**PRODUCT SUMMARY**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
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<tbody>
<tr>
<td>Stability</td>
<td>18 Months at 2-8°C</td>
</tr>
<tr>
<td>Linear Range</td>
<td>Up to 10 mmol/L (885 mg/dL)</td>
</tr>
<tr>
<td>Specimen Type</td>
<td>Serum or plasma</td>
</tr>
<tr>
<td>Method</td>
<td>Endpoint</td>
</tr>
<tr>
<td>Reagent Preparation</td>
<td>Supplied ready to use</td>
</tr>
</tbody>
</table>

**METHOD**

- **Endpoint**
- **Serum or plasma**

**Reagent Preparation**: Supplied ready to use.

**Linear Range**: Up to 10 mmol/L (885 mg/dL)

**Stability**: 18 Months at 2-8°C

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**INTENDED USE**

This reagent is intended for the in vitro quantitative determination of Triglycerides in human serum or plasma.

**CLINICAL SIGNIFICANCE**

Triglycerides are a family of lipids absorbed from the diet and produced endogenously from carbohydrates. Measurement of triglycerides is important in the diagnosis and management of hyperlipidaemias. These diseases can be genetic or secondary to other disorders including nephrosis, diabetes mellitus, and endocrine disturbances. Elevation of triglycerides has been identified as a risk factor for atherosclerotic disease.

**METHOD**

This reagent is based on the method of Wako and the modifications by McGowan et al. and Fossati et al.

1. Triglycerides + H₂O \[\rightarrow\] Lipase \[\rightarrow\] Glycerol + Free Fatty acids
2. Glycerol + ATP \[\rightarrow\] Glycerol-3-phosphate + ADP
3. Glycerol-3-phosphate + O₂ \[\rightarrow\] GPO \[\rightarrow\] DAP + 2H₂O₂
4. H₂O₂ + 4-AAP + 3,5 DHBS \[\rightarrow\] Quinoneimine dye + 2H₂O

**Stability and Storage**

Triglycerides are stable for 3 days at 4°C and several weeks at -20°C. For longer periods specimens should be stored at -70°C. Storage at room temperature may cause the release of glycerol from phospholipids with a resulting apparent increase in Triglycerides and hence is not recommended. Lipemic specimens, if they have been frozen may require warming to 37°C and vigorous mixing prior to use.

**ADDITIONAL EQUIPMENT REQUIRED BUT NOT PROVIDED**

- A clinical chemistry analyser capable of maintaining constant temperature (37°C) and measuring absorbance between 500 and 550nm.
- Analyser specific consumables, eg: samples cups.
- If required, pipettes for accurately dispensing measured volumes.
- Calibrator or a suitable aqueous Triglycerides standard.

**ASSAY PROCEDURE**

The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group.

**SYSTEM PARAMETERS**

- **Temperature**: 37°C
- **Primary Wavelength**: 500 nm (500-550nm)
- **Secondary Wavelength**: 660 nm (600-660nm)
- **Assay Type**: Endpoint
- **Direction**: Increase
- **Sample : Reagent Ratio**: 1:100
- **Incubation Time**: 300 seconds
- **Reagent Blank Limits**: Low 0.0 AU
- **Linearity**: 10 mmol/L (885 mg/dL)
- **Analytical Sensitivity**: 0.158 \(\Delta A\) per ml/mL

**CALCULATIONS**

Results are calculated, usually automatically by the instrument, as follows:

\[
\text{Triglycerides} = \frac{\text{Absorbance of Unknown}}{\text{Absorbance of Calibrator}} \times \text{Calibrator Value} 
\]

**Examples**

- **Absorbance of Calibrator**: 0.164
- **Absorbance of unknown**: 0.113
- **Value of Calibrator**: 2.9 mmol/L (257 mg/dL)

\[
\text{Triglycerides} = \frac{0.113}{0.164} \times 2.9 = 2.0 \text{ mmol/L} 
\]

**Triglycerides**

- **Absorbance of unknown**: 0.164
- **Value of Calibrator**: 2.9 mmol/L (257 mg/dL)

\[
\text{Triglycerides} = \frac{0.113}{0.164} \times 257 = 177 \text{ mg/dL} 
\]

**NOTES**

1. Specimens assayed with triglycerides values greater than 10 mmol/L (885 mg/dL) should be diluted with saline and reassayed. Multiply the result by the dilution factor.
2. The colour reaction is stable for at least 10 minutes at 37°C.
3. Unit conversion: mmol/L x 88.5 = mg/dL
CALIBRATION: Calibration is required. An aqueous standard or serum based calibrator, with and assigned value traceable to a primary standard (eg NIST or IRMM) is recommended. Aqueous glycerol standards can be used, however, glycerol can only be considered a primary standard for the indicator system, as it does not participate in the first reaction step. A serum based secondary calibrator, with a value close to 2.25 mmol/L (200 mg/dL) is recommended.

For calibration frequency on automated instruments, refer to the instrument manufacturers specifications. However, calibration stability is contingent upon optimum instrument performance and the use of reagents which have been stored as recommended in the stability and storage section of this package insert.

Recalibration is recommended at anytime if one of the following events occurs:

- The lot number of reagent changes.
- Preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.

QUALITY CONTROL

To ensure adequate quality control, normal and abnormal control with assayed values should be run as unknown samples:

- At least once per day or as established by the laboratory.
- When a new bottle of reagent is used.
- After preventative maintenance is performed or a critical component is replaced.
- With every calibration.

Control results falling outside the upper or lower limits of the established ranges indicate that the assay may be out of control. The following corrective actions are recommended in such situations:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results are still out of control, recalibrate with fresh calibrator, then repeat the test.
- If results are still out of control, perform a calibration with freshly prepared reagent, then repeat the test.
- If results are still out of control, contact Technical Services or your local distributor.

LIMITATIONS

1. Glycerol contamination will affect this assay, which may result in the limits of reagents which have been stored as recommended in the stability and storage section of this package insert.

Recalibration is recommended at anytime if one of the following events occurs:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results are still out of control, recalibrate with fresh calibrator, then repeat the test.
- If results are still out of control, perform a calibration with freshly prepared reagent, then repeat the test.
- If results are still out of control, contact Technical Services or your local distributor.

EXPECTED VALUES

Recommended (desirable) Triglycerides levels for adults:

Male: 0.45 - 1.81 mmol/L  40 - 160 mg/dL
Female: 0.40 - 1.53 mmol/L  35 - 135 mg/dL

The NIH consensus conference® classified hypertriglyceridaemia into two categories.

Distinct hypertriglyceridaemia: Triglyceride >5.6 mmol/L (>500 mg/dL)
Borderline hypertriglyceridaemia: Triglyceride value 2.8 - 5.6 mmol/L (250 - 500 mg/dL).

PERFORMANCE DATA

The following data was obtained using the Infinity Triglycerides Liquid Stable Reagent on a well maintained automated clinical chemistry analyser. Users should establish product performance on their specific analyser used.

IMPRECISION

<table>
<thead>
<tr>
<th>Within Run:</th>
<th>LEVEL I</th>
<th>LEVEL II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of samples</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Mean (mmol/L / mg/dL)</td>
<td>1.11 / 98.3</td>
<td>1.86 / 164.7</td>
</tr>
<tr>
<td>SD (mmol/L / mg/dL)</td>
<td>0.02 / 1.77</td>
<td>0.02 / 1.77</td>
</tr>
<tr>
<td>CV (%)</td>
<td>2.07</td>
<td>1.25</td>
</tr>
</tbody>
</table>

Total:

<table>
<thead>
<tr>
<th>LEVEL I</th>
<th>LEVEL II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of samples</td>
<td>40</td>
</tr>
<tr>
<td>Mean (mmol/L / mg/dL)</td>
<td>1.12 / 98.8</td>
</tr>
<tr>
<td>SD (mmol/L / mg/dL)</td>
<td>0.05 / 4.4</td>
</tr>
<tr>
<td>CV (%)</td>
<td>4.5</td>
</tr>
</tbody>
</table>

METHOD COMPARISON

Comparison studies were carried out on an automated clinical chemistry analyser using a similar commercially available Triglycerides reagent as a reference. Serum samples were assayed in parallel and the results compared by the least regression. The following statistics were obtained.

Number of sample pairs: 40
Range of sample results: 1.06 - 4.06 mmol/L (93.8 - 359.3 mg/dL)
Mean of reference method results: 1.93 mmol/L (170.8 mg/dL)
Mean of Triglycerides results: 2.01 mmol/L (177.9 mg/dL)
Slope: 0.96
Intercept: 0.22 mmol/L (19.5 mg/dL)
Correlation Coefficient: 0.995

LINEARITY

When run as recommended the assay is linear up to 10 mmol/L (885 mg/dL).

ANALYTICAL SENSITIVITY

When run as recommended the sensitivity of this assay is 0.158 ∆A per mmol/L or 0.002 ∆A per mg/dL (1cm lightpath, 500 nm).

REFERENCES

2. Product Data Sheet, Triglyceride - G Code No 997-68801, Wako Pure chemical Industries Ltd., Daisets TX.

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