YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.100

C 44

YY/T 1713-2020

Diagnostic kit for colloidal gold immunochromatographic assay

胶体金免疫层析法检测试剂盒

Issued on: September 27, 2020 **Implemented on: June 01, 2022**

Issued by: National Medical Products Administration

Table of Contents

Diagnostic kit for colloidal gold immunochromatographic assay

1 Scope

This Standard specifies relevant terms and definitions, requirements, test methods, labels and instructions for use, packaging, transportation and storage of diagnostic kit for colloidal gold immunochromatographic assay.

This Standard is applicable to diagnostic kit that uses the colloidal gold immunochromatographic assay as the principle to conduct quantitative, semiquantitative, qualitative examinations to human sample (blood, urine, feces, saliva and so on).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 21415, *In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials*

GB/T 29791.2, *In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 qualitative examination

a set of operations that identify or classify substances based on their chemical or physical properties

NOTE 1: Generally, only two types of examination results are reported (positive/negative, yes/no, yes/no, etc.).

NOTE 1: The existence of imprecision makes the examination results in this interval not always consistent.

NOTE 2: The letter c is short for concentration. The subscript (5, 50 or 95) indicates the percentage of positive results.

NOTE 3: Ideally, repeat the examination with c_5 and c_{95} concentrations of the analyte to respectively produce about 5% and 95% of the positive results (this is the result of the diagnostic kit test, not the clinical diagnosis result).

NOTE 4: The c_5-c_{95} interval is usually called the "examination gray zone" during qualitative inspection. Its width provides information about the precision of the qualitative test (the narrower the interval, the better the precision of the examination method).

NOTE 5: This interval is sometimes referred to as the "95% interval" of the method. But do not confuse this term with "95% confidence interval".

NOTE 6: Rewrite EP12-A2, 8.1.

3.6 limit of detection

the measured value obtained from a given measurement program; for this value, given that the false positive probability of a certain component in the claimed substance is α, the false positive probability of the non-existent component is β

NOTE 1: IUPAC recommends that the default values of α and β are equal to 0.05.

NOTE 2: It is used to describe a test procedure with a certain level of confidence that can be reported as the lowest measured value that exists. It is also used to refer to the minimum detectable concentration.

NOTE 3: It used to be called "lowest examination limit", "lowest examination limit" and "examination limit".

NOTE 4: Rewrite GB/T 29791.1-2013, definition A.3.14.

3.7 repeatability

the measurement precision under a set of measurement conditions, including repeated measurement on the same or similar test object with the same measurement procedure, by the same operator, with the same measurement system, under the same operating conditions and at the same location and with a short period of time

[GB/T 29791.1-2013, definition A.3.30]

3.8 analytical specificity

the ability of the examination procedure to only examine or measure the

4.1.1 Appearance

Meet the normal appearance requirements specified by the manufacturer.

4.1.2 Net content (when applicable)

If the kit contains liquid components, the volume shall meet the following requirements:

a) For liquid components that need to be extracted and used, the net content shall not be less than the labeled value;

b) For liquid components that do not need to be extracted, the net content shall specify its deviation requirements.

NOTE 1: Common liquid components include sample diluent, sample treatment liquid and so on.

NOTE 2: Under normal circumstances, the diluent or treatment liquid in single serving packaging does not need to be extracted for use. Multi-serving packaging needs to be extracted before use.

4.1.3 Film strip width

The manufacturer shall specify the width of the film strip (lower limit or deviation). The random test shall be no less than the manufacturer's claim.

4.1.4 Liquid moving speed

The manufacturer shall specify the moving speed requirements (lower limit or deviation). The random test shall be no less than the manufacturer's claim.

4.1.5 Limit of detection

The manufacturer shall specify the limit of detection level of the kit. Separately examine reference products/samples of different concentrations/level gradients. The result shall meet the manufacturer's claim.

The concentration/level setting and preparation of the reference product/sample shall follow the following principles:

a) The reference product/sample shall cover the concentration/level near c_5 and c_{95} on both sides of the critical value;

b) The setting of cutoff and gray zone shall consider whether it accords with the clinical diagnosis significance. The same test substance can be set with different cutoffs according to the sensitivity/specificity requirements for different clinical application situations such as screening reagents and confirmation reagents;

b) The positive reference/sample shall be determined, and/or tested by recognized methods, and/or clinically confirmed positive samples. It is recommended to use national reference materials. If prepared by the manufacturer, the matrix, preparation method and value assignment method shall be specified.

4.1.8 Analytical specificity (when applicable)

Examine the negative reference product/sample containing a certain concentration/level of cross-reactant 3 times. The examination result shall not be positive.

The analyte kit with a clear cross-reactant shall be applicable. Its setting shall follow the following principles:

a) The selection of cross-reactants and their concentrations shall be scientific and reasonable. And it shall be possible to exist in the sample to be tested. The acceptable degree of cross-reaction mainly depends on the relative content of the analyte and the cross-reactant in the human body;

b) Negative reference materials/samples shall be determined, and/or tested by recognized methods, and/or clinically confirmed negative samples. If it is prepared by the manufacturer, the matrix, preparation method and assignment method shall be clarified.

NOTE: If there are relevant requirements for cross-reactants in the "negative/positive reference product compliance rate", this item may not be applicable (such as pathogenic microorganism diagnostic kit).

4.1.9 High dose hook effect (when applicable)

Examine the high concentration/level positive reference product/sample claimed by the manufacturer 3 times. There shall be no false negatives in the examination results.

The double-antibody sandwich one-step examination kit shall generally be applicable. Its setting shall follow the following principles:

a) The high concentration/level claimed here shall be the higher concentration level of the analyte that is clinically visible;

b) This is not a requirement to claim that the concentration/level of the hook effect has occurred. In fact, at the examination concentration/level, the hook effect has not yet occurred or although the hook effect has occurred, no false negatives have occurred.

NOTE: This high concentration/level can also be regarded as the upper limit of the diagnostic kit claimed by the manufacturer.

on. However, if the specified time is exceeded, the product can be accepted if it meets the requirements.

NOTE 2: Thermal stability test cannot be used to derive product expiration date, unless it is a deduced formula based on a large amount of stability research data.

NOTE 3: A combination of a) and b) methods can be selected according to product characteristics. However, the selected method shall be able to verify the stability of the product, so as to ensure that the product performance meets the standard requirements within the validity period.

NOTE4: When the kit needs to be used multiple times after opening (for example, the initial packaging for multiple servings) or when it is not used immediately after opening, c) applies.

4.2 Diagnostic kit for semiquantitative examination

4.2.1 Appearance

Meet the normal appearance requirements specified by the manufacturer.

4.2.2 Net content (when applicable)

If the kit contains liquid components, the number of liquid components shall meet the following requirements:

a) For the liquid components that need to be extracted and used, the net content shall not be less than the labeled value;

b) For the liquid components directly used without extraction, the net content shall specify its deviation requirements.

NOTE 1: Common liquid components include sample diluent, sample treatment liquid and so on.

NOTE 2: Under normal circumstances, the diluent or treatment solution in the single-serving package does not need to be extracted for use, and the multi-serving package needs to be extracted before use.

4.2.3 Film strip width

The manufacturer shall specify the width of the film strip (lower limit or deviation). The random test shall be no less than the manufacturer's claim.

4.2.4 Liquid moving speed

The manufacturer shall specify the moving speed requirements (lower limit or deviation). The random test shall be no less than the manufacturer's claim.

4.2.9 Batch-to-batch difference

Extract 3 batches of diagnostic kits. Repeat the examination for each batch of different concentrations/levels of reference products (at least contain two orders of magnitude, weak positive and positive) at least 10 times each. The consistency rate of the measurement results of each magnitude shall not be less than 95%.

4.2.10 Stability

Stability shall meet the following requirements:

a) Stability of validity period

The diagnostic kit is stored under the specified storage conditions until the end of the validity period. If tested within a certain period of time after the expiry date, the performance of the product shall at least meet the requirements of 4.2.5, 4.2.6, 4.2.7, and 4.2.8.

b) Thermal stability

Take the kit within the validity period and place it at the temperature specified by the manufacturer for a specified time. The performance of the product shall at least meet the requirements of 4.2.5, 4.2.6, 4.2.7, and 4.2.8.

c) Opening stability

After the kit is opened, store under the specified storage conditions until the end of the expiry date of opening. The performance of the product shall at least meet the requirements of 4.2.5, 4.2.6, 4.2.7, and 4.2.8.

NOTE 1: Validity period stability test: Under normal circumstances, when the validity period is 1 year, select products that do not exceed 1 month for testing. When the validity period is half a year, choose a product that does not exceed half a month for testing, and so on. However, if the specified time is exceeded, the product can be accepted if it meets the requirements.

NOTE 2: Thermal stability test cannot be used to derive product expiration date, unless it is a deduced formula based on a large amount of stability research data.

NOTE 3: A combination of a) and b) methods can be selected according to product characteristics. However, the selected method shall be able to verify the stability of the product, so as to ensure that the product performance meets the standard requirements within the validity period.

NOTE 4: When the kit needs to be used multiple times after opening (for example, the initial packaging for multiple servings) or when it is not used immediately after opening,

Add the analyte of known concentration to the clinical sample matrix. The recovery rate shall be 80%~120%.

c) Comparison test

Conduct comparison test between the kit and the designated analysis system. The correlation coefficient (r) shall not be less than 0.95.

4.3.7 Limit of detection

The manufacturer shall provide the limit of detection of the kit. The test result shall conform to its claimed value.

4.3.8 Linear

The manufacturer shall provide the linear interval of the kit. In its given linear interval, the correlation coefficient (r) shall not be lower than 0.95.

4.3.9 Analytical specificity (when applicable)

Examine the negative reference product/sample containing a certain concentration/level of cross-reactant 3 times. The examination result shall conform to its claimed value.

4.3.10 Repeatability

Repeat the test 10 times with high and low concentration/level reference products/samples respectively. The coefficient of variation (CV) shall not be greater than 15%.

The concentration/level setting and preparation of the reference product/sample shall follow the following principles:

a) The concentration of the tested reference product/sample shall be selected near the medically determined level.

b) If the reference/sample used is prepared by the manufacturer, the matrix, preparation method and assignment method shall be clarified.

NOTE: High and low concentration/level can also choose different coefficient of variation (CV) requirements. For example, high concentration requires CV not greater than 8%; low concentration requires CV not more than 12%.

4.3.11 Batch-to-batch difference

Use 3 lot number kits to examine high and low concentrations/levels of reference products/samples 10 times. The inter-assay coefficient of variation (CV) shall not be greater than 20%.

5 Test methods

5.1 Diagnostic kit for qualitative examination

5.1.1 Appearance

Visually inspect with normal vision or corrected vision under natural light, which shall be in accordance with the requirements in 4.1.1.

5.1.2 Net content (when applicable)

Use a universal measuring tool to measure the number of liquid reagents, which shall be in accordance with the requirements in 4.1.2.

5.1.3 Film strip width

Use a Vernier caliper to measure the width of the test strip, which shall be in accordance with the requirements in 4.1.3.

5.1.4 Liquid moving speed

Follow the instructions for use. Use a stopwatch to start timing when the test paper is added to the sample liquid. Stop timing until the liquid reaches the end of the observation area (shall cover the detection area, quality control area and other reaction areas). The time used is recorded as t. Use a Vernier caliper to measure the length from the sample application area to the end of the observation area, recorded as L. Calculate L/t as the moving speed, which shall be in accordance with the requirements in 4.1.4.

5.1.5 Limit of detection

Respectively examine the reference product/sample of different gradients with the indicated concentration/level once each. The result shall meet the requirements of 4.1.5.

5.1.6 Negative coincidence rate (when applicable)

Respectively examine different reference products/samples used to evaluate the specificity of reagents once each. The result shall meet the requirements of 4.1.6.

5.1.7 Positive coincidence rate (when applicable)

Respectively examine different reference products/samples used to evaluate the sensitivity of reagents once each. The result shall meet the requirements of 4.1.7.

5.1.8 Analytical specificity (when applicable)

5.2.2 Net content (when applicable)

Use a universal measuring tool to measure the number of liquid reagents, which shall meet the requirements in 4.2.2.

5.2.3 Film strip width

Use a Vernier caliper to measure the width of the test strip, which shall meet the requirements in 4.2.3.

5.2.4 Liquid moving speed

Follow the instructions for use. Use a stopwatch to start timing when the test paper is added to the sample liquid. Stop timing until the liquid reaches the end of the observation area (shall cover the detection area, quality control area and other reaction areas). The time used is recorded as t. Use a Vernier caliper to measure the length from the sample application area to the end of the observation area, recorded as L. Calculate L/t as the moving speed, which shall meet the requirements of 4.2.4.

5.2.5 Accuracy

Respectively examine the concentration/level of each level of concentration reference product/sample once each. The result shall meet the requirements of 4.2.5.

5.2.6 Analytical specificity (when applicable)

Examine the negative reference product/sample containing the indicated concentration/level of the cross-reactant 3 times. The result shall meet the requirements of 4.2.6.

5.2.7 High dose hook effect (when applicable)

Examine the strong positive reference product/sample 3 times according to the concentration/level claimed by the manufacturer. The result shall meet the requirements of 4.2.7.

5.2.8 Repeatability

Respectively examine the concentration/level of different levels of concentration reference products/samples at least 10 times each. The result shall meet the requirements of 4.2.8.

5.2.9 Batch-to-batch difference

Extract 3 batches of kits. Each batch shall be tested respectively at least 10 times for the reference product/sample with the indicated concentration/level.

according to the kit instructions. Repeat the examination twice for each concentration of the sample. Calculate its average. Use the least square method to fit the result average and dilution ratio to a straight line. Calculate the linear correlation coefficient r. The result shall meet the requirements of 4.3.8.

5.3.9 Analytical specificity (when applicable)

Examine the negative reference product/sample containing the indicated concentration/level of the cross-reactant 3 times. The result shall meet the requirements of 4.3.9.

5.3.10 Repeatability

Respectively examine the high and low two reference products/samples with indicated concentrations/levels 10 times each. Calculate the coefficient of variation CV. The result shall meet the requirements of 4.3.10.

5.3.11 Batch-to-batch difference

Extract 3 batches of diagnostic kits. Each batch is tested for 10 times each of the high and low concentration reference products/samples with the indicated concentration/level. Calculate the coefficient of variation CV of 30 test results. The result shall meet the requirements of 4.3.11.

5.3.12 Stability

5.3.12.1 Stability of validity period

The diagnostic kit is stored under the specified storage conditions until the end of the validity period. Examine according to 5.3.6, 5.3.7, 5.3.8, 5.3.9, 5.3.10. The result shall meet the requirements of 4.3.12a).

5.3.12.2 Thermal stability

Take the diagnostic kit within the validity period and place it at the temperature specified by the manufacturer for a specified time. Examine according to 5.3.6, 5.3.7, 5.3.8, 5.3.9, 5.3.10. The result shall meet the requirements of 4.3.12b).

5.3.12.3 Opening stability

After the diagnostic kit is opened, store it under the specified storage conditions until the end of the expiry date of opening. Examine according to 5.3.6, 5.3.7, 5.3.8, 5.3.9, 5.3.10. The result shall meet the requirements of 4.3.12c).

6 Labels and instructions for use

Shall meet the requirements of GB/T 29791.2.

This is an excerpt of the PDF (Some pages are marked off intentionally)

------ The End ------