This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Approval No. 20900AMZ00373000

*Revised: January 2017 (4th edition)
Completely revised: April 2014 (3rd edition)

This package insert must be read carefully prior to use.

Treponema antibody assay kit

MEDIACE TPLA

(A)(M)

General Precautions

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
4. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
5. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
6. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components)

1. Sample Dilution Buffer
   Phosphate buffer solution containing bovine serum albumin
2. Latex Suspension
   Treponema pallidum antigen-coated latex

Intended Use

Measurement of anti-Treponema antibody in serum or plasma
(Aid in diagnosis of Treponema Pallidum infection)

Assay Principle

A sample is reacted under certain conditions with Treponema Pallidum antigen-coated latex, consequently anti-Treponema antibody in the sample causes agglutination of the latex. The anti-Treponema antibody titer in the sample is determined from the increase of turbidity due to formation of aggregates, which is calculated as the difference between the turbidity of the sample before and after reaction.

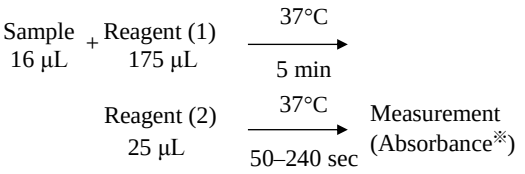
Procedural Precautions *

1. Properties of Samples and Sampling Methods
   1) Samples: Serum and plasma (heparin plasma and EDTA plasma) may be used.
   2) Samples should be tested while fresh.
   3) Handle the samples carefully to prevent infection
2. Interfering substances
   1) Assay results are not affected by bilirubin (up to 20 mg/dL), hemoglobin (up to 500 mg/dL), or rheumatoid factors (up to 500 IU/mL).
   2) Assay results may be affected by chyle. If chylemia is seen in the sample, centrifuge the sample (at 2000*g* or more for 10 minutes) before use.
3. Others
   1) Always use TPLA standard solution for calibration.
   2) Precautions for assay range
      If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

Dosage/Administration (Assay Procedure) *

1. Preparation of reagents
Reagent (1): Sample Dilution Buffer is ready to use.
Reagent (2): Latex Suspension is ready to use.
Before use, gently invert either Reagent (1) or (2) bottle to mix it thoroughly, and check that there are no bubbles.

2. Assay Procedure
This product is compatible with various types of automated analyzer. An example of the assay procedure is indicated below.



※Absorbance: The change of absorbance at 700 nm from approximately 50 seconds to 240 seconds.
Calibration material: TPLA standard solution (manufacture's assigned value)

Assessment of Assay Results

1. Assessment of Assay Results
When the result obtained by using this product is ≥ 10 T.U.,[Note] the sample is judged to be positive.
[Note]: T.U. is the abbreviation for TITER UNITS, which is a unit for the anti-treponema antibody titer measured using this product. Proceed with the WHO Standard (The International Standard for Syphilitic Human Serum [first international standard preparation] established in 1958): 1 T.U. is equal to 2 mIU.
2. When the assay result is positive using this product, perform further tests and interpret the results by taking the results of other examinations and the patient's symptoms into consideration.
3. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results. Do not make a diagnosis based on the results obtained with this product alone.
4. When a false-positive assay result due to a nonspecific reaction is suspected, perform additional tests such as the FTA-ABS test and make a final decision by also considering the

patient's symptoms and medical history.

5. Serum (plasma) samples from patients in the early stage of the antibody response or with impaired antibody production due to compromised immune function contain a low antibody titer and the test may be negative.

6. Nonspecific reactions may occur when serum (plasma) samples from patients with autoimmune diseases are tested. Clinicians should make a comprehensive clinical decision by also assessing the results of other examinations and the patient's symptoms.

7. Caution must be exercised, because false-positive assay results may be obtained with serum (plasma) samples from patients who have received blood products containing immunoglobulins.

8. Pay attention to the prozone phenomenon, because it generally occurs in immune responses.

Performance *

1. Performance

When used in accordance with the standard testing method specified by the manufacturer, the performance of this product is as follows.

1) Sensitivity
   (1) Change of turbidity in normal human serum (negative for syphilis): < 0.01
   (2) Proceed with positive control serum of around 450 T.U.: the change of turbidity is within the range of 0.10–0.70.
2) Accuracy
   Proceed with control serum having a known concentration: the result obtained with all positive reference serum samples is > 10 T.U. of the known concentration. The result obtained with all of the negative control serum samples is < 10 T.U. of the known concentration.
3) Within-run reproducibility
   Test the positive control serum with a known concentration 10 times simultaneously: the coefficient of variation (C.V.) of the change in turbidity is ≤ 15%.
4) Measurement range[2)]
   The measurement range of this product is 5–250 T.U. (on Hitachi 7170 automated analyzer).
   If the anti-treponema antibody titer in a sample exceeds 250 T.U., dilute the sample with physiological saline or another suitable reagent and perform re-measurement.

2. Correlation[1), 2)]

1) Serum N=171 r=0.828 y=106x+10.5
   Control method: Approved in vitro diagnostic (Treponema Pallidum hemagglutination assay)
2) Plasma
   - Lithium heparin plasma
     N = 74, r = 0.998, y = 1.03x+0.03
     Control method: Values obtained by using this product to test serum collected simultaneously
   - EDTA-2K plasma
     N = 74, r = 0.998, y = 0.96x + 0.38
     Control method: This product (Comparison with serum samples obtained simultaneously)

Precautions for Use or Handling *

1. Precautions for Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
2) Sodium azide is added as an antiseptic agent in the Sample Dilution Buffer and Latex Suspension. Therefore, if the reagent comes in accidentally contact with eyes, mouth or skin, rinse immediately with ample water as first aid, and consult the doctor if required.

2. Precautions for use

1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) Do not replenish the reagents.
4) After completion of measurement, this product should be stored as directed in a tightly-stopped container.
5) Do not mix materials from different kit lot numbers.
6) Prepare a new calibration curve for every assay. Do not change the bottle of Sample Dilution Buffer or Latex Suspension or start to use products from different lots during the assay.
7) Do not perform the assay under direct sunlight

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121 ºC for 20 minutes.
2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.
3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.
5) Sodium azide has been added as an antiseptic agent in the Sample Dilution Buffer and Latex Suspension. It can react with lead or copper pipes to produce the highly explosive metal azide. Therefore, the reagent should be flushed with large amounts of water during disposal.

4. Other precautions

Do not use the containers for other purposes.

Storage and Shelf Life *

1. Storage temperature: 2–8 °C (avoiding freezing)

2. Shelf life: 1 year (indicated on the outer box and the container)

Packaging

1.MEDIACE TPLA（A）

Reagent Name	Package
Sample Dilution Buffer	4 × 18 mL
Latex Suspension	1 × 10 mL

2.MEDIACE TPLA（M）

Reagent Name	Package
Sample Dilution Buffer	2 × 49 mL
Latex Suspension	1 × 14 mL

Constituent reagents are available in other configurations. For further details, contact SEKISUI MEDICAL CO., LTD.

References

1) Osato K. et al.: Clinical evaluation of latex agglutination test kits for detecting anti-syphilitic lipoidal antibodies and anti-treponemal antibodies, Japanese Journal of Sexually Transmitted Infections, 13, 124–130, 2002.
2) In house data, SEKISUI MEDICAL CO., LTD.

Contact

SEKISUI MEDICAL CO., LTD.
international@sekisui.com

Manufacturer *

SEKISUI MEDICAL CO., LTD.
1-3, Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan