DIRECT BILIRUBIN SYSTEM PACK

(DMSO METHOD)

B Auto 200, Unicorn 230, Unicorn 120 , Bonavera Chem 200 , Beaconic chem 200,Beaconic B200,Beaconic analyzer 120 & Bonavera chem 100(Fully Auto Biochemistry Analyzer)

BEACON

Code	Product Name	Pack Size
BA236	Direct Bilirubin System Pack	4x40 +4x10 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.

TOTAL BILIRUBIN = INDIRECT BILIRUBIN + DIRECT BILIRUBIN

Bilirubin Total is elevated in obstructive conditions of the bile duct, hepatitis, cirrhosis in haemolytic disorders and several inherited enzyme deficiencies.

PRINCIPLE

In the determination of Bilirubin Total, Bilirubin is coupled with diazotized sulfanilic 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:

Direct Bilirubin

Bilirubin + Sulphanilic acid + Sodium Nitrite ⟶ Azobilirubin

CONTENTS:

Reagent 1 : Direct Bilirubin Reagent

Buffer < 15 mmol/l

Sulphanilic Acid < 20 mmol/l

Reagent 2 : Direct Nitrate Reagent

Sodium Nitrite < 30 mmol/l

SAMPLES:

at +2 - + 8°C protected from light, as it is photosensitive.

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.

On board stability: Min 30 days (+8 - +25°C) if not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use unheamolytic serum

It is recommended to follow NCCLS procedures (or similar standardized

Stability: 1 day at +15 - +25°C

7 days at +2 - +8°C

Discard contaminated specimens.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

Its recommended to run normal and abnormal control sera to validate reagents performance.

UNIT CONVERSION

mg/dl x 16.95 = µmol/l

NORMAL VALUE :

Serum :

Direct Bilirubin : upto 0.3 mg/dl

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

PERFORMANCE DATA

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

Limit of quantification: 0.0052 mg/dl

Linearity: 20 mg/dl

Measuring range: 0.0052 - 20 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	0.793	0.005	0.62
Sample 2	2.137	0.02	1.35
Inter-assay precision Run to run (n=20)	**Mean (mg/dl)**	**SD (mg/dl)**	**CV (%)**
Sample 1	1.235	0.02	1.27

COMPARISON

A Comparison between Direct Bilirubin System Pack (y) and commercially available test (x) using 20 samples gave following results:

y = 0.998x - 0.008 mg/dl , r = 1

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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. MSDS will be provided on request.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 , Bonavera Chem 200,Beaconic chem 200,Beaconic B200,Beaconic analyzer 120 & Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Test Name	Direct Bilirubin
Full Name	Direct Bilirubin
PRI Wave	546 nm
SEC Wave	700 nm
Assay/point	2 POINT END
Start	16
End	34
Decimal	2
Unit	mg/dl
Linearity Range Low	0.0052
Linearity Range High	20
Sample Volume	15 µl
Reagent 1 (R1) Volume	200 µl
Reagent 1 (R2) Volume	10 µl
Substrate Depleted/Abs.limit	-
Linearity	20 mg/dl
Out Of Linearity Range	-
Calibration Type	2 POINT LINEAR
Points	2
Blank Type	REAGENT
Concentration Blank	0.00
Concentartion Std	Refer calibrator value sheet

NOTE

Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

REFERENCES

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3. Chromy, V., Fischer,J.: Clin.Chem. 23,754, 1977.
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6. Ashwood, ER., Bruns, D.E.; 5th edition, WB Saunders 1980

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

BEA/24/BDD/SB/IFU Ver: 03
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