BIOBASE

Immunoglobulin IgA (IgA) Test Kit (Immunoturbidimetric) Test Kit

(Immunoturbidimetry)

【NAME】

Immunoglobulin IgA (IgA) Test Kit (Immunoturbidimetry)

【INTEND USE】

This reagent is intended for the in vitro quantitative determination of Immunoglobulin IgA (IgA) in human serum. The percentage of IgA is 15% in the soluble immunoglobulin. About 90% of serum IgA exists as a monomer, and the rest as dimer and multimeric forms. Most of IgA is not in the serum, but exists in tears, saliva, digestive and respiratory secretions in another important form of secretory IgA. Decline in IgA concentrations occur in primary and secondary immunodeficiency syndrome, Protein loses from intestinal and the burnt skin, which can also cause decrease of IgA concentration. Elevated IgA level relates with severe infections and autoimmune diseases, in particular, liver inflammation can cause elevated serum IgA levels.

【METHODOLOGY】

Based on the detected IgA antibody reaction between an antigen and IgA, formation of immune complexes, at a wavelength of Detecting changes in turbidity at 340nm, which is proportional to the degree of variation and IgA levels in the sample.

【STABILITY AND STORAGE】

Unopened, avoid light preservation in 2 ~ 8 ℃, valid for 12 months;
Opened, avoid contamination preservation in 2 ~ 8 ℃, valid for 1 month.
Reagent is not allowed frozen.

【SPECIMEN COLLECTION AND HANDLING】

It is best to fresh Serum, heparin anticoagulant blood plasma, and EDTA plasma. Serum or plasma should be separated from the blood cells within 2 hours after collection.

Sample stability:2～8℃ preservation stability in 3 months .

Do not use the contaminated samples. Specimens cannot be repeated freezing and thawing.

When the ascorbic acid concentration of sample≤1704 μmol/L;bilirubin concentrations≤598 μmol/L,hemoglobin hemoglobin≤5.00g/L, TG≤ 22.6mmol/L,was not observed clearly disturbance.

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

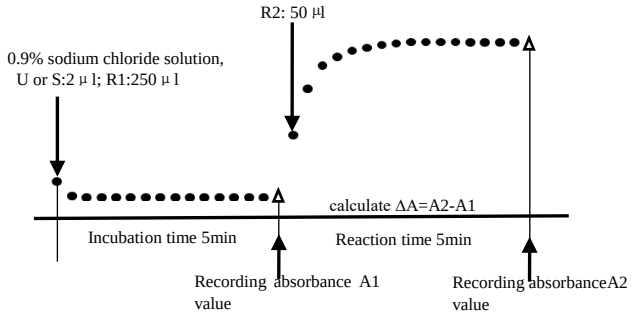
【SYSTEM PARAMETERS】

The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group

Temperature	37° C
Cuvette light path	1.0cm
Primary Wavelength	340 nm
Assay Type	Two Point End
Direction	Increase
Sample : Reagent 1: Reagent 2 Ratio	2:250:50
eg : Sample Vol.	2 μL
Reagent1 Vol.	250 μL
Reagent2 Vol.	50 μL
Linearity	0～550 mg/dL
Testing	Deducting the reagent blank

【OPERATION STEPS】

R1: Reagent 1 R2: Reagent 2 S: Calibrator U: Sample



【CALCULATION】

$$\text{IgA sample concentration} = \frac{\text{Sample } \triangle A}{\text{Calibrator } \triangle A} \times \text{calibrator concentration}$$

According to the calibration requirements, with different levels of calibration solution, together with 9 g/L sodium chloride solution as the blank. After measurement,the instrument automatic synthesize calibration curve for the calibration response quantity through the appropriate mathematical model (such as Logit/ Spline).Using IgA calibration values to calibrate instrument ,within the scope of the reportable results,the instrument directly report reliable test results.

【REFERENCE RANGE】

70~ 400mg/dL

By clinical trials, choose no less than 100 newborn or adults blood specimens, tested by automatic biochemical analyzer, and then processing the testing value with statistical method, calculating out the reference range.

Recommendation: The laboratory set up its own reference range!

【THE LIMITATION OF TEST RESULTS】

Immunoglobulin IgA (IgA) testing is just one of the standard that clinicist diagnose the patient. Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

【THE INTERPRETATION OF TEST RESULTS】

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result；When one sample deviates from the expected value too far, need to be tested again.

【PERFORMANCE INDEX】

1.Reagent blank absorbance ≤0.25,(340nm,lcm optical path).
2.Precision: repeatability CV≤10%;batch variations R≤10%.
3.Accuracy: relative deviation ≤10%.
4.Linearity range: 0～550 mg/dL,r≥0.990.
5. Stability: All package reagent, non corrosive gas and avoid light, preservation in 2~8 ℃, stable 12 months.

【ATTENTION】

1. After the kit is opened airtight storage method should be designated.
2. detect contact with the specimen tubes and other equipment should be disposed of medical waste treatment methods.
3.Other models recommended that each laboratory instrument independently verified. For detailed measurement parameters can contact me.

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