

LIQUIZYMÉ

# TOTAL BILIRUBIN

(DMSO Method)



**BEACON**

| Code   | Product Name              | Pack Size |
|--------|---------------------------|-----------|
| LS054A | Liquizyme Total Bilirubin | 240 ml    |
| LS054B | Liquizyme Total Bilirubin | 1200 ml   |

## Intended Use

Diagnostic reagent for quantitative *in vitro* determination of Bilirubin in human serum.

## Clinical Significance

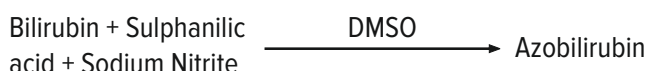
Bilirubin is a breakdown product of haemoglobin. Bilirubin formed in the reticulo endothelial system is transported bound by albumin to the liver. This bilirubin is water insoluble and is known as indirect or unconjugated bilirubin. In the liver, bilirubin is conjugated to glucuronic acid to form direct bilirubin. Conjugated bilirubin is excreted via the biliary system into the intestine. Here it is metabolised by bacteria to urobilinogen & stercobilinogen.

## Principle

In the determination of Bilirubin Total, Bilirubin is coupled with diazotized sulphanilic acid in the presence of ethylene glycol and dimethylsulfoxide as solvents to produce an intensely colored diazo dye. The intensity of colour of this solution is proportional to the concentration of the bilirubin total in the sample.

## Reaction

### Total Bilirubin



## Contents:

### Reagent 1 : Total Bilirubin Reagent

Buffer : < 15 mmol/l  
Sulphanilic Acid : >20 mmol/l

### Reagent 2 : Total Nitrite Reagent

Sodium Nitrite : > 10 mmol/l

### Reagent 3: Bilirubin Artificial Standard : 10 mg/dl

Ready to use

## Unit Conversion

mg/dl x 16.95 = µmol/l

## Normal Value :

Serum Total Bilirubin : upto 1.0 mg/dl

Each Laboratory should establish it's own normal range representing its patient population.

## Reagent Preparation

Reagents are liquid, ready to use.

## Stability and storage

The unopened reagents are stable till the expiry date stated on the bottle and label when stored at room temperature.

## Total Bilirubin

### Performance Data

Data contained within this section is representative of performance on Beacon system. Data obtained in your laboratory may differ from these values.

Limit of quantification : 0.0052 mg  
Linearity : 20 mg/dl  
Measuring range : 0.0052 – 20 mg/dl

| Intra-assay precision<br>Within run (n=20) | Mean<br>(mg/dl) | SD<br>(mg/dl) | CV<br>(%) |
|--|-----------------|---------------|-----------|
| Sample 1                                   | 1.06            | 0.03          | 3.16      |
| Sample 2                                   | 4.47            | 0.04          | 0.92      |
| Inter-assay precision<br>Run to run (n=20) | Mean<br>(mg/dl) | SD<br>(mg/dl) | CV<br>(%) |
| Sample 1                                   | 4.06            | 0.01          | 0.35      |

## Comparison

A comparison between Beacon Total Bilirubin (y) and a commercially available test (x) using 20 samples gave following results:

y = 0.999 x + 0.042 mg/dl  
r = 0.999

## Linearity:

This procedure is linear upto 20 mg/dl. If the values exceed this limit, dilute the sample with normal saline (NaCl 0.9%) and repeat the assay. Multiply result by dilution factor.

## Interferences

Following substances do not interfere:  
haemoglobin up to 7.5 g/l, triglycerides up to 1500 mg/dl.

## Warning And Precautions

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person.

**Procedure:**

Pipette into clean dry test tubes labeled as **Blank (B)**, and **Test (T)** :

**Total Bilirubin**

| Addition Sequence         | (B)     | (T)     |
|---------------------------|---------|---------|
| Total Bilirubin Reagent   | 1000 µl | 1000 µl |
| Total Bilirubin Activator | -       | 20 µl   |
| Serum                     | 50 µl   | 50 µl   |

Mix well and incubate at 37°C for exactly 5 minutes. Measure the absorbance of the Test Samples (Abs. T) immediately against their respective Blanks.

**Calculation****With factor:**

Total Bilirubin = OD of test - OD of sample blank x Factor (20)

**With artificial standard:**

$$\text{Bilirubin Concentration (mg/dl)} = \frac{\text{OD test} - \text{OD of sample Blank}}{\text{OD of standard}} \times 10$$

**Assay Parameters For Photometers**

| Mode                           | End Point |
|--------------------------------|-----------|
| Wavelength                     | 546       |
| Sample Volume (µl)             | 50        |
| Total Bilirubin Reagent (µl)   | 1000      |
| Total Bilirubin Activator (µl) | 20        |
| Incubation Time                | 5 min     |
| Reaction temperature (°C)      | 37        |
| Linearity Low (mg/dl)          | 0.0052    |
| Linearity High (mg/dl)         | 20        |
| Blank with                     | Serum     |
| Standard Concentration         | 10 mg/dl  |
| Unit                           | mg/dl     |

**References**

1. Cornall, A. G., Bardawill, C. J., David, M. M.: J. Biol. Chem. 177, 751, 1949.
2. Doumas, B. T., Bayse, D. D. a kol.: Clin. Chem. 27, 1642, 1981.
3. Chromý, V., Fischer, J.: Clin. Chem. 23, 754, 1977.
4. Chromý, V., Fischer, J., Vozníček, J.: Z. Med. Labor. Diagn. 21, 333, 1980.
5. Tietz Textbook of Clinical Chemistry and Molecular diagnostics. Burtis, C.A.
6. Ashwood, E.R., Bruns, D.E.; 5th edition, WB Saunders.

**Symbols Used On Labels**

Catalogue  
Number



Manufacturer



See Instruction  
for Use



Lot Number



Content



Storage Temperature



Expiry Date



In Vitro Diagnostics

BEA/24/BTD/LS/IFU Ver-01  
23/07/2024

