**Bilirubin Auto Direct FS**

Diagnostic reagent for quantitative in vitro determination of direct bilirubin in serum or plasma on DiaSys respons®910

**Order Information**
Cat. No. 1 0821 99 10 920
4 twin containers for 200 tests each

**Method**
Photometric test using 2,4-dichloroaniline (DCA)

**Principle**
Direct bilirubin in presence of diazotized 2,4-dichloroaniline forms a red colored azocompound in acidic solution.

**Reagents**
Components and Concentrations

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1: EDTA-Na₂</td>
<td>0.1 mmol/L</td>
</tr>
<tr>
<td>NaCl</td>
<td>150 mmol/L</td>
</tr>
<tr>
<td>Sulfamic acid</td>
<td>100 mmol/L</td>
</tr>
<tr>
<td>HCl</td>
<td>0.5 mmol/L</td>
</tr>
<tr>
<td>R2: 2,4-Dichlorophenyl-diazonium salt</td>
<td>0.5 mmol/L</td>
</tr>
<tr>
<td>EDTA-Na₂</td>
<td>0.13 mmol/L</td>
</tr>
</tbody>
</table>

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents.

**Warnings and Precautions**
1. Reagents: Warning, H290 May be corrosive to metals. P234
2. In very rare cases, samples of patients with gammopathy might give falsified results [6].
3. To avoid contamination and carryover, special care should be taken in combination with Rheumatoid factor FS reagent.
4. Etrombogapag medication leads to falsely low or high results in patient samples.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.
6. For professional use only!

**Waste Management**
Please refer to local legal requirements.

**Reagent Preparation**
The reagents are ready to use. The bottles are placed directly into the reagent rotor.

**Specimen**
Serum or heparin plasma
It is very important to store the samples protected from light!

Stability [1]:
- 2 days at 20 – 25 °C
- 7 days at 4 – 8 °C
- 6 months at –20 °C in case of immediate freezing. Discard contaminated specimens. Freeze only once.

**Calibrators and Controls**
DiaSys TruCal U is recommended for calibration. This method has been standardized against the manual Jendrassik-Gróf test. DiaSys TruLab N and P should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

Cat. No. | Kit size
---|---
TruCal U | 5 9100 99 10 063 20 x 3 mL
TruLab N | 5 9000 99 10 062 20 x 5 mL
TruLab P | 5 9050 99 10 062 20 x 5 mL

**Performance Characteristics**

- Measuring range up to 7 mg/dL bilirubin (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).
- Limit of detection** 0.1 mg/dL direct bilirubin
- On-board stability 6 weeks
- Calibration stability 3 weeks

**Interfering substance**

<table>
<thead>
<tr>
<th>Interferences</th>
<th>Direct bilirubin [mg/dL]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbate</td>
<td>up to 30 mg/dL</td>
</tr>
<tr>
<td>Naproxen</td>
<td>up to 1 mmol/L</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>up to 10 mg/dL</td>
</tr>
<tr>
<td>Lipemia **</td>
<td>up to 25 mg/dL</td>
</tr>
<tr>
<td>Lipemia **</td>
<td>up to 400 mg/dL</td>
</tr>
<tr>
<td>Lipemia **</td>
<td>up to 2000 mg/dL</td>
</tr>
</tbody>
</table>

For further information on interfering substances refer to Young DS [5].

**Precision**

<table>
<thead>
<tr>
<th>Precision Parameter</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coefficient of variation [%]</td>
<td>2.69</td>
<td>1.18</td>
<td>0.85</td>
</tr>
<tr>
<td>Mean [mg/dL]</td>
<td>0.28</td>
<td>0.58</td>
<td>1.58</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.999</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Method comparison (n=102)**

**Conversion factor**

Bilirubin [mg/dL] x 17.1 = Bilirubin [µmol/L]

**Reference Range** [3]

 Adults and children ≤ 0.2 mg/dL (≤ 3.4 µmol/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

**Literature**


**Manufacturer**
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
Bilirubin Auto Direct FS
Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

### Identification
- This method is usable for analysis: Yes
- Twin reaction: No
- Name: DBIL
- Reagent barcode reference: 018

### Results
- Decimals: 2
- Units: mg/dL
- Correlation factor-Offset: 0.000
- Correlation factor-Slope: 1.000

### Range
- Gender: All
- Age
- URINE: >= <=0.2
- PLASMA: >= <=0.2
- CSF: Whole blood
- Gender: All
- Age

### Contaminants
- Please refer to r910 Carryover Pair Table

### Linear Kinetics
- Substrate depletion: Absorbance
- Linearity: Maximum deviation [%]

### Fixed Time Kinetics
- Substrate depletion: Absorbance limit
- Endpoint
- Stability: Largest remaining slope
- Prozone Limit [%]

### Reagents
- Decimals
- Units

### Sample
- Diluent: DIL A (NaCl)
- Hemolysis:
  - Agent [µL]: 0 (no hemolysis)
  - Cleaner
  - Sample [µL]: 0
- Technical limits
  - Concentration technical limits-Lower: 0.1
  - Concentration technical limits-Upper: 7

### SERUM
- Normal volume [µL]: 8
- Normal dilution (factor): 1
- Below normal volume [µL]: 15
- Below normal dilution (factor): 1
- Above normal volume [µL]: 2
- Above normal dilution (factor): 1

### URINE
- Normal volume [µL]: 8
- Normal dilution (factor): 1
- Below normal volume [µL]: 15
- Below normal dilution (factor): 1
- Above normal volume [µL]: 2
- Above normal dilution (factor): 1

### PLASMA
- Normal volume [µL]: 8
- Normal dilution (factor): 1
- Below normal volume [µL]: 15
- Below normal dilution (factor): 1
- Above normal volume [µL]: 2
- Above normal dilution (factor): 1
- Whole blood
- Normal volume [µL]: 8
- Normal dilution (factor): 1
- Below normal volume [µL]: 15
- Below normal dilution (factor): 1
- Above normal volume [µL]: 2
- Above normal dilution (factor): 1

### Calculations
- Model: X
- Degree: 1

* Enter calibrator value