# TP Syphilis Test

# Diagnostic Sensitivity and Diagnostic Specific Test Report

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## Core Technology Co., Ltd.

## 1. Test purpose

Different samples were tested through the "TP Syphilis Test" produced by Core Technology Co., Ltd., and parallel control tests were carried out with similar colloidal gold reagents from other manufacturers to judge the test results, calculate the proportion of its correctness, and analyze the diagnostic sensitivity and diagnostic specificity.

## 2. Reagents and materials

2.1 Test reagent

Product name: TP Syphilis Test

Manufacturer: Core Technology Co., Ltd.

Specification: 1 test/pouch

Lot number: 20140518

Storage conditions: The shelf life is 24 months at 2-30℃

Reference reagent: TP SYPHILIS TEST STRIP

Manufacturer: Nantong Dios Technology Co., Ltd.

Specification: 1 test/pouch

Lot number: 20140521

2.2 Experimental design

2.2.1 Selection of samples

100 clinical samples from hospitals were selected. The 100 blood samples were tested in parallel with the examination reagent and the reference reagent respectively, and the test results were recorded. The number of TP antibody positive samples in 100 samples was not less than 1/3 of the total number of samples, and the TP antibody concentration of positive samples should be randomly distributed in high, medium and low, 17 samples with S/CO greater than 5, and 11 positive samples with S/CO value of 2-4, 10 positive samples with S/CO value of 1-2 and 2 samples with S/ CO value of 0.2-0.8; The negative samples are about 2/3 of the total samples, which should contain some sera from people infected with other diseases.

2.2.2 Sample requirements

Blood samples must be collected in clean plastic centrifuge tubes or glass blood collection vessels. Samples should be used as soon as possible after collection, and should not be stored at room temperature for a long time. Whole blood samples with anticoagulants should be used within 24 hours; Serum or plasma samples can be refrigerated at 2-8 ℃ for one week. For long-term storage, they need to be frozen at -20 ℃, and repeated freezing and thawing is prohibited.

2.2.3 Test method

The same sample shall be tested in parallel with the test reagent and the reference reagent, operate in strict accordance with the reagent instructions, and judge the test results within the time specified in the instructions. During operation, professional laboratory inspectors must carry out synchronous blind operation. For samples with inconsistent test results of two reagents, if the above reasons are excluded, select the listed third-party reagent for the above repeated test.

**3. Test results**

Table1 Summary and comparison of test results of test reagents and reference reagents

| Reference reagent / Test reagent | | Reference reagent test result | | |
|---|---|---|---|---|
| | | positive | negative | total |
| Test reagent test result | positive | 37 (A) | 2 (B) | 39 |
| | negative | 1 (C) | 60 (D) | 61 |
| | total | 38 | 62 | 100 |

It can be seen from the above table that the test results of "TP Syphilis Test" produced by Core Technology Co., Ltd. are completely consistent with those of the listed reference reagent: TP Syphilis Test reagent produced by Nantong dios Biotechnology Co., Ltd., and there were two inconsistencies, two missed and one false positive.

Positive coincidence rate: A/(A+C)×100%=97.3%

Negative coincidence rate: D/(B+D)×100%=96.8%

Total coincidence rate: (A + D)/(A + B + C + D)×100%=97%

Calculation of consistency coefficient Kappa(K) value:

Kappa(K)=2(AD-BC)/[(A+B)(B+D)+(A+C)(C+D)]=0.94

**4. Result analysis**

The "TP Syphilis Test" produced by Core Technology Co., Ltd. and the listed reference reagent: "TP Syphilis Test" of Nantong Dios Biotechnology Co., Ltd. simultaneously detected 100 human blood samples. The positive coincidence rate was 97.3%, the negative coincidence rate was 96.8%, the total coincidence rate was 97%, and the consistency number k = 0.94.

Through this pre clinical trial, it can be seen that the clinical performance of the "TP Syphilis Test" produced by Core Technology Co., Ltd. has reached the standard of listed products and can be used for qualitative detection of TP antibody in human blood.