BIOBASE

Immune Globulin G (IgG) Test Kit

(Immunoturbidimetric)

【NAME】

Immune Globulin G (IgG) Test Kit (Immunoturbidimetric)

【INTEND USE】

For the detection of human serum or plasma immunoglobulin G levels.

IgG is produced by plasma cells up to a number of immunoglobulins the total immunoglobulin 75% white. Its main function is to bind to antigens, trigger further decomposition antigen. IgG Decreased concentrations occur in primary and secondary immunodeficiency syndrome. May also be due to lower Loss of protein from the intestines or by being scalded skin caused by the loss. Serious infections andAutoimmune diseases can cause increased IgG concentration, such as lupus, infectious diseases and cystic fibrosis disease processes.

【METHODOLOGY】

The IgG antibody detection based on the reaction between the antigen and IgG, immune complexes are formed, at 700nm Wavelength to detect changes in turbidity, which is proportional to the degree of change in IgG concentration in the sample.

【STABILITY AND STORAGE】

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

【SPECIMEN COLLECTION AND HANDLING】

Serum, heparin or EDTA-plasma.
Serum or plasma should be separated from the blood cells within 2 hours after collection.
Sample stability: stored at 2-8 ℃ 3 months.

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

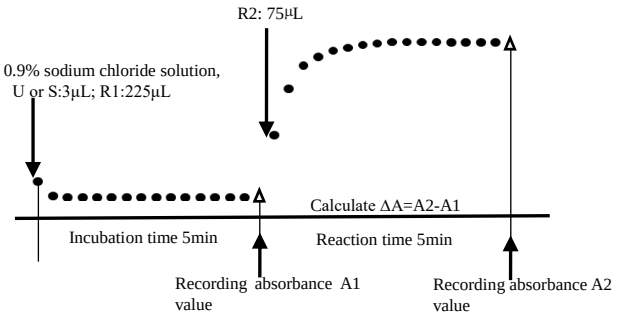
【TESTING SPECIFICATION】

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	700 nm
Assay Type	Two Point End
Direction	Increase
Sample : Reagent 1: Reagent 2 Ratio	2:250:50
eg : Sample Vol	2μL
Reagent1 Vol	250 μL
Reagent2 Vol	50 μL
Linearity	0 ~ 2500 mg / dL
Testing	Deducting the reagent blank

【OPERATION STEPS】

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



【CALCULATION】

ΔAbs = [（A2- A1）Calibrator or Sample] － [（A2- A1）Blank]
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 IgG calibration values to calibrate instrument ,within the scope of the reportable results,the instrument directly report reliable test results.

【REFERENCE RANGE】

700 ~1600mg/dL (7 ~ 16 g/L)
Unit Conversion: mg/dLx 0.01 = g/L
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.

【THE LIMITATIONS OF TESTING RESULTS】

Immunoglobulin IgG (IgG) was measured just one of the indicators clinicians diagnose patients were,Clinicians also according to the patient's physical symptoms, medical history and other diagnostic programs, diagnostic tools Comprehensive judgments.

【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. The reagent blank absorbance ≤0. 300, (700nm, lcm light path).
2. Precision: repeatability CV≤10%; difference between batches R≤10%.
3. Accuracy: relative deviation ≤10%.
4. The linear range: 0 ~ 2500 mg / dL,
5. Stability: The reagent at 2 ℃ ~ 8 ℃, dark environment, non-corrosive gases stored for 12 months.

【ATTENTION】

1. The reagent contains sodium azide (toxic), strayed into the eyes, mouth, or your skin to immediately contaminated Rinse thoroughly with water, if necessary, to the hospital. Sodium azide can be copper, lead, metal Generate strong reactions occur metal azide, so please fully diluted waste when discarded and rinse Drain, in order to avoid remaining in the drain pipes.
2. Sample bilirubin ≤600 μ mol / L, hemolysis ≤5g / L, lipid ≤5g / L was not observed significant interference.
3. After the kit is opened airtight storage method should be designated.
4. detect contact with the specimen tubes and other equipment should be disposed of medical waste treatment methods.
5. Other models recommended that each laboratory instrument independently verified. For detailed measurement parameters can contact me.
6. You can not mix different batches of reagents, reagent lot to replace, recalibration!
7. different batches calibrators, controls the target values and ranges, see the corresponding label

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