Direct bilirubin (D-BIL) Test Kit

(DCA Method)

【NAME】

Direct bilirubin (D-BIL) Test Kit (DCA Method)

【INTEND USE】

This reagent is intended for the in vitro quantitative determination of Direct bilirubin (D-BIL) in human serum. Decrease of direct bilirubin was observed in various types of hepatitis, liver cirrhosis and obstructive jaundice, and it is more sensitive than transaminase, especially for the diagnosis of chronic hepatitis and early cirrhosis prognosis evaluation. Reduction of direct bilirubin was observed in severe anemia.

【METHODOLOGY】

D-BIL with 2, 4-2 Chloro aniline diazonium salt form diazo compound, red color under the condition of acid.

【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.

Sample stability: Sample must avoid light preservation.

2～8℃ preservation stability in 12h;

-20℃ preservation stability in 3 months.

Do not use the contaminated samples.

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

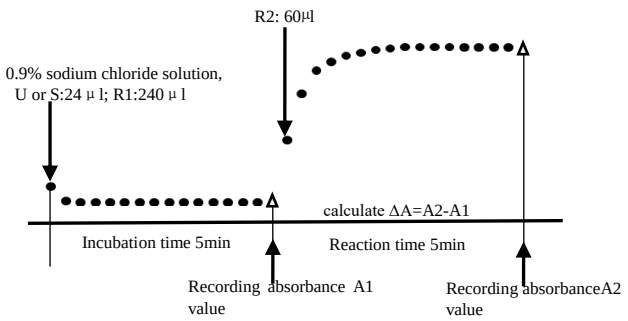
【SYSTEM PARAMETERS】

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	546 nm
Secondary Wavelength	700nm
Assay Type	Two Point End
Direction	Increase
Sample : Reagent 1: Reagent 2 Ratio	2: 20: 5
eg : Sample Vol.	24 μL
Reagent1 Vol.	240 μL
Reagent2 Vol.	60 μL
Linearity	0～160μmol/L
Testing	Deducting the reagent blank

【OPERATION STEPS】

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



【CALCULATION】

Use The Calibrator

$$\text{Sample D-BIL concentration} = \frac{\text{Sample } \triangle A}{\text{Calibrator } \triangle A} \times \text{Calibrator concentration}$$

【REFERENCE RANGE】

0～8.8μmol/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】

Direct bilirubin (D-BIL) 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 ≤0.3,(546nm,lcm optical path).

2.Precision: repeatability CV≤5%;batch variations R≤5%.

3.Accuracy: relative deviation ≤10%.

4.Linearity range: 0～160μmol/L,r≥0.990.

【ATTENTION】

1. Reagent contains sodium azide (toxic) preservatives, avoid contact with skin and mucous membrane. If necessary preventive measures should be taken use of reagents, reagent contact with skin and mucous membrane, please rinse with water, please go to a doctor if necessary.
2. The maximum linearity is 160μmol.If testing results is upper limit, dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.
3. Liquid waste disposal: Suggest follow local regulations.
4. This specification is applied to the double reagent.
5. Different batches reagents cannot mix, when replacing reagents batch number, please calibration again.

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