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REAGENT 2 x 38 mL

IVD CE 2797

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FRANCE

Yumizen C Triglycerides

- **Yumizen C230**
- **Yumizen C240**

Diagnostic reagent for quantitative *in vitro* determination of Triglycerides in serum or plasma by colorimetry.

Intended Use

Yumizen C Triglycerides reagent is intended for the quantitative *in vitro* diagnostic determination of triglycerides in human serum and plasma based on an enzymatic colorimetric assay.
Clinical laboratories use.
Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.
Assessing the physiologic and pathologic variations of Triglycerides concentration in human serum and plasma is useful for screening or follow-up of these diseases.

Clinical Interest (1, 2)

Triglycerides constitute 95% of fat stocked in tissues and their main role is to provide energy to cells. They are synthetised on one hand in the intestine from fat brought by food and on the other hand in liver from ingested saccharides, and are then transported in the blood by chylomycrons and very low density lipoproteins (VLDL).
High levels of triglycerides are associated with important risks of atherosclerosis. They may be caused by diseases such as different lipid metabolism troubles (hyperlipoproteinemia, deficit in lipase activity, deficit in apolipoprotein CII), but also by diabetes, renal or endocrinal troubles.

Method (3)

Enzymatic determination of triglycerides according to the following reactions:

$$\text{Triglycerides} + H_2O \xrightarrow{\text{Lipoprotein lipase}} \text{Glycerol} + \text{fatty acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{Glycerokinase}} \text{Glycerol-3-phosphate} + \text{ADP}$$

$$\text{Glycerol-3-Phosphate} + O_2 \xrightarrow{\text{Glycerol-3-phosphate Oxidase}} H_2O_2 + \text{DHAP}$$

$$2H_2O_2 + \text{4-AAP} + \text{p-Chlorophenol} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 4H_2O$$

(DHAP = Dihydroxyacetone phosphate, 4-AAP = 4-aminoantipyrine)

Reagents

Yumizen C Triglycerides is ready-to-use.

Reagent:	
Good's buffer pH 7.00	
4-Chlorophenol	2.7 mmol/L
ATP	3.15 mmol/L
4-aminoantipyrine (4-AAP)	0.31 mmol/L
Lipoprotein lipase	≥ 2000 U/L
Glycerokinase	≥ 500 U/L
Glycerol-3-phosphate-oxidase	≥ 4000 U/L
Peroxidase	≥ 500 U/L
Sodium azide	< 0.1%

Also contains magnesium salt, FAD and detergents for optimal performance.

Yumizen C Triglycerides should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Remove the cap of the cassette.
2. If present, remove foam by using a plastic pipette.

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3. Place the cassette into the refrigerated reagent compartment.

Calibrator

For calibration, use:
ABX Pentra Multical (A11A01652) (not included)
10 x 3 mL (lyophilisate)

Control

For internal quality control, use:

- **ABX Pentra N MultiControl** (1300054414) (not included)
  10 x 5 mL (lyophilisate)
- **ABX Pentra P MultiControl** (1300054415) (not included)
  10 x 5 mL (lyophilisate)

Each control should be assayed daily and/or after a calibration.
The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. You should follow federal, state and local guidelines for testing quality control materials. The results must be within the range of the defined confidence limits. Each laboratory should establish a procedure to follow if the results exceed these confidence limits.

Materials Required but not Provided

- Automated clinical chemistry analyzer: Yumizen C230/C240
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
- Standard laboratory equipment.

Specimen (4)

This device intended testing population is general population.

Specimen types

- Serum.
- Plasma in lithium heparin.

Anticoagulants other than those listed have not been tested by HORIBA and are therefore not recommended for use with this assay.

These specimens should be drawn from the patient after 12 - 14h fast.

Stability (4)

No significant change of triglycerides concentration after storage for 4 days at 4°C.

Reference Range (2)

Each laboratory should establish its own reference ranges. The values given here are used as guidelines only.

In a study conducted within the NCEP (National Cholesterol Education Program, launched by the US Ministry of Health), the triglycerides values in serum have been classified according to the risk of developing cardiovascular diseases:

Normal:	< 150 mg/dL
Low risk:	150 - 200 mg/dL
High:	200 - 500 mg/dL
Extremely high:	> 500 mg/dL

Clinical sensitivity and specificity, positive predictive value and negative predictive value are not commonly reported for this analyte. This is largely attributed to the fact that this analyte is not sole indicator for the intended purpose and patient treatment decision making. To arrive at a diagnosis and a course of treatment, results from others routine clinical chemistry tests should be used in conjunction with other diagnostic information and the attending health-care professional's evaluation of the patient's condition.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-8°C.

Stability after opening:

Refer to the paragraph "Performance on Yumizen C230/C240".

Note: the reagents' colour may change to brown in the course of time, but this does not affect the reagent performance.

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Waste Management

- Please refer to local legal requirements.
- This reagent contains less than 0.1% of sodium azide as a preservative.

General Precautions

- This reagent is for professional *in vitro* diagnostic use only.
  For laboratory use.
- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- **Warning:** This reagent is obtained from substances of animal origin. Consequently, it should be treated as potentially infectious and handled with the appropriate cautions in accordance with good laboratory practices (5).
- Do not pipette by mouth.
- Do not replenish the reagents.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The reagent cassettes are disposable and should be disposed of in accordance with the local legal requirements.
- Please refer to the SDS associated with the reagent.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the reagent used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

Performance on Yumizen C230/C240

Lot to Lot Variability

The recovery of samples (serum and plasma) done during QC release of three consecutive lots of reagent shows that the lot to lot variability is within specification: +/- 8%.

Serum, plasma

The performance data listed below have been obtained on the Yumizen C230/C240 analyzer.

Number of tests: approximately 346 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Yumizen C230/C240 compartment is stable for 56 days.

Sample volume: 2 µL/test

Lowest Detectable Level

The lowest detectable level represents the lowest measurable level of analyte that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample. The lowest detectable level is estimated at 0.006 mmol/L (0.525 mg/dL).

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (6) and equals 0.10 mmol/L (8.75 mg/dL).

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the CLSI (NCCLS), EP05-A3 protocol (7) with samples tested 20 times:

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	1.26	109.81	1.3
Control specimen 2	2.39	208.78	1.0
Specimen 1	0.56	48.62	0.9

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	Mean value mmol/L	Mean value mg/dL	CV %
Specimen 2	1.55	136.05	0.7
Specimen 3	3.04	266.17	1.2

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP05-A3 protocol (7) with samples tested in duplicate for 20 days (2 series per day):

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value mmol/L	Mean value mg/dL	CV %
Control specimen 1	1.26	110.25	2.2
Control specimen 2	2.37	207.38	1.9
Specimen 1	0.50	43.75	2.3
Specimen 2	1.50	131.25	2.4
Specimen 3	3.14	274.75	2.1

Measuring Range

The assay confirmed a measuring range from 0.10 mmol/L (8.75 mg/dL) to 13.0 mmol/L (1137.5 mg/dL). The measuring range is extended up to 52 mmol/L (4550 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 13.0 mmol/L (1137.5 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (8).

Correlation

Patient samples: Serum
Number of patient samples: 102
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (9).
Values ranged from 0.20 mmol/L (17.50 mg/dL) to 11.48 mmol/L (1004.50mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (10) is:
Y = 0.9722 x + 0.042 (mmol/L)
Y = 0.9722 x + 3.675 (mg/dL)
with a correlation coefficient r^2 = 0.996.

Interferences

Haemoglobin: No significant influence is observed up to 145 µmol/L (250 mg/dL).

Total Bilirubin: No significant influence is observed up to 180.10 µmol/L (10.54 mg/dL).

Direct Bilirubin: No significant influence is observed up to 86.79 µmol/L (5.08 mg/dL).

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (11, 12).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 14 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor

mmol/L x 0.875 = g/L
mmol/L x 87.5 = mg/dL

Reference

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6. Evaluation of detection capability for clinical laboratory measurement procedures. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP17-A2 (2012) **32** (8).
7. Evaluation of Precision of Quantitative Measurement Procedures. Approved Guideline, CLSI (NCCLS) document EP05-A3 (2014) **24** (25).
8. Evaluation of Linearity of Quantitative Measurement Procedures. 2nd Edition, CLSI (NCCLS) guideline EP06-Ed2 (2020) **40** (16).

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9. Measurement Procedure Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 3rd ed., CLSI (NCCLS) document EP09c (2018) **38** (12).
10. Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J. Clin. Chem. Clin. Biochem. (1983) **21**: 709-720.
11. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th Edition, Washington, DC, AACC Press (2000).
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