

### **Intended Use**

For the quantitative determination of direct bilirubin in human serum. For *in vitro* diagnostic use.

## Principle

Bilirubin reacts with diazotized sulfanilic acid to produce azobilirubin, which has an absorbance maximum at 560 nm in the aqueous solution. The intensity of the color produced is directly proportional to the amount of direct bilirubin concentration present in the sample.

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# Teco Diagnostics

#### Test:

Direct Bilirubin Reagent (B538-480)

#### **Number of Tests:**

480 tests

4 x 120mL bottles

#### Format:

Liquid

#### Method:

Colorimetric

#### **Testing Procedure:**

Manual

#### **Storage Temperature:**

15-30°C

#### Wavelength:

560 nm

#### Linearity:

20 mg/dL

#### **Expected Values:**

Infant (after one month) & adults: 0-0.5 mg/dL

It is strongly suggested that each laboratory establish its own range of expected values.

#### **Reagent Deterioration:**

The reagent should be discarded if: (1) Sodium Nitrate reagent has a yellow discoloration; (2) Working reagent fails to achieve assigned assay values of fresh control sera.

#### **Limitations of Procedure:**

Sera with values above 20mg/dL must be diluted 1:1 with isotonic saline, reassayed, and the final result multiplied by two.

In this assay materials which come in contact with specimens should be clean and free of contamination by heavy metals, detergents and other chemicals.