GP

CE IVD

Anti-TP
Fast Test Kit
(Immunofluorescence Assay)

IF1058 for Getein 1100
IF5058 for Getein 1160
IF3058 for Getein 1180
REF IF2058 for Getein 1600
IF4058 for Getein 1200

Instructions for Use

INTENDED USE

Anti-TP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* qualitative determination of treponema pallidum (TP) antibody in serum or plasma samples. This test is suitable for the auxiliary diagnosis and management of syphilis. For professional and laboratory use only.

SUMMARY

Syphilis is a disease caused by Treponema pallidum (TP), primarily transmitted through sexual contact, but it can also be passed from mother to fetus during pregnancy or childbirth. If left untreated, the disease can spread and cause severe organ damage. Detecting Treponema pallidum-specific antibodies can serve as a serologic marker for relapse or reinfection, as these antibodies typically appear in the early stages of initial infection or reinfection. Immunochromatographic assays provide a rapid method for detecting Treponema pallidum-specific antibodies, which may help identify patients who still have active infections or are at risk of relapse after treatment.

PRINCIPLE

Anti-TP Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunochromatographic assay for the detection of TP antibody in human serum or plasma samples. After sample has been applied to the test strip, the fluorescence -labelled TP antigen binds with the TP antibody in sample and forms marked antigen-antibody complex. This marked antigen-antibody complex moves to the detection zone on the test card by capillary action and is captured by another TP antigen. The fluorescence intensity of the test line increases in proportion to the amount of TP antibody in sample. Fluorescent signals intensity can be analyzed by applicable device thus the TP antibody in sample be detected.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
Anti-TP test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 pcs	10 pcs	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

* Anti-TP test card
A test card mainly consists of: Fluorescence-labelled TP antigen, TP antigen.
**Sample diluent
(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 0.2 mL contained in each tube consists of:
- Sample diluent mainly contains phosphate buffer (20 mmol/L), NaN_3 (<0.1%).
(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:
- Phosphate buffer (20 mmol/L), NaN_3 (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box)

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:
Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.
In-use stability:
-For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.
-For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

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 or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card or pipet.
6. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
7. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum and plasma samples**.
2. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma samples.
3. It is recommended to test the sample within 4 hours after collection. If testing is delayed, serum and plasma samples are stable for 5 days when stored at 2~8°C and 6 months when stored at -20°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. Sample volume (**Getein 1100/Getein 1160/Getein 1180**): 100 μL.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

1) Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2) Select the corresponding “Sample” on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch before use and put the test card on a clean table, horizontally placed.
4) Use disposable pipet or pipette to drop 100 μL of sample into one tube of sample diluent, mix gently and thoroughly, then add **100 μL** of sample mixture into the sample well on the test card.
5) Reaction time: **15 minutes**. Insert the test card into Getein 1100 and click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

1) Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2) Select the corresponding “Sample” on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4)Use disposable pipet or pipette to drop 100 μL of sample into one tube of sample diluent, mix gently and thoroughly, then add **100 μL** mixture into the sample well on the test card.
5) Insert the test card into Getein 1160/Getein 1180 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 displayed automatically.

For Getein 1200/Getein 1600:

1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.

2) Put the sample diluent at the correct position in Getein 1200/Getein 1600.
3) Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the insertion of test card and the sample are correct and complete.

TEST RESULTS

1. Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.
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.

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.
3. Triglyceride and bilirubin in the sample may interfere with the test results, and the maximum allowable concentrations are 18 g/L and 0.1 g/L respectively.

EXPECTED VALUE

The expected normal value for TP antibody was determined by testing 78 TP positive and 500 TP negative serum samples. The reference range of Anti-TP is <1.00 S/CO by statistical analysis.

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

1. Positive enterprise reference compliance rate 100%;
2. Negative enterprise reference compliance rate 100%;
3. Within-run Precision: ≤10%;
4. Between-lot Precision: ≤15%;

REFERENCES

1. Lixin Li, Bei Cai, Chuanmin Tao, etal. Performance Evaluation of CLIA for Treponema Pallidum Specific Antibodies Detection in Comparison with ELISA [J]. Journal of Clinical Laboratory Analysis, 2016, 30 (3).
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 details 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		Caution

Thank you for using Anti-TP Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

Version: WIF58-S-09

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