Triglycerides

CYPRESS DIAGNOSTICS

CE

IVD

Enzymatic. Colorimetric.
GPO-POD
Liquid

Store at 2-8 °C

Configuration

REF	HBL060	HBL060A	HBL060M
VOL	2 x 125 mL	8 x 125 mL	8 x 30 mL
Reagent	2 x 125 mL	8 x 125 mL	8 x 30 mL
Standard	1 x 5 mL	4 x 5 mL	-
Instrument	Universal	Universal	Mindray BS-120, BS-200, BS-200E, BS-230, BS-240, BS-240 Pro

Intended use

The Cypress Diagnostics Triglycerides kit is an in vitro diagnostic medical device intended to be used by healthcare professionals for the quantitative measurement of triglycerides in human serum or plasma.
The measurement of triglycerides is intended to be used for the diagnosis of hypertriglyceridemia for coronary heart disease and pancreatitis risk assessment and the monitoring of the effectiveness of triglyceride-lowering therapy.
For *in vitro* diagnostic use only. For professional use only.

Clinical significance

Triglycerides, esters of glycerol and three fatty acids, are the main constituent of tissue storage fat and serve as a source of energy for the body. They are transported in the bloodstream in lipoprotein complexes. The clinical significance of triglycerides and other lipids relates to their contribution to coronary heart disease and lipoprotein disorders. Disease states or conditions associated with an elevation in triglycerides include type 2 diabetes, obesity, pregnancy, infection, inflammation, nephrotic syndrome, chronic renal failure and biliary cirrhosis/obstruction.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle

Triglycerides in the sample are enzymatically hydrolyzed to glycerol and free fatty acids by lipoprotein lipase. Liberated glycerol is first phosphorylated by glycerol kinase and subsequently oxidized by glycerol 3-phosphate oxidase, resulting in the formation of an equivalent amount of H_2O_2, which then participates in a modified Trinder reaction yielding a red quinoneimine dye. The intensity of the color formed is proportional to the triglyceride concentration in the sample.

$$\text{Triglyceride} + 3H_2O \xrightarrow{\text{LPL}} \text{Glycerol} + 3\ \text{Fatty acids}$$

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

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

$$H_2O_2 + \text{4-AAP} + \text{DHBS} \xrightarrow{\text{POD}} \text{Quinoneimine dye} + 2H_2O$$

Reagent composition

Reagent	PIPES pH 7,0 (50 mmol/L) DHBS (1 mmol/L) Lipoprotein lipase (LPL) (1500 U/L) Glycerol kinase (GK) (700 U/L) Glycerol 3-phosphate oxidase (GPO) (1500 U/L) Peroxidase (POD) (2000 U/L) 4–Aminoantipyrine (4-AAP) (0,8 mmol/L) ATP (1,5 mmol/L)
Standard	Triglycerides aqueous (as glycerol) (see value on label)

Precautions

- All body fluid samples should be considered potentially infectious materials and the appropriate precautions should be taken. Wear personal protective equipment such as gloves, safety glasses, lab coats or aprons when working with possible biohazard contaminants.
- Use Good Laboratory Practices (GLP) when handling this product.
- Please refer to the MSDS, available on our website, for further information.

Preparation

The reagent and standard are ready to use.

Storage, stability and disposal

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 510 nm ≥ 0,23, the reagent should be discarded.
Do not use the product if deterioration or contamination is suspected or beyond the expiration date or open container stability period. Dispose unused or deteriorated product and waste in compliance with local regulations.

Additional material required but not provided

- Spectrophotometer or colorimeter measuring at 510 nm
- Matched cuvettes 1,0 cm light path
- General laboratory equipment

Samples

Serum or plasma. The stability of the sample: 5 days at 2-8 °C.

Procedure

Make sure the reagents and samples are at room temperature.
1. Wavelength 510 nm (500-550); Temperature 37 °C/15-25 °C; Cuvette (1 cm light path).
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

For Blank	1 mL Reagent
For Standard[Note 3]	10 µL Standard + 1 mL Reagent
For Sample	10 µL Sample + 1 mL Reagent
Mix, incubate 5 min at 37 °C or 10 min at room temperature (15-25 °C). Read the absorbance (A) of sample and standard against blank. The color is stable for at least 30 minutes.	

Calculation

$$\text{Triglycerides (mg/dL)} = \frac{A_{Sample} - A_{Blank}}{A_{Standard} - A_{Blank}}\ x\ stand.conc.\ (mg/dL)$$

Conversion Factor: mmol/L = 0,0113 x mg/dL

Quality control

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02).
Prepare and measure these controls the same as samples. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

Reference values

Normal	< 150 mg/dL (< 1,7 mmol/L)
High	150 - 199 mg/dL (1,7 - 2,2 mmol/L)
Hypertriglyceridemic	200 - 499 mg/dL (2,3 - 5,6 mmol/L)
Very high	> 499 mg/dL (> 5,6 mmol/L)

These values are for orientation purpose. Each laboratory should establish its own reference range.

Performance characteristics

Measuring range: from 1,01 mg/dL (detection limit) to 1000 mg/dL (linearity limit). If the obtained results are greater than 1000 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

Precision:

	intra-assay (n=20)		inter-assay (n=20)	
Mean (mg/dL)	114	210	116	213
SD	1,30	2,65	1,08	2,66
CV (%)	1,14	1,26	0,93	1,25

Sensitivity: 1 mg/dL = 0,0021 AU

Accuracy: Results obtained using CYPRESS DIAGNOSTICS reagents did not show systematic differences when compared with other commercial reagents.
The results of the performance characteristics depend on the analyzer used.

Interferences

No interferences were observed with bilirubin up to 10 mg/dL and hemoglobin up to 6 g/L. A list of drugs and other interfering substances with triglycerides determination has been reported by Young et al.

Notes

1. For best use of this kit on a Cypress Diagnostics analyzer, we kindly advise to follow the application sheets of the respective analyzer. Please log in to our website (www.diagnostics.be) as a registered user to download the latest application sheets, which are located under the section of the corresponding analyzer. Compatible Cypress analyzers: CYANSmart, CYANStart, CYANExpert 130, CYANVision.

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2. For this kit, application sheets for the following Mindray analyzers are available (see website): BS-120, BS-200, BS200E.
3. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In this case, it is recommended to use a serum based Biochemistry calibrator (HBC03).
4. Free glycerol present in samples is also measured with this method. In healthy individuals, endogenous glycerol typically accounts for a ≤10 mg/dL overestimation of triglycerides.
5. The use of certain plastic recipients may lead to a change in the color of the reagent. Where possible, use glass containers for reagent aliquots (e.g. in manual procedures).

Bibliography

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Notice: Any serious incident that has occurred in relation to the device shall be reported to Cypress Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

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