lot numbers for the kit and test cards; these lot numbers are traceable.