BIOBASE

Complement C4（C4） Test Kit

(Immunoturbidimetry)

【NAME】

Complement C4（C4）Test Kit (Immunoturbidimetry)

【INTEND USE】

This reagent is intended for the in vitro quantitative determination of Complement C4（C4） in human serum. Complement is mainly synthesized in the liver, where the complement C3 and C4 are the most frequently detected. C4 is an important component of the classical pathway of complement activation, its determination will help SLE and other autoimmune diseases diagnosis and treatment. Autoimmune chronic active hepatitis, SLE, multiple sclerosis, rheumatoid arthritis and LgA nephropathy can lead to C4 content decrease. In SLE, C4 decreases often earlier than other complement components, and in the process of remission, C4 picks up later than other ingredients. When compared with non-lupus nephritis, C4 was significantly lower in lupus nephritis patients. The acute phase of rheumatic fever, around nodosa, dermatomyositis, myocardial infarction, Rditer's syndrome and various types of polyarthritis can lead to C4 levels increase.

【METHODOLOGY】

C4 and C4 antibody latex particle reagent is reaction, And generate immune complex. Detection of the turbidity of change at 340nm, the degree of change is proportional to the C4 levels in the samples.

【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】

Using serum as sample.Heparin or EDTA plasma can also be used as a sample.

When the blood fat of sample≤5g/L, bilirubin≤600umol/,hemolysis ≤ 5g/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.	250μL
Reagent2 Vol.	50 μL
Linearity	0～130mg/dL
Testing	Deducting the reagent blank

【ATTENTION】

1.Should be according to the specified method to store reagent after opening reagent.

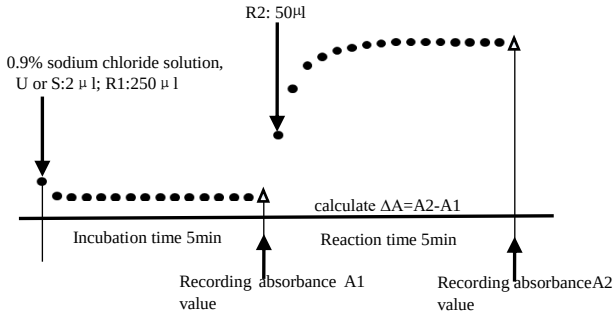
2..Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.

3.According to medical waste disposal method,deal with contact test specimen tube apparatus.

4..Other type of instrument, it is recommended that each laboratory to verify, if you need detailed measurement parameters can be contact with my company.

【OPERATION STEPS】

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



【CALCULATION】

$$\text{C4 sample concentration} = \frac{\text{Sample}\triangle A}{\text{Calibrator}\triangle A} \times \text{Standard concentration}$$

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 C4 calibration values to calibrate instrument ,within the scope of the reportable results,the instrument directly report reliable test results.

【REFERENCE RANGE】

Adults: 10~40 mg/dL (0.1~0.4 g/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.

Recommendation: The laboratory set up its own reference range!

【THE LIMITATION OF TEST RESULTS】

Complement C4（C4）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 ≤0.5,(340nm,lcm optical path).

2.Precision: repeatability CV≤10%;batch variations R≤10%.

3.Accuracy: relative deviation ≤10%.

4.Linearity range: 0～130mg/dL, r≥0.990.

5. Stability: All package reagent, non corrosive gas and avoid light, preservation in 2~8 ℃, stable 12 months.

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