**Intended use**
Quantitative measurement of triglyceride concentration in plasma or serum. For in vitro diagnostic use only.

**Procedure**
1. Read in the new QC card when you switch to a new box of slides.
2. Set slides on FUJI DRI-CHEM ANALYZER.
3. Set a sample tube in the specified sample rack.
4. Input a sequence No. and a sample ID if appropriate.
5. Press the "START" key to initiate testing.

**CAUTION:** Use immediately after opening the individual package.
For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

**Internal quality control**
The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL OP-L and/or OP-H.
1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL OP-L and/or OP-H in the same way as patient samples.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL OP-L or OP-H, investigate the cause.
For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL OP-L or OP-H.

**Reference intervals**
50–149 mg/dL (0.56–1.68 mmol/L)
As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals.

**Limitation of the examination procedure**
The clinical diagnosis must be made by the doctor in charge based on the measured results in the light of clinical symptoms and other test results.

**Known interfering substances**
(1) No significant effect was observed to the following concentration for each substance.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbic acid</td>
<td>20 mg/dL (0.07 mmol/L)</td>
<td>No effect</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>20 mg/dL (340 μmol/L)</td>
<td>No effect</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>5000 mg/L</td>
<td>No effect</td>
</tr>
<tr>
<td>Total protein</td>
<td>60–95 g/L</td>
<td>No effect</td>
</tr>
<tr>
<td>Glycerol</td>
<td>0.56–1.68 mmol/L</td>
<td>Plus bias</td>
</tr>
</tbody>
</table>

(2) Dobutamine hydrochloride (cardiotonic reagent) and dopamine hydrochloride (cardiotonic reagent) give minus bias.
(3) Glycerol gives plus bias.
These results are representative; test condition may have some influence on your results.
Interferences from other substances are not predictable.

**Performance characteristics**
1. Dynamic range 10–500 mg/dL (0.11–5.65 mmol/L)

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>10–100 mg/dL</td>
<td>Within ± 5 mg/dL (Within ± 0.17 mmol/L)</td>
</tr>
<tr>
<td>100–500 mg/dL</td>
<td>Within ± 15%</td>
</tr>
</tbody>
</table>

2. Accuracy 10–500 mg/dL (0.11–5.65 mmol/L)

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>10–100 mg/dL</td>
<td>SD ± 6 mg/dL (SD ± 0.07 mmol/L)</td>
</tr>
<tr>
<td>100–500 mg/dL</td>
<td>CV ± 6%</td>
</tr>
</tbody>
</table>

3. Precision

<table>
<thead>
<tr>
<th>n</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>81</td>
<td>0.977</td>
<td>3.52</td>
<td>0.998</td>
</tr>
</tbody>
</table>

**Correlation**
Correlation was evaluated between GPO method and FUJI DRI-CHEM system.
GPO method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

**Repeatability of calibrators and control materials**
Triglyceride: ReCCS (CQT, 224)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
ReCCS: Reference Material Institute for Clinical Chemistry Standards
Symbols

- Do not touch the center part of the slide.
- Warmed up to room temperature before opening the individual packages.
- SLIDE CODE
- Do not reuse
- Lot number
- Use by
- Contains sufficient for <n> tests
- Temperature limitation
- Consult instructions for use
- In vitro diagnostic medical devices
- Manufacturer
- Authorized representative in the European Community