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Glycated albumin assay kit (enzymatic method)

糖化白蛋白测定试剂盒（酶法）

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Glycated albumin assay kit (enzymatic method)

1 Scope

This standard specifies the requirements, test methods, labeling and instruction manuals, packaging, transportation and storage requirements for glycated albumin assay kits.

This standard applies to the use of enzymatic kits for quantitative detection of glycated albumin in human serum or plasma, including reagents used on manual and semi-automatic, fully automatic biochemical analyzers.

If the glycated albumin assay kit contains the albumin test component, the technical requirements of the albumin assay reagent refer to the corresponding standards.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this standard.

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 Appearance

The appearance of the assay kit shall meet:

a) The components of the assay kit shall be complete and intact, with no leakage of liquid;

b) The text symbols on the packaging labels shall be clear.

3.2 Loading

It shall not be less than the marked value.

greater than 15%. The 95% of the test samples shall meet the above requirements.

3.8 Stability

3.8.1 General

It may verify the stability of the expiration date and thermal stability.

3.8.2 Validity period stability

The manufacturer shall specify the validity period of the product. After taking the product within a certain period of time, the detection reagent's blank absorbance, analytical sensitivity, linearity, repeatability, accuracy shall meet the requirements of 3.3, 3.4, 3.5, 3.6.1, 3.7.

3.8.3 Thermal stability test

The detection reagent's blank absorbance, analytical sensitivity, linearity, repeatability, accuracy shall meet the requirements of 3.3, 3.4, 3.5, 3.6.1, 3.7.

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

Note 2: In general, when the products have a validity period of 1 year, select products of not more than 1 month; when the products have a validity period of half a year, select products of not more than half a month, and so on. But if it exceeds the specified time, the product can also be accepted when it meets the requirements.

Note 3: According to the product characteristics, it may select any combination of methods of 3.8.2 and 3.8.3, but the selected method should be able to verify the stability of the product, to ensure that the product performance meets the standard requirements during the validity period.

4 Test method

4.1 Basic requirements for instruments and materials

4.1.1 Spectrophotometer or biochemical analyzer, whose wavelength range shall meet the needs of reagents. The biochemical analyzer shall be equipped with a constant temperature device (the temperature value is within ± 0.3 °C of the set value, the fluctuation is not more than ± 0.2 °C); the resolution of the absorbance measurement is above 0.001.

4.1.2 The albumin concentration of the samples used in 4.5 ~ 4.7 is 40 g/L ~ 50

the method of relative deviation is preferred.

4.8.2 Relative deviation

The kit test can be used to evaluate the certified reference material (CRM) of conventional methods or other recognized reference materials 3 times, the test result is recorded as (X_i). Use the formula (4) to respectively calculate the relative deviation B_i. If the results of the 3 tests meet the requirement of 3.7a), it is judged as qualified. If more than or equal to 2 test results does not match, it is judged as unqualified. If one of the results does not meet the requirements, it shall re-test 20 times in succession; calculate the relative deviation according to equation (4) respectively. If the results of 19 or more tests meet the requirements of 3.7a), the accuracy meets the requirements of 3.7a).

$$B_i = \frac{X_i - T}{T} \times 100\% \qquad \cdots\cdots(4)$$

Where:

B_i - Relative deviation;

X_i - Measured concentration;

T - Reference substance’s calibration concentration.

4.8.3 Comparison test

Use no less than 40 human source samples covering different concentrations within the detection concentration range, to conduct a comparison test by a traceability analysis system designated by the manufacturer. Each sample is tested separately according to the requirements of the reagent kit to be tested and the selected analysis system. Each sample is measured once; the two sets of results are linearly fitted using the linear regression method, to obtain the correlation coefficient (r) and slope of the linear regression equation. Calculate the absolute deviation or relative deviation of the measured value of the test kit of each sample and the measured value of the control system, which shall meet the requirements of 3.7b).

4.9 Stability

4.9.1 Validity period stability

The samples beyond the validity period are taken shall be tested according to the methods of 4.4, 4.5, 4.6, 4.7.1, 4.8, which shall meet the requirements of 3.8.2.

4.9.2 Thermal stability test

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