Bilirubin Auto Direct FS*

Diagnostic reagent for quantitative in vitro determination of direct bilirubin in serum or plasma on DiaSys repons®920

Order Information
Cat. No. 1 0821 99 10 920
4 twin containers for 200 determinations 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
R1: EDTA-Na₂ 0.1 mmol/L
NaCl 150 mmol/L
Sulfamic acid 100 mmol/L

R2: 2.4-Dichlorophenyl-diazonium salt 0.5 mmol/L
HCl 900 mmol/L
EDTA-Na₂ 0.13 mmol/L

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 Keep only in original container. P390 Absorb spillage to prevent material damage.
2. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. Eltrombopag 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
For calibration, DiaSys TruCal U calibrator is recommended. This method has been standardized against the manual Jendrassik-Grôl test. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics
Measuring range up to 10 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** 0.01 mg/dL bilirubin
On-board stability 4 weeks
Calibration stability 4 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 50 mg/dL
Naproxen up to 50 mg/dL
Lipemia (triglycerides) up to 1000 mg/dL
For further information on interfering substances refer to Young DS [2].

Conversion factor
Bilirubin [mg/dL] \times 17.1 = Bilirubin [µmol/L]

Reference Range
For 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

<table>
<thead>
<tr>
<th>Test Details</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>DBIL</td>
<td>Auto Rerun</td>
</tr>
<tr>
<td>Report Name</td>
<td>Direct Bilirubin</td>
<td>Online Calibration</td>
</tr>
<tr>
<td>Unit</td>
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<td>M2 Start</td>
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<td>M2 End : 33</td>
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<td>Prozone Check : Lower</td>
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<td>Delta Abs./Min. : 0.0000</td>
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<tr>
<td>Technical Minimum</td>
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<td>Technical Maximum : 10.0</td>
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<tr>
<td>Y = aX + b a =</td>
<td>1.0000</td>
<td>b =</td>
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*Enter calibrator value*

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<tr>
<th>Test Details</th>
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</thead>
<tbody>
<tr>
<td>Sample Type</td>
<td>Serum</td>
<td></td>
</tr>
</tbody>
</table>

**Sample Volumes**

| Normal       | 8.00 µL | Dilution Ratio : 1 X |
| Increase     | 15.00 µL | Dilution Ratio : 1 X |
| Decrease     | 3.00 µL  | Dilution Ratio : 1 X |

**Standard Volume** : 8.00 µL

**Reagent Volumes and Stirrer Speed**

| RGT-1 Volume | 180 µL | R1 Stirrer Speed : High |
| RGT-2 Volume | 45 µL  | R2 Stirrer Speed : High |

**Test Details**

| Test          | DBIL       |                  |
| Sample Type   | Serum      |                  |

**Reference Range**

| Category | Male |                  |

**Reference Range**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>Upper Limit</th>
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<td>(mg/dL)</td>
<td>(mg/dL)</td>
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<tr>
<td>Panic</td>
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**Sample Types**

- Serum
- Urine
- CSF
- Plasma
- Whole Blood
- Other

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April 2020/9