

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%	5.35	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%	7.19	7.56

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 μ mol/L) for total and 0.04 mg/dL (0.68 μ mol/L) for direct bilirubin.

Linearity

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

Interfering substances

Haemolysis

Avoid haemolysis since it interferes with the test.

Lipemia

Lipemic specimens interfere with the test.

Drugs

Theophylline and propranolol may cause artificially low total bilirubin levels.

Expected Values

Direct Bilirubin 0 – 0.3 mg/dL (0 – 51 μ mol/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 μ mol/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

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



Egyptian Company for Biotechnology (S.A.E)

Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.

Tel: +202 4489 2248 - Fax: +202 4489 2247

www.spectrum-diagnostics.com

E-mail: info@spectrum-diagnostics.com



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



IFUFCC65

Rev.(7), 8/6/2022