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Allergy-specific IgE detection kit

过敏原特异性 IgE 抗体检测试剂盒

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Allergy-specific IgE detection kit

1 Scope

This Standard specifies the requirements, test methods, label and instructions for use, packaging, transportation, and storage of allergy-specific IgE detection kit.

This Standard is applicable to the kit in the medical laboratory for quantitative/semi-quantitative/qualitative detection of allergy-specific IgE in human serum or plasma using enzyme-linked immunosorbent assay, chemiluminescence, fluorescence immunoassay, colloidal gold method, immunoblotting as the principle (hereinafter known as “kit” for short).

2 Normative references

The following documents are indispensable for the application of this document. For the dated references, only the editions with the dates indicated are applicable to this document. For the undated references, the latest edition (including all the amendments) are applicable to this document.

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 Requirements

3.1 Requirements for quantitative detection kit

3.1.1 Appearance

The components of the kit shall be complete and free of liquid leakage.

3.1.2 Value assignment to calibrators

The manufacturing enterprise shall, according to GB/T 21415 and relevant regulations, provide the source, value assignment process, measurement uncertainty, and other contents of calibrators.

IU/mL and no specific IgE, IgA sample with a concentration of not less than 700 μg/mL, IgM sample of 500 μg/mL, and IgG sample of 7000 μg/mL. The determination results shall not be higher than the detection limit.

3.1.9 Stability

The expiration date stability and thermal stability can be verified:

a) Expiration date stability: The manufacturing enterprise shall specify the expiration date of the kit. TAKE the product within a certain period of time after the expiration date to detect accuracy, detection limit, linearity, repeatability, etc.. It shall meet the requirements of 3.1.3, 3.1.4, 3.1.5, 3.1.6;

b) Thermal stability test: Detect the accuracy, detection limit, linearity, repeatability, etc.. It shall meet the requirements of 3.1.3, 3.1.4, 3.1.5, 3.1.6.

Note 1: Thermal stability cannot be used to derive the expiration date of a product, unless a derivation formula based on a large amount of stability study data is used.

Note 2: Generally, when the expiration date is 1 year, SELECT the product which has expired no more than 1 month; when the expiration date is half a year, SELECT the product which has expired no more than half a month, and so on. However, if the specified time is exceeded, but the product meets the requirements, it can also be accepted.

Note 3: According to the product characteristics, any combination of the methods of 3.1.9a) and 3.1.9b) can be selected. But the selected method shall be able to verify the stability of product, to ensure that the product performance during the expiration date meets the standard requirements.

3.2 Requirements for semi-quantitative detection kit

3.2.1 Appearance

The components of the kit shall be complete and free of liquid leakage.

3.2.2 Negative reference material coincidence rate

Detect negative national reference materials, or negative reference materials provided by the manufacturing enterprise. The results shall be negative.

3.2.3 Positive reference material coincidence rate

Detect national reference materials, or positive reference materials provided by the manufacturing enterprise. The results shall be positive. The results are

TAKE the product within a certain period of time after the expiration date to detect negative reference material coincidence rate, positive reference material coincidence rate, detection limit, correlation, repeatability, etc.. It shall meet the requirements of 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6;

b) Detect negative reference material coincidence rate, positive reference material coincidence rate, detection limit, correlation, repeatability, etc.. It shall meet the requirements of 3.2.2, 3.2.3, 3.2.4, 3.2.5, 3.2.6.

Note 1: Thermal stability cannot be used to derive the expiration date of a product, unless a derivation formula based on a large amount of stability study data is used.

Note 2: Generally, when the expiration date is 1 year, SELECT the product which has expired no more than 1 month; when the expiration date is half a year, SELECT the product which has expired no more than half a month, and so on. However, if the specified time is exceeded, but the product meets the requirements, it can also be accepted.

Note 3: According to the product characteristics, any combination of the methods of 3.2.8a) and 3.2.8b) can be selected. But the selected method shall be able to verify the stability of product, to ensure that the product performance during the expiration date meets the standard requirements.

3.3 Requirements for qualitative detection kit

3.3.1 Appearance

The components of the kit shall be complete and free of liquid leakage.

3.3.2 Negative reference material coincidence rate

Detect negative national reference materials, or negative reference materials provided by the manufacturing enterprise. The results shall be negative.

3.3.3 Positive reference material coincidence rate

Detect national reference materials, or positive reference materials provided by the manufacturing enterprise. The results shall be positive.

3.3.4 Detection limit

It shall be less than or equal to 0.35 IU/mL.

3.3.5 Repeatability

One of the following methods can be used to verify:

kit. According to the information provided by the manufacturing enterprise, detect 5 low-value samples with approximate detection limits of concentration. Each sample is detected 5 times. SORT the detection results by size. If the following conditions are met, it can be considered that the setting of blank limit and detection limit provided by the manufacturing enterprise is basically reasonable. The result shall meet the requirements of 3.1.4:

a) The number of the detection results below the blank limit value provided by the manufacturing enterprise shall be less than or equal to 3;

b) There is no detection result higher than the lower limit of the reference interval provided by the manufacturing enterprise.

4.1.5 Linearity

Detect each of the allergy items in the mixed/combined/multivalent allergy detection items. USE low-concentration sample or sample diluent near the lower limit of linear interval to dilute high-concentration sample near the upper limit of linear interval; and MIX them into at least 5 dilution concentrations (x_i). USE the kit to test the above samples separately. Each dilution concentration is tested 3 times. The mean value (y_i) of each dilution concentration detection result is calculated respectively. USE the dilution concentration (x_i) as the independent variable; USE the mean value (y_i) of the detection result as the dependent variable; and obtain the linear regression equation. Calculate the correlation coefficient (r) of linear regression. It shall meet the requirements of 3.1.5.

4.1.6 Repeatability

USE samples of at least two concentration levels of 0.35 IU/mL~0.7 IU/mL and 3.5 IU/mL~17.5 IU/mL for repeated detection 10 times respectively. Calculate the mean value M and standard deviation SD of the 10 measured concentration results. According to formula (3), the coefficient of variation CV is obtained. The result shall meet the requirements of 3.1.6.

$$CV = \frac{SD}{M} \times 100\% \qquad \cdots\cdots(3)$$

Where:

CV - Coefficient of variation;

SD - Standard deviation of measured values;

M - Mean value of measured values.

4.2.3 Positive reference material coincidence rate

Detect each of the allergy items in the mixed/combined/multivalent allergy detection items. Detect positive national reference materials, or positive reference materials provided by the manufacturing enterprise. Reference materials provided by the manufacturing enterprise shall contain strongly positive, positive, weakly positive reference materials. Operate according to the instructions of the kit. The results shall meet the requirements of 3.2.3.

4.2.4 Detection limit

Detect each of the allergy items in the mixed/combined/multivalent allergy detection items. SET the product detection limit. Detect the national reference materials of detection limit, or the series of reference materials provided by the manufacturing enterprise. If the concentration is higher than the detection limit, the reference material shall be detected positive. If the concentration is lower than the detection limit, the reference material shall be detected negative. The detection limit reference materials can be detected negative or positive. The detection limit shall meet the requirement of 3.2.4.

4.2.5 Correlation

Detect the reference material at each concentration level of all detection items (The preparation method of reference material is based on the information provided by the manufacturer). Each concentration level is repeatedly detected 3 times. Calculate the difference between the magnitude of the detection result and the reference solution labelling concentration. It shall meet the requirements of 3.2.5.

4.2.6 Repeatability

4.2.6.1 USE at least 2 different levels of positive and weakly positive samples for repeated detection 10 times respectively. Calculate the mean value M and standard deviation SD of the 10 measured results. According to formula (3), the coefficient of variation CV is obtained. The result shall meet the requirements of 3.2.6a).

4.2.6.2 USE repetitive national reference materials or repetitive reference materials provided by the manufacturing enterprise for repeated detection 10 times. The enterprise's reference materials shall contain at least 2 levels of positive and weakly positive reference materials. The result shall meet the requirements of 3.2.6b).

4.2.7 Inter-batch difference

4.2.7.1 USE kits of 3 batch numbers to detect 2 levels of positive and weakly

reference materials provided by the manufacturing enterprise. Reference materials provided by the manufacturing enterprise shall contain strongly positive, positive, weakly positive reference materials. Operate according to the instructions of the kit. The results shall meet the requirements of 3.3.3.

4.3.4 Detection limit

Detect each of the allergy items in the mixed/combined/multivalent allergy detection items. SET the product detection limit. Detect the national reference materials of detection limit, or the series of reference materials provided by the manufacturing enterprise. If the concentration is higher than the detection limit, the reference material shall be detected positive. If the concentration is lower than the detection limit, the reference material shall be detected negative. The detection limit reference materials can be detected negative or positive. The detection limit shall meet the requirement of 3.3.4.

4.3.5 Repeatability

4.3.5.1 USE at least 2 different levels of positive and weakly positive samples for repeated detection 10 times respectively. Calculate the mean value M and standard deviation SD of the 10 measured results. According to formula (3), the coefficient of variation CV is obtained. The result shall meet the requirements of 3.3.5a).

4.3.5.2 USE repetitive national reference materials or repetitive reference materials provided by the manufacturing enterprise for repeated detection 10 times. The enterprise's reference materials shall contain at least 2 levels of positive and weakly positive reference materials. The result shall meet the requirements of 3.3.5b).

4.3.6 Inter-batch difference

4.3.6.1 USE kits of 3 batch numbers to detect 2 levels of positive and weakly positive samples. REPEAT 10 times respectively. Calculate the mean value M and standard deviation SD of the 30 measured results. According to formula (3), the coefficient of variation CV is obtained. The result shall meet the requirements of 3.3.6a).

4.3.6.2 USE kits of 3 batch numbers to detect repetitive national reference materials or repetitive reference materials provided by the manufacturing enterprise respectively. The enterprise's reference materials shall contain at least 2 levels of positive and weakly positive reference materials. Repeatedly detect 10 times respectively. The results of the 30 detections shall meet the requirements of 3.3.6b).

4.3.7 Stability

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