台塑生醫科技股份有限公司
FORMOSA BIOMEDICAL TECHNOLOGY CORP.

BILIRUBIN DIRECT DBIL

FOR BECKMAN CX AND LX SYSTEMS

INTENDED USE

For the quantitative determination of direct Bilirubin in serum

CLINICAL SIGNIFICANCE

An increase in the formation or retention of Bilirubin in the body results in increased levels of serum Bilirubin and jaundice. This hyperbilirubinemia is classified as either pre-hepatic, hepatic or post-hepatic depending on the principal cause of condition. Therefore, determination of the total Bilirubin and its conjugated (direct) Bilirubin is important for the differential diagnosis of hyperbilirubinemia.

PRINCIPLE

Direct bilirubin in aqueous solution reacts with diazotized sulfanilic acid to form an azobilirubin.
The reaction formula is as follows:

Direct Bilirubin + diazo + H^+ ———→ azobilirubin (red color)

SPECIMEN COLLECTION AND PREPARATION

The sample be collected without hemolysis, since hemoglobin inhibits the diazo reaction.
Avoid direct light exposure to the specimen since Bilirubin values may decrease as much as 50% in one hour (vaidze et. al.). Serum specimen may be kept in dark in 2~8℃ for up to one week, and in freezer for 3 months without appreciable change in the Bilirubin levels.

REAGENT

· Each kit contains 2 cartridges of total Direct Bilirubin reagent (2×400 tests)
· Ready to use
· Components:

	Sulfanilic acid	27 mM;
	Sodium nitrite	0.12mM;
	HCl	51 mM..

PRECAUTIONS:

1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

STORAGE: 2~8℃

PROCEDURE:

Use open channel and follows the attached parameters and procedures to perform the tests.

EXPECTED VALUE:

Adults < 0.35mg/dl (6.0μmol/l)

Serum Bilirubin levels are usually higher in the newborn, but fall rapidly after the first week and reach adult levels by the fourth week of life.
Since normal values are affected by age, sex, diet, geographical location, and other factors, each laboratory should establish its own 'normal' value based upon the specific situation in daily laboratory operation.

NOTE: It is generally recommended that each laboratory establish its own range of normal values for commonly performed tests.

REFERENCES:

1. Malloy, H.T. and Evelyn, K.A. 1960, j.Biol. Chem. 119,48.
2. Valdez, O.S.et.al.1971 J.Pediat 79,1015.
3. Henry, R.J. 1974. Clinical Chemistry: Principles and Technics. Medical Department, Harper and Row, New York.
4. Young, D.S.et.al. 1975. Clin.Chem. 21,No.5.
5. Winston, S.B.Cehelyk. 1968. Clin.Chem. 14:107.
6. Walters, M.and Gerarde H. 1970. Microchem J. 15:231.