BIOBASE

Total bilirubin (T-BIL) Test Kit

(Diazonium 2, 4-Dichloroaniline)

【NAME】

Total bilirubin (T-BIL) Test Kit (Diazonium 2, 4-Dichloroaniline)

【INTEND USE】

This reagent is intended for the in vitro quantitative determination of Total bilirubin (T-BIL) in human serum. When exceeding 20.1 umol/L, Clinical manifestations of total bilirubin is jaundice; When exceeding 34.2 umol/L, Clinical manifestations of total bilirubin is signs of jaundice. Extensive damage to red blood cells, biliary obstruction and liver disease, can lead to increased serum bilirubin and cause jaundice. Therefore, the determination of total bilirubin has important clinical significance in jaundice or not, the damage extent of liver cell and prognosis. Severe liver failure, aplastic anemia, chronic nephritis will lead to low serum total bilirubin levels.

【METHODOLOGY】

In the presence of surfactant, bilirubin and 2, 4-2 chloro aniline diazonium reaction into diazo compound, becomes red under the acid condition.

【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:15-25℃ preservation stability in 1 day.

2-8℃ preservation stability in 1 week.

-20℃ preservation stability in 3 months.

Do not use the contaminated samples.

【APPLICABLE INSTRUMENT】

Fully automatic biochemical analyzer.

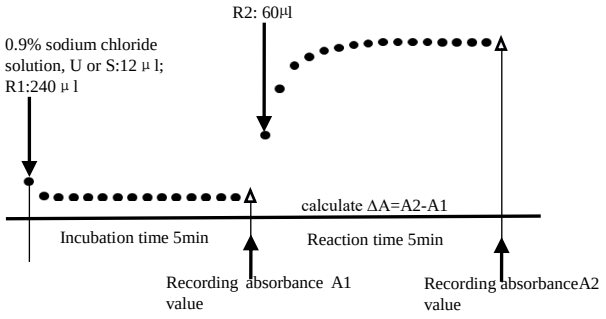
【SYSTEM PARAMETERS】

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
Assay Type	Two Point End
Direction	Increase
Sample : Reagent 1: Reagent 2 Ratio	10:200:50
eg : Sample Vol.	10 μL
Reagent1 Vol.	200 μL
Reagent2 Vol.	50 μL
Linearity	0～500 μmol/L
Testing	Deducting the reagent blank

【OPERATION STEPS】

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



【CALCULATION】

$$\text{Sample TBIL concentration} = \frac{\text{Sample}\triangle\text{Abs}}{\text{Calibrator}\triangle\text{Abs}} \times \text{Calibrator concentration}$$

【REFERENCE RANGE】

Newborn: within 24h 0～227 μ mol/L Adult: 0～20.0 μ mol/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】

Total bilirubin (T-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,(546 nm,lcm optical path).

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

3.Accuracy: relative deviation ≤10%.

4.Linearity range: 0～500μmol/L, r≥0.990.

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

【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 2.50g/L.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.

Biobase Biodustry(Shandong)Co.,Ltd

Add: Biobase Biological Industrial Park, Mingshui Economic Development Zone, Jinan, China, 250200

Tel: 0086-531-81219801/03 Fax: 0086-531-81219804