BILIRUBIN TOTAL & DIRECT

INTENDED USE
Diagnostic reagent for quantitative in vitro determination of Total & Direct Bilirubin in human serum and plasma.

CLINICAL SIGNIFICANCE
Bilirubin is a breakdown product of haemoglobin. Bilirubin formed in the reticuloendothelial system is transported by albumin to the liver. This bilirubin is water insoluble and is known as indirect or unconjugated bilirubin. In the liver, bilirubin is conjugated to glucuronic acid to form direct bilirubin. Conjugated bilirubin is excreted via the biliary system into the intestine. Here it is metabolised by bacteria to urobilinogen and stercobilinogen.

TOTAL BILIRUBIN = INDIRECT BILIRUBIN + DIRECT BILIRUBIN

Working reagent stability
The working total & direct bilirubin reagents are stable for 7 days at 2-8°C, when protected from contamination and light. It is recommended to prepare fresh working solution before assay is performed.

STABILITY AND STORAGE
The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2-8°C.

SPECIMEN COLLECTION AND HANDLING
Use unheamolytic serum or plasma (heparin, EDTA). It is recommended to follow NCCLS procedures (or similar standardized conditions).

QUALITY CONTROL
For quality control ERBA NORM, Cat. No. BLT00080 and ERBA PATH, Cat. No. BLT00081 are recommended.

UNIT CONVERSION
mg/dl x 16.95 = µmol/l

EXPECTED VALUES
Total Bilirubin:
Adults: 0 – 2 mg/dl
Newborns: 0 – 0.2 mg/dl

Direct Bilirubin:
Newborns: up to 7.5 g/l

INTERFERENCES
Following substances do not interfere:
Bilirubin Total: haemoglobin up to 7.5 g/l, triglycerides up to 1500 mg/dl.
Bilirubin Direct: haemoglobin up to 10 g/l, triglycerides up to 1000 mg/dl.

ASSAY PROCEDURE

WORKING REAGENT STABILITY
The working total & direct bilirubin reagents are stable for 2 days at 15-25°C, 7 days at 2-8°C, 3 month at -20°C. In case of immediate freezing.

Freeze only once!
Discard contaminated specimens.

APPLICATIONS FOR AUTOMATIC ANALYSERS ARE AVAILABLE ON REQUEST.

ASSAY PARAMETERS FOR PHOTOMETERS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Bilirubin Total</th>
<th>Bilirubin Direct</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode</td>
<td>End Point</td>
<td>End Point</td>
</tr>
<tr>
<td>Wave length (nm)</td>
<td>546</td>
<td>546</td>
</tr>
<tr>
<td>Wavelength (nm)</td>
<td>630 (670)</td>
<td>630 (670)</td>
</tr>
<tr>
<td>Sample volume (µl)</td>
<td>25/50</td>
<td>25/50</td>
</tr>
<tr>
<td>Working reagent (µl)</td>
<td>100/200</td>
<td>100/200</td>
</tr>
<tr>
<td>Absorbance limit (max.)</td>
<td>0.2</td>
<td>0.2</td>
</tr>
</tbody>
</table>

COMPARISON
A comparison between XL-Systems Bilirubin Total & Direct (y) and a commercially available test (x) using 40 samples gave following results:

<table>
<thead>
<tr>
<th>Test</th>
<th>Working reagent (µl)</th>
<th>Add</th>
<th>Mean (mg/dl)</th>
<th>SD (mg/dl)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin Total</td>
<td>10 ml</td>
<td>–</td>
<td>1.58</td>
<td>0.015</td>
<td>0.93</td>
</tr>
<tr>
<td></td>
<td>50 ml</td>
<td>–</td>
<td>3.09</td>
<td>0.035</td>
<td>0.90</td>
</tr>
<tr>
<td></td>
<td>100 ml</td>
<td>–</td>
<td>5.23</td>
<td>0.068</td>
<td>1.31</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Run to run (n=20)</th>
<th>Add</th>
<th>Mean (mg/dl)</th>
<th>SD (mg/dl)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-assay precision</td>
<td>Sample 1</td>
<td>–</td>
<td>1.36</td>
<td>0.023</td>
<td>1.67</td>
</tr>
<tr>
<td></td>
<td>Sample 2</td>
<td>–</td>
<td>2.53</td>
<td>0.068</td>
<td>1.31</td>
</tr>
<tr>
<td>Inter-assay precision</td>
<td>Sample 1</td>
<td>–</td>
<td>9.18</td>
<td>0.23</td>
<td>2.45</td>
</tr>
<tr>
<td></td>
<td>Sample 2</td>
<td>–</td>
<td>15.12</td>
<td>0.32</td>
<td>2.10</td>
</tr>
</tbody>
</table>

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<th>Run to run (n=20)</th>
<th>Add</th>
<th>Mean (mg/dl)</th>
<th>SD (mg/dl)</th>
<th>CV (%)</th>
</tr>
</thead>
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<td>Intra-assay precision</td>
<td>Sample 1</td>
<td>–</td>
<td>2.54</td>
<td>0.10</td>
<td>3.78</td>
</tr>
<tr>
<td></td>
<td>Sample 2</td>
<td>–</td>
<td>0.78</td>
<td>0.03</td>
<td>3.37</td>
</tr>
</tbody>
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<tr>
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<th>Add</th>
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<th>SD (mg/dl)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin Direct</td>
<td>10 ml</td>
<td>–</td>
<td>1.029x + 0.037 mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>50 ml</td>
<td>–</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Bilirubin Total: y = 1.091x - 0.087 mg/dl
Bilirubin Direct: y = 1.029x + 0.037 mg/dl

CALIBRATION
Calibration with the factor (see ASSAY PARAMETERS table) or with calibrator XL MULTICAL, Cat. No. XSYS0034 is recommended.

WASTE MANAGEMENT
Please refer to local legal requirements.

Xi
39 Harmful if swallowed.

Safety phrases (S):
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32 Do not empty into drains.
S 46 If swallowed seek medical advice immediately.

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REFERENCES


SYMBOLS USED ON LABELS

REF Catalogue Number

LOT Lot Number

CE Mark - Device comply with the Directive 98/78/EC

Storage Temperature

Expiry Date

IVD In Vitro Diagnostics

CONT Content

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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