Diagnostic reagent for quantitative in vitro determination of triglycerides in serum or plasma on DiaSys respons®20

Order Information
Cat. No. 1 5710 99 10 923
4 containers for 200 determinations each

Method
Colorimetric enzymatic test using glycerol-3-phosphate-oxidase (GPO)

Principle
Determination of triglycerides after enzymatic splitting with lipoprotein lipase. Indicator is quinoneimine which is generated from 4-aminantipyrine and 4-chlorophenol by hydrogen peroxide under the catalytic action of peroxidase.

Triglycerides \( \text{LPL} \) Glycerol + fatty acid
Glycerol + ATP \( \text{GK} \) Glycerol-3-phosphate + ADP
Glycerol-3-phosphate + O2 \( \text{POD} \) Quinoneimine + HCl + H2O

Reagent
Components and Concentrations
Good's buffer pH 7.2 50 mmol/L
4-Chlorophenol 4 mmol/L
ATP 2 mmol/L
Mg\(^{2+}\) 15 mmol/L
Glycerokinase (GK) \( \geq 0.4\) kU/L
Peroxidase (POD) \( \geq 2\) kU/L
Lipoprotein lipase (LPL) \( \geq 2\) kU/L
4-Aminantipyrine 0.5 mmol/L
Glycerol-3-phosphate-oxidase (GPO) \( \geq 0.5\) kU/L

Storage Instructions and Reagent Stability
The reagent is stable up to the end of the indicated month of expiry, if stored at 2° to 8°C. Protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagent!

Warnings and Precautions
1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 1 contains animal material. Handle the product as potentially infectious according to general recommendations.
3. To avoid carryover interference, please take care of efficient washing steps with the recommended cleaning solution. Please refer to the DiaSys respons® 20 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.
4. In very rare cases, samples of patients with gammapathy might give falsified results [6].
5. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
6. 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.
7. For professional use only!

Waste Management
Please refer to local legal requirements.

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

Specimen
Serum, heparin plasma or EDTA plasma

Stability [1]:
2 days at \( \leq 20°\) C
7 days at \( \leq 4°\) C
at least one year at \( \leq -20°\) C
Discard contaminated specimens. Freeze only once.

Calibrators and Controls
DiaSys TruCal U calibrator is recommended for calibration. The assigned values of the calibrator have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). For internal quality control DiaSys TruCal N and P or TruLab L controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

TruCal U
Cat. No. 5 9100 99 10 063
Kit size 20 x 3 mL
TruLab N
5 9000 99 10 062
20 x 2 mL
TruLab P
5 9000 99 10 061
20 x 5 mL
TruLab L Level 1
5 9020 99 10 065
3 x 3 mL
TruLab L Level 2
5 9030 99 10 065
3 x 3 mL

Performance Characteristics
Measuring range up to 1000 mg/dL triglycerides (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).

Limit of detection** 2 mg/dL triglycerides
On-board stability 4 weeks
Calibration stability 2 weeks

Interferences < 10% by
Ascorbate up to 6 mg/dL
Hemoglobin up to 400 mg/dL
Conjugated bilirubin up to 18 mg/dL
Unconjugated bilirubin up to 10 mg/dL

For further information on interfering substances refer to Young DS [2].

Precision

<table>
<thead>
<tr>
<th></th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>106</td>
<td>163</td>
<td>241</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>1.83</td>
<td>2.12</td>
<td>0.95</td>
</tr>
<tr>
<td>Between run (n=20)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean [mg/dL]</td>
<td>111</td>
<td>169</td>
<td>247</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>1.14</td>
<td>1.09</td>
<td>2.47</td>
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</tbody>
</table>

Method comparison (n=97)
Test x DiaSys Triglycerides FS (Hitachi 917)
Test y DiaSys Triglycerides FS (respons®20)
Slope 1.02
Intercept -4.36 mg/dL
Coefficient of correlation 0.997

** Lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Conversion factor
Triglycerides [mg/dL] x 0.01126 = Triglycerides [mmol/L]

Reference Range [3]
Desirable: \(< 200\) mg/dL (fasting) (2.3 mmol/L)
Borderline high: 200 – 400 mg/dL (2.3 – 4.5 mmol/L)
Elevated: \(> 400\) mg/dL (4.5 mmol/L)
Each laboratory should check if the reference ranges are applicable to its own patient population and determine own reference ranges if necessary.

Clinical Interpretation [4]
Epidemiological studies have observed that a combination of plasma triglycerides > 180 mg/dL (> 2.0 mmol/L) and HDL-cholesterol < 40 mg/dL (1.0 mmol/L) predict a high risk of CHD. Borderline levels (200 mg/dL) should always be regarded in association with other risk factors for CHD.
Literature


Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 8 · 65558 Holzheim · Germany
### Test Details

<table>
<thead>
<tr>
<th>Test</th>
<th>TRIG</th>
</tr>
</thead>
</table>

### Test Volumes

| Sample Type | Serum |

#### Normal
- Volume: 2.00 µL
- Dilution Ratio: 1 X

#### Increase
- Volume: 4.00 µL
- Dilution Ratio: 1 X

#### Decrease
- Volume: 2.00 µL
- Dilution Ratio: 2 X

#### Standard Volume
- Volume: 2.00 µL

### Reagent Volumes and Stirrer Speed

<table>
<thead>
<tr>
<th>RGT-1 Volume</th>
<th>180 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 Stirrer Speed</td>
<td>High</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RGT-2 Volume</th>
<th>µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>R2 Stirrer Speed</td>
<td></td>
</tr>
</tbody>
</table>

### Reference Ranges

#### Lower Limit
- Normal: 0.00 (mg/dL)
- Panic: 0.00 (mg/dL)

#### Upper Limit
- Normal: 200.00 (mg/dL)
- Panic: 0.00 (mg/dL)

### Sample Types

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