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**Algorithm and report of immunological testing for infectious  
diseases**

**(English Translation)**

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### Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard was drafted. Beijing Hospital, Peking Union Medical College Hospital of Chinese Academy of Medical Sciences, Chaoyang Hospital affiliated to Capital Medical University.

### 1 Scope

This standard specifies the clinical testing procedures, results report and interpretation of immunoassay for infectious diseases.

This standard applies to medical laboratories for the immunoassay of various infectious diseases.

### 2 Terms and definitions

The following terms and definitions apply to this document.

Screening test

A method for detecting the presence of a test substance (infectious pathogen antigen or related antibody) in an entire population or a part of a population.

Usually, the screening test results are negative, indicating that the test subject is highly likely to be negative, and the screening test results are positive only prompt the possibility of a positive result requires further confirmation.

## Diagnostic test

A method for detecting the presence of a corresponding test substance (infectious pathogen antigen or related antibody) in a clinically diseased population. Such as If the infectious pathogen antigen or related antibody to be tested is important for treatment and prognosis, the diagnostic test should be sufficiently high.

Sensitivity and specificity.

## Confirmatory test

A test method used to verify the results of a screening test or diagnostic test. For confirmatory testing, specificity and positive predictive value are better than sensitivity and Negative predictive values are more important and the specificity of the test should be greater than 98%.

### 3.1 General principles

Test methods involved in pathogens generally include. immunological screening tests or diagnostic tests, immunological confirmation tests, culture, smears or Nucleic acid detection. When detecting a pathogen, the corresponding test procedure can be established according to the specific project involved in the pathogen and its test method.

sequence. Some reagent kits have their own test procedures in the reagent instructions, which can be carried out according to their instructions.

### 3.2 Screening test and diagnostic test

When testing for pathogens, a screening test or a diagnostic test should be performed first. Generally, a reagent with high sensitivity should be selected to maximize the possibility.

High detection rate to avoid missed inspection. At present, the immunological methods used in clinical practice include agglutination test, enzyme-linked immunosorbent assay, radioimmunoassay, and chemotherapy.

Study of luminescent immunoassay, fluorescent immunoassay, immunochromatographic test, and the like. Whether the above method can be used as a screening test or a diagnostic test it is determined by the sensitivity of the specific test for a certain pathogen antigen or antibody test. If the sensitivity of the test is low, it is not suitable as a screening test.

Or a diagnostic test.

The requirements for its specificity (and positive predictive value) depend on a comprehensive consideration of various factors, such as whether a false positive result will be detected.

Whether a person has serious adverse effects in economic or psychological terms, and

whether treatment of misdiagnosed cases has serious consequences (for example, due to rubella resistance High level of body, and suspected infection during pregnancy, in order to avoid the adverse consequences of infection, it is recommended to terminate the pregnancy), whether there is a positive screening Check the results to confirm the method, confirm whether it is easy to execute, and check whether the method is expensive.

Whether the screening test uses repeated testing can be selected according to the specific conditions of the laboratory. Repeat the test can use the same reagent, or use the original There are reagents and reagents of a different principle (or manufacturer), or reagents using two other different principles (or manufacturers).

In the screening test or diagnostic test, if the sample is found to be hemolyzed, contaminated, etc., it should be resampled.

### **3.3 Confirmation of positive results in screening tests and diagnostic tests**

Suspected and positive reaction results detected in screening tests or diagnostic tests, such as having a significant impact on the subject, or a small positive predictive value at 95%, positive results need to be confirmed. Confirmation methods include. confirmatory test, follow-up test, repeated test and other related signs Object detection. The laboratory can select and establish testing procedures according to the specific situation.

Immunoassay methods for confirmatory testing are Western blot (WB), recombinant immunoblotting (recombinant immunoblot assay, RIBA), antibody neutralization assay, and the like. Confirmatory tests also include nucleic acid testing, pathogen culture Wait.

Both confirmatory testing and follow-up testing are effective means of confirming the results of immunoassays and often require complementary applications. For example protein Western blotting tests, etc., may be indeterminate. In this case, the patient needs to be followed up to determine whether it exists.

Pathogen infection. For example, HCV RNA test results are positive, HCV infection can be established; but the test results are negative, can not completely rule out HCV Infections are often associated with the natural history of pathogen infection and the limitations of detection methods. Therefore, the confirmation test is included in the test procedure in the middle, it is necessary to fully consider how to apply the confirmatory test according to the characteristics of different pathogens, how to report the results, and whether further follow-up examination is needed.

Test, give the corresponding program. If the immunoassay of the pathogen does not have an ideal confirmation test, or is expensive, difficult to perform, etc., A corresponding explanation or suggestion is given in the results report to resample the test after a few weeks or months.

#### **4.1.1 Screening test and diagnostic test**

The results of the screening test and the diagnostic test are reported as follows.

a) If the result is a negative reaction, a negative result can be reported and the lower limit of detection of the negative result can be indicated;

b) The result is a positive reaction and should be reported according to the following principles.

1) If there is a significant impact on the subject, it is recommended to confirm the positive reaction result;

2) If the positive predictive value is greater than 95%, the positive report may be directly reported, but it should be stated that the test is not confirmed, and there is a possibility of 5% or less.

Sexually positive, at the request of the patient and the doctor, a confirmatory test can be performed;

3) If the positive predictive value is less than 95%, and the result is not confirmed for the time being, it is recommended to report a positive reaction and explain the result.

It only represents a positive reaction, has the possibility of a false positive, and gives advice on further confirmation methods.

#### **4.1.2 Confirmation test**

The results of the confirmation test are reported as follows.

a) If the result is a negative reaction, a negative result can be reported and the lower limit of detection of the negative result can be indicated;

b) The result is a positive reaction and can be directly reported positive;

c) The test results are uncertain. At the same time as the report, recommendations for follow-up testing or other testing methods (such as nucleic acid testing) should be given.

#### **4.2 Interpretation of results**

While reporting the results, the results should be interpreted as necessary. The interpretation should clearly state the diagnostic significance of the results for infectious diseases.

That is to say, the detection result indicates the possibility of pathogen infection, such as the possibility of pathogen infection, and it is necessary to explain the case of small probability.

It is possible to show that there is no infection (such as a window infection) and to give a