Clinical Chemistry

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REAGENT 90 mL

IVD CE

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ABX Pentra Triglycerides CP

- **Pentra C200**

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

Application Release

Serum, plasma: TRIG
01.xx

Intended Use

ABX Pentra Triglycerides CP reagent is intended for the quantitative *in vitro* diagnostic determination of triglycerides in human serum and plasma based on an enzymatic colorimetric assay. Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

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:

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

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

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

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

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

Reagents

ABX Pentra Triglycerides CP is ready-to-use.

Reagent:	
PIPES free acid	50 mmol/L
Sodium hydroxide	3.36 g/L
Triton X-100	1 mL/L
Magnesium salt	14.8 mmol/L
p-chlorophenol	2.7 mmol/L
ATP	3.15 mmol/L
Sodium azide	7.99 mmol/L
Potassium ferrocyanide	10 µmol/L
4-aminoantipyrine	0.31 mmol/L
Lipoprotein lipase	≥ 2000 U/L
Glycerokinase	≥ 500 U/L
Glycerol phosphate Oxidase	≥ 4000 U/L
Peroxidase	≥ 500 U/L

ABX Pentra Triglycerides CP should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

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Handling

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

For internal quality control, use:

- **ABX Pentra N Control / ABX Pentra N MultiControl** (A11A01653 / 1300054414) (not included)
  10 x 5 mL (lyophilisate)
- **ABX Pentra P Control / ABX Pentra P MultiControl** (A11A01654 / 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 [a]

- Automated clinical chemistry analyzer: Pentra C200
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
  ABX Pentra N Control / ABX Pentra N MultiControl (A11A01653 / 1300054414)
  ABX Pentra P Control / ABX Pentra P MultiControl (A11A01654 / 1300054415)
- Standard laboratory equipment.

Specimen (4)

- Serum.
- Plasma in lithium heparin.

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

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

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 Pentra C200".

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

Waste Management

- Please refer to local legal requirements.
- This reagent contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

[a]Modification: new control.

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General Precautions [b]

- This reagent is for professional *in vitro* diagnostic use only.
- 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.
- It is the user's responsibility to verify that this document is applicable to the reagent used.

Performance on Pentra C200

Serum, plasma

The performance data listed below have been obtained on the Pentra C200 analyzer.

Number of tests: approximately 268 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C200 compartment is stable for 49 days.

Sample volume: 3 µL/test

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A 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 Valtec 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	1.39	122	3.44
Control specimen 2	2.29	200	2.61
Specimen 1	0.50	44	1.87
Specimen 2	1.42	124	1.04
Specimen 3	2.87	251	1.49

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (8) 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	1.38	121.2	2.94
Control specimen 2	2.17	190.3	2.97
Specimen 1	0.52	45.1	4.89
Specimen 2	1.48	129.3	2.92
Specimen 3	3.02	264.2	2.49

Measuring Range

The assay confirmed a measuring range from 0.10 mmol/L (9 mg/dL) to 10.0 mmol/L (875 mg/dL).
The measuring range is extended up to 60.0 mmol/L (5250 mg/dL) with the automatic post-dilution.
The reagent linearity has been assessed up to 10.0 mmol/L (875 mg/dL) according to the recommendations found in the CLSI (NCCLS), EP6-A protocol (9).

Correlation [c]

Patient samples: Serum
Number of patient samples: 144
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP9-A2 protocol (10).
Values ranged from 0.14 mmol/L (12.3 mg/dL) to 8.97 mmol/L (784.0 mg/dL).
The equation for the allometric line obtained using Passing-Bablok regression procedure (11) is:
Y = 1.01 X - 0.01 (mmol/L)

[b]Modification: general precautions modification.
[c]Modification: modification of correlation.

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Y = 1.01 X - 0.84 (mg/dL)
with a correlation coefficient r^2 = 0.9975.

Interferences [d]

Haemoglobin:	No significant influence is observed up to 290 µmol/L (500 mg/dL).
Total Bilirubin:	No significant influence is observed up to 100 µmol/L (5.9 mg/L).
Direct Bilirubin:	No significant influence is observed up to 187 µmol/L (11.0 mg/dL).
N-Acetylcysteine (NAC):	Patients treated with N-Acetylcysteine (NAC) for Paracetamol overdose may generate a false low result.

The presence of N-Acetylbenzoquinoneimine (NAPQI) in serum/plasma can cause false results.
Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (12, 13).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 32 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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[d]Modification: modification of interferences.