



## 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

Theophylline 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

- 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



Spectrum For Diagnostic Industries - Free Zone

Ismailia Free Zone, Block 5 .

Cairo- Port said Avenue.

Ismailia, Egypt

Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015

www.sdi-fz.com



**MDSS GmbH**  
Schiffgraben 41  
30175 Hannover, Germany



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