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CE IVD

Anti-TP
Fast Test Kit
(Immunofluorescence Assay)

REF

IF1058 for Getein1100
IF5058 for Getein1160
IF3058 for Getein1180
IF4058 for Getein1200
IF2058 for Getein1600

User Manual

INTENDED USE

Anti-TP Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of treponema pallidum (TP) antibody in serum or plasma samples. This test is suitable for syphilis diagnosis and management.

SUMMARY

Syphilis is a treatable infection caused by the bacteria Treponema pallidum (TP) that is mainly transmitted sexually, but can also be transmitted from mother to fetus during pregnancy or birth. If left untreated the disease can spread and cause considerable organ damage.

Serological tests in addition to patients' clinical history, are currently the primary methods for the diagnosis and management of syphilis.

PRINCIPLE

This test uses an human TP antigen Ⅰ conjugated with fluorescence latex and another human TP antigen Ⅱ coated on the test line. After sample has been applied to the test strip, the fluorescence latex-labelled human TP antigen Ⅰ binds with the TP antibody in sample and forms marked antigen-antibody complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the human TP antigen Ⅱ. The fluorescence intensity of the test line increases in proportion to the amount of TP antibody in the sample.

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of TP antibody in the sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:

Package specifications: 25 tests/kit, 10 tests/kit

1) Getein Anti-TP test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/kit
5) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit

Sealed cartridge with 24/48 Getein Anti-TP test cards

User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. Sample diluent composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labeled human TP antigen Ⅰ, the test line is coated with another human TP antigen Ⅱ, and the control line is coated with streptavidin), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.

Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should follow by local regulations.
8. Carefully read and follow the user manual to ensure an appropriate test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples. Heparin, sodium citrate and EDTA*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should be performed within 4 hours after blood collection.
3. If testing will be delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing.
4. Refrigerated or frozen sample should be reached to room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated or hemolysis samples.
6. SAMPLE VOLUME(***for Getein1100/Getein1160/Getein1180***) : ***100 μL***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature before testing.

For Getein1100:

1. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent and mix thoroughly. Then drop ***100 μL*** of sample mixture into sample well on the test card.
5. ***Reaction time: 15 minutes***. Insert the test card into Getein1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

1. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent and mix thoroughly. Then drop ***100 μL*** of sample mixture into sample well on the test card.
6. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD card" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

1. Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.
2. Samples with concentration <1.00 S/CO are considered negative and no further testing is required.
3. Samples with concentration ≥1.00 S/CO are considered

positive. All positive samples that are initially tested should be retested twice. If both retests are negative, the sample must be considered Anti-TP negative. If any of the retest values are positive, it is considered Anti-TP positive.

4. The result unit of TP antibody detection uses S/CO.
5. Due to different methodologies or antibody specificity, there may be deviations between the test results of different manufacturers, so they can't be compared directly.

EXPECTED VALUE

Not applicable.

PERFORMANCE CHARACTERISTICS

1. Positive coincidence rate: 20 positive TP antibody national positive reference products or enterprise positive reference products TP/TP by national reference products, the coincidence rate (+/+) should not be less than 19/20.
2. Negative coincidence rate: 20 negative TP antibody national positive reference products or enterprise negative reference products TP/TP by national reference products, the coincidence rate (-/-) should not be less than 19/20.
3. Measuring Range 1.00-50.00 S/CO
4. Lower Detection Limit ≤ 1.00 S/CO
5. Within-run Precision ≤ 10%
6. Between-run Precision ≤ 15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Patient who has been diagnosed or treated by a mouse monoclonal antibody may contain a human anti-mouse antibody (HAMA). When such a sample is tested using a test kit containing a mouse monoclonal antibody, the detected value may be falsely increased or decreased. Need to use other clinical or diagnostic information to determine the patient's condition.

REFERENCES

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2. Lin Li-Rong, Tong Man-Li, Fu Zuo-Gen, etal. Evaluation of a colloidal gold immunochromatography assay in the detection of Treponema pallidum specific IgM antibody in syphilis serofast reaction patients: a serologic marker for the relapse and infection of syphilis.[J]. Diagnostic Microbiology and Infectious Disease, 2011, 70 (1).
3. G Karakatsanis, A Patsatsi, E Vakirlis, etal. A rapid diagnostic procedure for the detection of Treponema pallidum [J]. Journal of the European Academy of Dermatology and Venereology, 2007, 21 (10): 43 (3).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Anti-TP Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1：2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/ European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing Anti-TP Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

Version: WIF58-S-07

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