BIOBASE

Immunoglobulin IgM（IgM）Test Kit

（Immunoturbidimetric）

【NAME】

Name:Immunoglobulin IgM（IgM）Test Kit（Immunoturbidimetric）

【INTEND USE】

For serum or plasma levels of immunoglobulin IgM (IgM) testing.

IgM concentrations decreased occurrence in primary and secondary immunodeficiency syndrome. IgM values reduce protein loss is common in intestinal diseases and burns. Severe infections and autoimmune diseases can cause IgM concentration rises. Multiple macroglobulinemia, bacteria and parasites infectious diseases, liver disease, rheumatoid arthritis and cystic fibrosis can increase IgM concentrations.

【METHODOLOGY】

The IgM antibody detection based on the reaction between an antigen and IgM, formation of immune complexes, at 340nm Detecting a turbidity change of wavelength, which is proportional to the degree of change in the sample of IgM levels.

【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.

When sample bilirubin ≤600 μ mol / L, hemolysis ≤5g / L, lipid ≤5g / L was not observed significant interference.

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

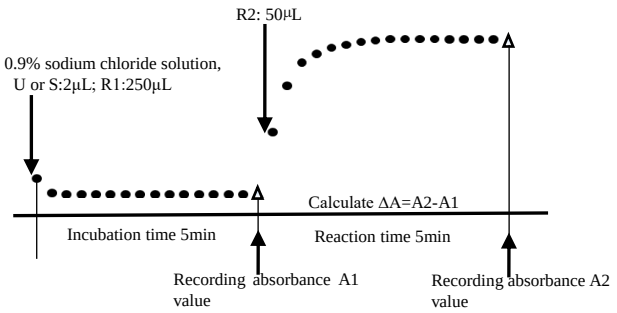
【TESTING SPECIFICATION】

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	340 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 ~ 500mg / 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 IgM calibration values to calibrate instrument ,within the scope of the reportable results, the instrument directly report reliable test results.

【REFERENCE RANGE】

40 ~ 230mg/dL (0.4 ~ 2.3g/L)

Unit Conversion: mg/dL x 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 IgM (IgM) measuring 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 into 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. The reagent blank absorbance ≤0.1500, (340nm, lcm light path).
2. Precision: repeatability CV≤10%; difference between batches R≤10%.
3. Accuracy: relative deviation ≤10%.
4. The linear range: 0 ~ 500mg / 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. After the kit is opened airtight storage method should be designated.
3. detect contact with the specimen tubes and other equipment should be disposed of medical waste treatment methods.
4. Other models recommended that each laboratory instrument independently verified. For detailed measurement parameters can contact me.
5. You can not mix different batches of reagents, reagent lot to replace, recalibration!
6. Different batches calibrators, controls the target values and ranges, see the corresponding label.Recommended that each laboratory establish its own quality control range.

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