BILIRUBIN SYSTEM PACK

(TOTAL & DIRECT)

Unicorn 480, Bonavera Chem 480 & Bonavera Chem 400

(Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI09A	Bilirubin System Pack	4 x 40 + 4 x 5 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:

Total Bilirubin

Bilirubin+Sulphanilic acid+Sodium Nitrite $\xrightarrow{\text{DMSO}}$ Azobilirubin

Direct Bilirubin

Bilirubin + Sulphanilic acid + Sodium Nitrite $\longrightarrow$ Azobilirubin

CONTENTS:

Reagent 1 : Total Bilirubin Reagent

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

Reagent 2 : Direct Bilirubin Reagent

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

Reagent 3 : Total Bilirubin Activator

Sodium Nitrite : > 30 mmol/l

Reagent 4 : Direct Bilirubin Activator

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 temperture.

On board stability: Min 30 days if refrigerated (2-10°C) and 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
3 months at -20°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 :
Total Bilirubin : upto 1.0 mg/dl

Direct Bilirubin : upto 0.3 mg/dl

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

TOTAL BILIRUBIN

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
Linearity: 20 mg/dl
Measuring range: 0.0052 – 20 mg/dl

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	1.06	0.03	3.16
Sample 2	4.47	0.04	0.92

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	4.06	0.01	0.35

COMPARISON

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

y = 0.990 x - 0.042 mg/dl
r = 0.999

DIRECT BILIRUBIN

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
Linearity: 20 mg/dl
Measuring range: 0.0052 – 20 mg/dl

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	0.251	0.01	3.59
Sample 2	1.15	0.01	0.47

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	1.16	0.01	1.02

COMPARISON

A comparision between Bilirubin System Pack (y) and commercially available test (x) using 20 samples gave folloing results:
y = 0.993 x - 0.011 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.

Parameter for Unicorn 480, Bonavera Chem 480 & Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

FOR TOTAL BILIRUBIN

TEST NAME	Bilirubin
FULL NAME	Bilirubin
PRI WAVE	546 nm
SEC WAVE	700 nm
ASSAY/POINT	2 Point End
START	7
END	33
DECIMAL	2
UNIT	mg/dl
LINEARITY RANGE LOW	0.0052
LINEARITY RANGE HIGH	20
SAMPLE VOLUME	15 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	10 µl
SUBSATRATE DEPLETED	-
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.
SAMPLE VOLUME	15 µ l

Parameter for Unicorn 480, Bonavera Chem 480 & Bonavera chem 400 (Fully Auto Biochemistry Analyzer)

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TEST NAME	Bilirubin
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BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTARTION STD	Refer calibrator value sheet.
SAMPLE VOLUME	15 µ l

REFERENCES

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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., Vozníèek, 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

IVD

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