

Performance Characteristics

Precision

Within run (Repeatability)

	Direct	
	Level 1	Level 2
n	20	20
Mean (mg/dL)	0.299	0.77
SD	0.016	0.057
CV%	5.41	7.4

Run to run (Reproducibility)

	Direct	
	Level 1	Level 2
n	20	20
Mean (mg/dL)	0.32	0.82
SD	0.023	0.062
CV%	5.57	8.1

Methods Comparison

A comparison between Spectrum Diagnostics Bilirubin and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.975 was obtained.

Sensitivity

When run as recommended, the sensitivity of this assay is 0.1 mg/dL (1.7 µmol/L) for total and 0.04 mg/dL (0.68 µmol/L) for direct bilirubin.

Linearity

The reaction is linear up to a direct bilirubin concentration of 18 mg/dL (308 µmol/L). Specimens showing higher concentration should be diluted 1+4 with physiological saline and repeat the assay (result*5).

Interfering substances

Serum, plasma

Haemolysis

Avoid haemolysis since it interferes with the test.

Lipemia

Lipemic specimens interfere with the test.

Drugs

Theophyllin and propranolol may cause artificially low total bilirubin levels.

Expected Values

Direct Bilirubin 0 – 0.3 mg/dL (0 – 51 µmol/L)

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Analytical Range

Direct bilirubin : 0.04 – 18 mg/dL (0.68 – 308 µmol/L)

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Balistreri WF, Shaw LM. Liver function. In: Tietz NW, ed. Fundamentals of clinical chemistry. 3rd ed. Philadelphia: WB Saunders; 1987:729-761.
2. Malloy HT, Evelyn KA. The determination of bilirubin with the photoelectric colorimetric method. J Biol Chem. 1937;119:481-490.
3. Tietz NW, ed. Clinical guide to laboratory tests. 3rd ed. Philadelphia: WB Saunders; 1995:268-273.

ORDERING INFORMATION

CATALOG NO.	QUANTITY
224 001	60 test



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