Aurora TP Ab Assay

CARBONTECHNOLOGIES

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AU242007	50

Intended Use

The Aurora TP Ab Assay is used to qualitatively detect the antibodies to Treponema Pallidum (TP) in human serum or plasma.

Summary

Syphilis is a chronic and systematic infectious disease caused by infection with TP, which could be transmitted by congenital transmission or sexual contact. When human is infected with TP, there will be three weeks of incubation period, during which the clinical manifestation of infection with syphilis is not significant and serological test may be used for detection.

Test Principle

This reagent employs double-antigen sandwich method and CMIA to qualitatively detect the TP antibody in human serum or plasma with the analyzer. In the first step, sample, reactive diluent and magnetic microparticles are combined. During the incubation, TP antibodies in samples bind to the magnetic microparticles coated with recombinant TP antigens. After rinsing, add recombinant TP antigens labeled with the acridinium ester, then complex "magnetic microparticles coated with TP recombinant antigen-TP antibody- antigen-acridinium ester" is formed. Re-wash to remove the materials not binded with magnetic microparticles. Then add pre-trigger solution and trigger solution. The resulting chemiluminescent reaction is measured as relative light unit (RLU). A direct relationship exists between the amount of TP antibodies in the sample and the RLU detected by the analyzer. The presence or absence of TP antibodies in the sample is determined by comparing the chemiluminescence signal in reaction to the Cutoff signal determined via calibrators. If the chemiluminescence reaction signal in the sample is greater than or equal to Cutoff signal, the sample will be regarded as tested positive for TP antibody.

Reagents

R1	Magnetic microparticles coated with recombinant TP antigens are prepared in the TRIS-HCl buffer containing preservative ProClin300.
R2	Recombinant TP antigens labeled with the acridinium ester are prepared in the TRIS-HCl buffer containing protein stabilizer and preservative ProClin300.
R3	Reactive dilution for antibody to TP detection is prepared in the TRIS-HCl buffer containing protein stabilizer and preservative ProClin300.
CAL 1	Inactivated TP antibody positive human serum or plasma, with positive reaction to TP Ab, containing preservative ProClin300.
CAL 2	Inactivated TP antibody negative human serum or plasma, with negative reaction to TP Ab, containing preservative ProClin300.
CON	Contains 2 levels, 1.0 mL each level.

Required Materials

- Pre-Trigger Solution: Hydrogen peroxide solution.
- Trigger Solution: Sodium hydroxide solution.
- Wash Buffer: Phosphate buffered saline solution with 0.05% ProClin 300.

Storage Condition

1-Store at 2-8℃ with a validity period of 12 months.

2-The kit should be stored upright, not upside down or horizontally.

3-The reagent could be used in the analyzer immediately after being taken out from 2-8℃, which could be stored on board the analyzer for a maximum of 30 days. After 30 days, the analyzer will automatically remind that the kit has expired.

4-After each use, return the calibrator to 2-8℃ storage with a validity period of 4 weeks.

5-See label for manufacture date and expiration date.

Applicable Analyzer

Automatic Chemiluminescence Immunoassay Analyzer (model: Aurora S-01).

Sample Requirements

1-Collect samples in accordance with the general sampling techniques and process based on the standard operation steps.

2-The sample tested by this reagent is human serum or plasma. The samples containing anticoagulant of EDTA, sodium citrate or heparin are applicable for the reagent and do not use the plasma sample with improper proportion of anticoagulant.

3-The analyzer does not provide the capacity to identify sample types. It is the responsibility of the operator to verify that the correct sample types are used.

4-You must be careful when manually processing the patient's sample under special condition, and it is recommended to use disposable pipettes or tips to avoid cross- contamination.

5-Do not use heat-inactivated samples; do not detect samples containing suspending fibrin or aggregates or grossly hemolyzed (hemoglobin content≥400mg/dL); it's allowed to detect jaundice samples (bilirubin content less than 1.71mmol/L) or hyperlipidemia samples (triglyceride content less than 170mmol/L); in case that a sample contains macroscopic particles, fiber or red blood cell, the sample should be centrifuged before process. If the sample is covered with the lipid layer after centrifugation, it should be moved to a sample cup or new tube. Avoid absorbing the lipid layer.

6-The influences of microbial contaminated samples on the results have not been determined and such samples are not recommended for use.

7-For optimal results, check all the samples for bubbles. Remove the bubbles by using swabs prior to analysis. Use a new swab for each sample to avoid cross-contamination.

8-Ensure that the temperatures of the patient samples, calibrators, controls are balanced to room temperature prior to the initiation of the analyses.

9-Avoid the samples from repeated freezing-thawing, thaw the frozen samples before test, invert the sample 180 degree upright and repeat 10 times to mix well the thawed sample. Observe whether the sample is layered. If layering is observed, repeat the above- mentioned procedure until the sample is well distributed, and make use of it after centrifugation.

10-Samples without clots, serum separators or red blood cells can be stored at 2℃-8℃ up to 7 days; and it should be kept at -20℃ or lower for long-term storage.

11-Because of possible volatilization influence, the samples, calibrators and controls positioned on the analyzer should be tested within two hours.

12-When shipped, samples must be packaged and labeled in compliance with the regulations of the International Air Transport Association (IATA) or other relevant provisions and ensure that samples are transported at low temperature. Do not exceed the time range for storage specified in this package specification (this section). Before shipment, it is recommended that the samples be separated from blood clots, serum separating tubes or from red blood cells.

Assay Procedures

1-For the first time to load the Aurora TP Ab Assay on the analyzer, it is needed to well mix the reagent in the Reagent 1 vial, and to resuspend the microparticles that have settled during the shipment.

- Invert the vial of Reagent 1 for 30 times and control the flip-flop speed to avoid generating bubbles.
- Visually inspect the vial of Reagent 1 to ensure microparticles are resuspended. If the microparticles remain adhered to the vial, continue inverting the vial until the microparticles have completely resuspended. If they do not resuspend, do not use.

2-Calibrators may not be used immediately after removal from 2-8℃ storage. Prior to use, mix by gentle inversion (5-10 times). After each use, tightly close the cap and return the calibrator to 2℃-8℃ storage.

3-Check the sample volume in the sample cup to ensure the volume maintaining 310μL before each test.

4-Execute the calibration order when necessary: See Operation Manual of the analyzer for information about executing calibration order.

5-Calibrator 1 and Calibrator 2 should be mixed by gentle inversion for 5-10 times prior to use.

6-Load sample: See Operation Manual of the analyzer for information about sample loading.

7-Press Test Start (run). The analyzer performs the following actions:

- Move the sample delivery unit to the sampling point
- Load the reaction cup into the reaction plate
- Suction and transfer the sample into the reaction cup
- Move the reaction cup forward one position and add Reagent 1 and Reagent 3 to the reaction cup
- Mix well and incubate
- Add Reagent 2 to the reaction cup
- Mix well, incubate and rinse the reactant mixture
- Add pre-trigger solution and trigger solution
- Detect the relative luminous intensity (RLU) and calculate the contents of the substances to be measured in the sample
- Pipette the content in the reaction cup to the waste liquid and discard the reaction cup into the solid waste bucket
- Results display

To perform calibration, test Calibrator 1 and Calibrator 2 in replicates of three, once the calibration is passed and stored, all subsequent samples can be detected without further calibration, unless conditions that diagnostic kit of new batch is used or the controls (QC) values are out of range. Meanwhile, the calibration result should be within the validity period.

The test results of the controls (purchased or self-prepared) should be within the specified range, when the values of the controls exceed the specified range, they may indicate reagent deterioration or technical problems. The relevant results may be invalid and it requires test again. Re-calibrate if necessary. See Operation Manual of the analyzer for information about trouble-shooting.

Positive Determination Value

The analyzer calculates the Cutoff (CO) using the mean value from three replicates of the relative luminous intensity (RLU) for calibrator 1 and calibrator 2.

CO = mean RLU value of calibrator 1×0.1+ mean RLU value of calibrator 2×1. S/CO=Sample RLU/Cutoff.

Results

1-Negative judgment: When S/CO was less than 1.0, it is considered to be negative for the detection of TP Ab.

2-Positive judgment: When S/CO was greater than or equal to 1.0, it is considered to be positive for the detection of TP Ab. TP Ab positive samples should be tested by two replicate experiments. If the repeated replicate test of the sample is negative, it should be judged as negative, on the contrary positive.

3-The following factors can lead to the non-repetitive responses:

- The sample to be tested is not in line with the sample requirements;
- The operations are not in accordance with the instructions and the analyzer requirements;
- The experimental environment or reagent is contaminated.

Limits

1-This reagent is for qualitative test and cannot be used as a quantitative reagent.

2-This reagent can only be used for the test of human serum or plasma samples, instead of saliva, urine or other bodily fluids.

3-The positive result of this reagent must be confirmed by other methods and analyzed in combination with the patient's clinical information. It cannot be ruled out that the reagent may produce false positive results.

4-Due to the limitation of methodological principles, the negative result only represents that TP Ab in sample did not reach the lowest limit of detection of the reagent but cannot be regarded as no TP Ab existed in the sample.

Performance characteristics

1-Meet the national criteria when testing with national reference.

2-Meet the following criteria when testing the enterprise reference materials:

- The coincidence rate of negative references (N1~N20) should be 20/20.
- The coincidence rate of positive references (P1~P10) should be 10/10.

- Sensitivity references: L1 and L2 should be positive, L3 can be positive or negative, L4 should be negative.
- Precision reference, CV (%) should not be greater than 10%.

Sensitivity

The lowest limit detection of this reagent is 0.125NCU/mL.

Specificity

- There's no cross contamination in samples containing HAV IgM, HBsAg, HCV antibody, HIV Ab, HTLV antibody, HDV IgG, HEV IgG, Tox IgM, RV IgM, CMV IgM, HSV-1 IgM and EBV IgM positive.
- The samples processed with different anticoagulants (EDTA, heparin sodium and sodium citrate) will not affect the detection results.
- This reagent can detect three common TP genotype serum samples of 14d/f, 14a/a and 14a/f.
- The interference factors of hemolysis (the hemoglobin less than 400mg/dL), blood lipid (triglyceride less than 170mmol/L), jaundice (bilirubin less than 1.71mmol/L), increased ALT and existence of rheumatoid factor will not affect the detection results.
- All components include 0.1% CMIT/MIT.

Warning

-H319: Causes serious eye irritation.

-H315: Causes skin irritation.

-H317: May cause an allergic skin reaction.

-H411: Toxic to aquatic life with long lasting effects.

-P280: Wear protective gloves/protective clothing/eye protection/face protection.

-P302 + P352: IF ON SKIN: Wash with plenty of water.

-P337 + P313: If eye irritation persists: Get medical advice/attention.

-P362: Take off contaminated clothing.

-P333 + P313: If skin irritation or a rash occurs: Get medical advice/attention.

-P362 + P364: Take off contaminated clothing and wash it before reuse.

-P273: Avoid release to the environment.

-P391: Collect spillage.

Cautions

1-This product is only used for in vitro diagnosis, not for other purposes, the operations should be proceeded strictly in accordance with the instructions.

2-Do not use expired kit and calibrator; do not pool reagents between reagent kits; do not mix up the calibrator with different lots; do not mix up with the reagent and calibrator from another manufacturer.

3-Due to the influence of test method, recognition site, specificity and interference factor, there may be different results for some specific samples. The laboratory technicians must indicate the experimental methodological information when issuing a test report to clinicians. The results obtained by different test methods cannot be directly compared, and direct cross-utilization may mislead the interpretation of their clinical significance. In the continuous monitoring of efficacy in patients, sufficient parallel experiments between the old and the new methods must be conducted and the feasibility must be validated prior to a halfway method change.

4-Pay special attention to the fact that all the samples, waste liquid and other materials, such as tubes, buffer and pipette tips, may contain infectious materials. During the operations, operators should wear coveralls and gloves, it is strictly prohibited to suction samples with mouth, and if contact the wound accidentally, seek medical advice in time. Use disinfectant for disinfection treatment immediately in case there is liquid overflow during the experiment. After trial, all the samples and experimental items used should be treated as medical wastes.

5-This reagent contains certain component such as ProClin300 which may lead to allergic reactions in a very few people. Avoid prolonged exposure to the skin, and wash hands completely after contact.

6-The manufacturer only guarantees the function for in vitro diagnosis in the specific range described in the instruction of the Aurora TP Ab Assay when operating the test based on the product instruction, and the manufacturer assumes no responsibility for other warranty or suggestion, including other purposes of commercial value and range of application. The manufacturer only takes the responsibility for replacement or returning payment for goods and does not take the responsibility for any injury or property damage of customer purchasing product or the third party caused during the use process of the product.

Symbols

	Manufacturer
	Date of manufacture
	Use-by date
	Contains sufficient for <n> tests
	Consult instructions for use
	Biological risks
	Temperature limit
	CE Marking
EC REP	EU Representative
IVD	In Vitro diagnostic medal device
REF	Catalogue Number
LOT	Batch code
REAGENT	Reagent
R1	Microparticles
R2	Conjugate
R3	Assay auxiliary.
CAL	Calibrator
CON	Control

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