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Colloidal gold immunochromatography reader

胶体金免疫层析分析仪

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Colloidal gold immunochromatography reader

1 Scope

This standard specifies the requirements, test methods, labels and instructions for use, packaging, transportation and storage of colloidal gold immunochromatography analyzers.

This standard is applicable to instruments that interpret the results of samples by measuring the reflectivity of the bands in the reaction zone of the colloidal gold reagent card (hereinafter referred to as analyzers).

This standard does not apply to instruments that use fluorescent labels or other labeling methods for rapid immunoassay.

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this document. For undated references, the latest version (including all amendments) applies to this document.

GB/T 191 Packaging - Pictorial marking for handling of goods

GB 4793.1 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

GB 4793.9 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 9: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

GB/T 14710 Environmental requirement and test methods for medical electrical equipment

GB/T 18268.1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

GB/T 18268.26 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 26: Particular requirements - In vitro diagnostic (IVD) medical equipment

GB/T 29791.3 In vitro diagnostic medical devices - Information supplied by

3.4 Repeatability

It may choose one of the following methods:

a) Test quality control strips: Test three quality control strips with high, medium and low reflectivity in the range of [0.20, 0.80], respectively; the coefficient of variation (CV) shall not be greater than 3%.

b) Use of matching reagent test sample: Test samples with high, medium and low concentrations in the linear range, the coefficient of variation (CV) shall not be greater than 20%.

3.5 Linearity

It may choose one of the following methods:

a) Test quality control strip: Within the linear range of reflectivity [0.20, 0.80], the linear correlation coefficient (r) shall not be less than 0.990.

b) Use of matching reagent test sample: Within the linear range declared by the manufacturer, the linear correlation coefficient (r) shall not be less than 0.950.

3.6 Channel consistency (if applicable)

Test the quality control strip, the relative range (R_p) of the measurement results of each channel shall not be greater than 5%.

3.7 Stability

Test the quality control strip, the relative range (R) shall not exceed 5%.

3.8 Function

At least the following functions shall be included; the enterprise shall also determine other functions according to the characteristics of the product:

a) Self-check function;

b) Function of input calibration information;

c) Function of result storage and query;

d) Fault prompt function.

3.9 Safety requirements

It shall meet the requirements of applicable clauses in GB 4793.1, GB 4793.9, YY 0648.

A_2 - The reflectivity of quality control strip 2;

S_2 - The response value of quality control strip 2.

4.3.2 Use of matching reagent test sample

Test a pair of samples which has a concentration difference not greater than 15% at the medical decision level (i.e., $0<\frac{X_2-X_1}{X_2}\leqslant 15\%$); repeat the measurement 10 times; if each measurement meets $S_1 - S_2 < 0$, then it meets the requirements of 3.2b).

Where:

X_1 - The concentration of sample 1;

S_1 - The measurement result of sample 1;

X_2 - Sample with medical decision level concentration;

S_2 - The measurement result of sample 2.

4.4 Accuracy

4.4.1 Relative deviation

Use matching reagents to test certified reference materials. The measured value is recorded as (X_i). Use the formula (1) to respectively calculate the relative deviation B. If the three measurement results meet the requirements of 3.3a), it is deemed qualified. If more than or equal to 2 measurement results do not meet, it is judged as unqualified. If one measurement does not meet the requirements, it shall make 20 tests continuously again; use the formula (1) to calculate the relative deviation. If greater than or equal to 19 measurement results meet the requirements of 3.3a), it is judged as qualified.

$$B=\frac{X_i-T}{T}\times 100\% \qquad \cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots (1)$$

Where:

X_i - Each measured value;

T - The labeled value of the reference material.

4.4.2 Comparison test

Use matching reagents; refer to the method of CLSI EP09-A2; use no less than 40 clinical samples with different concentrations within the measurement

d) The name, residence, production address, contact information and production license number of the production enterprise. In case of entrusted production, the name, residence, production address, production license number of the entrusted enterprise shall also be marked;

e) Production date, use period or expiration date;

f) Power connection conditions and input power;

g) Graphics, symbols and other related content that shall be marked according to product characteristics;

h) Necessary warnings and precautions;

i) Special storage, operating conditions or instructions.

Note: If it is not possible to indicate all the above content due to location or size limitation, at least the product name, model, specification, production date and expiration date shall be indicated, meanwhile the label shall clearly indicate that "see the instruction manual for other contents".

5.3 Instruction manual

The instruction manual shall meet the requirements of the Provisions on the Administration of Medical Device Instructions and Labels; it shall at least include the following:

a) Descriptions for normal operation of the product;

b) Description of normal working conditions;

c) Handling methods for common faults;

d) Descriptions of product structure;

e) Description of product consumables and accessories;

f) Recommended service life of key components;

g) Descriptions for matching reagents.

6 Packaging, transportation and storage

6.1 Packaging

The packaging shall meet the following requirements:

$$R_n = R_{std} \times \frac{L_n}{L_{std}} \quad \cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots (A.1)$$

Where:

R_n - The reflectivity value of the measurement gray block for metering calibration which has a serial number n;

R_{std} - The standard reflectivity value of the standard reflectivity whiteboard;

L_n - The measured brightness value of the gray scale block for metering calibration which has a serial number n;

L_{std} -The measured brightness value of the standard reflectivity whiteboard.

According to the above method, the number of measurements must be greater than 2; take the arithmetic mean as the final result.

A.2.4 Reflectivity value of quality control strip

Calculate the reflectivity value of the cut-out measurement grey-scale block for metering calibration according to the method in A.2.3. This series of reflectivity values is the reflectivity value of the required quality control strip.

A.2.5 Traceability method

Trace the source in the following ways:

a) The reflection optical densitometer has the measurement calibration report of the national measurement institutions at all levels;

b) For the preparation of the reflectivity measurement card by itself, the state measurement institutions at all levels shall make measurement according to the method A.2 and issue a metering calibration report;

c) Entrust national measurement institutions at all levels to prepare quality control strips and issue measurement calibration reports in accordance with A.1.

A.2.6 Validity period and storage method of measurement traceability of quality control strip

The quality control strip shall be properly stored after being cut and measured to prevent moisture, pollution, or long-term strong light exposure. It is recommended that the validity period of the quantity measurement of a properly kept quality control strip is 1 year.

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