Triglycerides FS*

Order Information

Cat. No.	Kit size	Instrument	Σ
1 5710 99 10 970	R 4 x 31.7 mL	BX-3010	800 (4 x 200)
		BX-4000	616 (4 x 154)

Intended Use

Diagnostic reagent for quantitative in vitro determination of triglycerides in human serum or heparin plasma on automated Sysmex BX-Series.

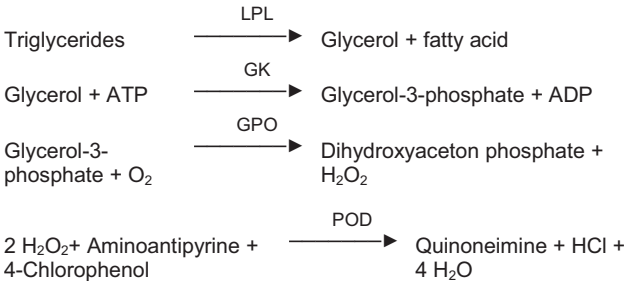
Summary

Triglycerides are esters of glycerol with three fatty acids. They represent the most abundant naturally occurring lipids. They are transported in plasma bound to apolipoproteins forming very low-density lipoproteins (VLDL) and chylomicrons. Measurement of triglycerides is used in screening of the lipid status to detect atherosclerotic risks and in monitoring of lipid lowering therapy. Studies have shown that elevated triglyceride concentrations combined with increased low-density lipoprotein (LDL) concentrations constitute an especially high risk for coronary heart disease (CHD). High triglyceride levels also occur in various diseases of liver, kidneys and pancreas. [1,2]

Method

Colorimetric enzymatic test using glycerol-3-phosphate-oxidase (GPO)

Determination of triglycerides after enzymatic splitting with lipoprotein lipase. Quinoneimine is the indicator, generated from 4-aminoantipyrine and 4-chlorophenol by hydrogen peroxide under the catalytic action of peroxidase.



Reagent

Components and Concentrations

Good's buffer	pH 7.2	50 mmol/L
4-Chlorophenol		4 mmol/L
ATP		2 mmol/L
Mg^{2+}		15 mmol/L
Glycerokinase	(GK)	≥ 0.4 kU/L
Peroxidase	(POD)	≥ 2 kU/L
Lipoprotein lipase	(LPL)	≥ 2 kU/L
4-Aminoantipyrine		0.5 mmol/L
Glycerol-3-phosphate-oxidase	(GPO)	≥ 0.5 kU/L

Storage and Stability

The reagent is stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Protect the reagent from light.

Warnings and Precautions

1. The reagent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. The reagent contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
4. In very rare cases, samples of patients with gammopathy might give falsified results [3].
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagent is ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Stability [4]:

2 days	at	20 – 25°C
7 days	at	4 – 8°C
At least 1 year	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). Use DiaSys TruLab N and P or TruLab L Level 1 and Level 2 for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab L Level 1	5 9020 99 10 065	3 x 3 mL
TruLab L Level 2	5 9030 99 10 065	3 x 3 mL

Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 1000 mg/dL (11.3 mmol/L). In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	2 mg/dL (0.023 mmol/L)
Onboard stability	12 weeks
Calibration stability	9 week

Interfering substance	Interferences ≤ 10% up to	Analyte concentration
Ascorbic acid	6 mg/dL	84.8 mg/dL (0.955 mmol/L)
Bilirubin (conjugated)	13 mg/dL	237 mg/dL (2.66 mmol/L)
Bilirubin (unconjugated)	35 mg/dL	227 mg/dL (2.56 mmol/L)
Hemoglobin	575 mg/dL	223 mg/dL (2.52 mmol/L)
For further information on interfering substances refer to Young DS [5.6].		

Precision BX-3010			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	81.7	165	265
Mean [mmol/L]	0.920	1.85	2.98
CV [%]	1.43	1.47	1.41
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	83.6	164	263
Mean [mmol/L]	0.941	1.85	2.96
CV [%]	2.29	1.48	1.18

Method comparison (n=106)	
Test x	DiaSys Triglycerides FS (BioMajesty® JCA-BM6010C)
Test y	DiaSys Triglycerides FS (BX-3010)
Slope	1.03
Intercept	–5.87 mg/dL (0.066 mmol/L)
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Conversion Factor
Triglycerides [mg/dL] x 0.01126 = Triglycerides [mmol/L]

Reference Range [2]

Desirable	< 200 mg/dL (fasting)	< 2.3 mmol/L
Borderline high	200 – 400 mg/dL	2.3 – 4.5 mmol/L
Elevated	> 400 mg/dL	> 4.5 mmol/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Clinical Interpretation

Epidemiological studies have observed that a combination of plasma triglycerides > 180 mg/dL (> 2.0 mmol/L) and HDL-cholesterol < 40 mg/dL (1.0 mmol/L) predict a high risk of CHD. Borderline levels (> 200 mg/dL) should always be regarded in association with other risk factors for CHD [7].

Literature

1. Rifai N, Bachorik PS, Albers JJ. Lipids, lipoproteins and apolipoproteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999, p. 809-61.
2. Cole TG, Klotzsch SG, McNamara J. Measurement of triglyceride concentration. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 2000; 2nd edition, p. 207-19.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 46-7.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in July 2021. Published by AACC Press and John Wiley and Sons, Inc.
7. Recommendation of the Second Joint Task Force of European and other Societies on Coronary Prevention. Prevention of coronary heart disease in clinical practice. Eur Heart J 1998;19: 1434-503.

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* Fluid Stable

Triglycerides FS

Chemistry Code 100 74

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*	Method Name	TRIG	Reagent Name	Reagent (µL)	Water (µL)
Print Name	Triglycerides	MethodColor		R1	TRIG	135	
Sample Type	Serum			R2	Disable		
Unit	mg/dL			Diluent	Disable		
Assay Type	End			Sample Ppt. Wash	Disable		

Measuring points

	Start		End
1	45	–	46
2	Disable	–	

Stirring Speed R1: Middle R2:

Wave Length: Prim. 510 Sec. 700

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Normal Sample Volume (µL) Low	Normal	High	Diluted Sample (µL)	Diluent (µL)	Technical Range		
☐ Diluent	0.0 <	1.5 <	0.0			(Conc)	2 –	1000
						(mAbs/10)	* –	*
Rerun (High/Prozone)								
☐ Diluent	0.0 <	1.5 <	0.0			Previous Result Comparison (%)	*	* %
Rerun (Low)								
☐ Diluent	0.0 <	1.5 <	0.0			Abnormal Range (Conc)	* –	*
						Panic Range (Conc)	* –	*

Decimal Point: 0 Profile SI: Disable

***Entered by user**

Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * Method Name TRIG Sample Serum

Limit Checks

- ✓ Duplicate Limit: 90 mAbs/10
- ✓ Sensitivity Limit: 1200 mAbs/10
- ✓ Linearity Limit: % ; (mAbs/10)/min
- ☐ Prozone Limit: Higher %
- SL1-S – SL1-F
- SL2-S – SL2-F
- Sensitivity: mAbs/10
- ✓ Absorbance Limit
  - Abs. in reaction: Increase
  - Limit: 25000 mAbs/10

Blank measurement

- Blank measurement: Disable reagent blank and C1 blank
- Measurement of Reagent Blank during Run: None
- Reagent blank measurement at calibration: Reagent blank (No sample)
- The number of measurement: Duplicate
- Reagent blank limit checks:
  - ✓ Duplicate Limit: 60 mAbs/10

Instrument Factor

a 1.00 b 0.00

Triglycerides FS

Chemistry Code 100 74

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name TRIG

Sample Type Serum

Replication Duplicate

Check Interval 63

Test without calibration
Disable

Calibration Type Linear

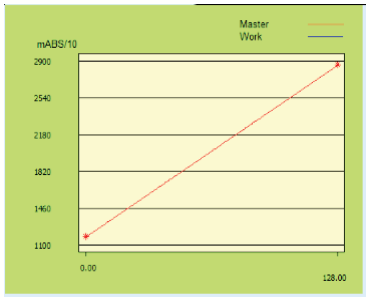
Reagent Lot New Add

Calibrator Name TruCal U

	Conc.	WORK	MASTER	Calibr. Lot No. ☐ All
C1	0	Automatic entry	Automatic entry	*
C2	*	Automatic entry	Automatic entry	*
C3	*			
C4	*			
C5	*			
C6	*			
C7	*			

K Automatic entry ☐ C1 Blank
☐ Reagent Blank for C1

Reagent Lot No.
(R1) *
(R2) *
Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

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Triglycerides FS

Chemistry Code 100 74

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method	*	Name	TRIG	Reagent Name	Reagent (µL)	Water (µL)
Print Name	Triglycerides			R1	TRIG	180	
Sample	Serum			R2 ✓ Enable			
Unit	mg/dL						
Assay Type	End			Diluent ☐ Enable		

Measuring points		Start		End
	1	67	–	68
☐ Enable	2		–	

Decimal Points: 0

Wave Length: Prim. 510 Sec ☐ Disable 700

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Normal Sampling	Sample (µL)	Diluent (µL)
☐ Dilution	2.0		
Rerun (High/Prozone)			
☐ Dilution	2.0		
Rerun (Low)			
☐ Dilution	2.0		

Technical Range: (Conc) 2 – 1000; (mAbs/10) –

SPT Wash ☐ Enable — Reagent Name

Stirring Speed: R1 Middle R2

***Entered by user**

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No. * Name TRIG Sample Serum

Limit Checks

✓ Duplicate Limit	90	mAbs/10	
✓ Sensitivity Limit	1200	mAbs/10	
✓ Linearity Limit		%	(mAbs/10)/min
☐ Prozone Limit		%	Upper
SL1-S		– SL1-F	
SL2-S		– SL2-F	
Sensitivity		mAbs/10	
✓ Absorbance Limit			
Reaction	Increase		
Limit	25000	mAbs/10	

Blank measurement

Blank measurement: Disable reagent blank and S1 blank

Measurement of Reagent Blank during Run: None

Reagent blank measurement at calibration: Reagent blank (No sample)

The number of measurement: Duplicate

Reagent blank limit checks:
✓ Duplicate Limit 60 mAbs/10

Instrument Factor: a 1.00 b 0.00

Triglycerides FS

Chemistry Code 100 74

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * Name: TRIG

Sample: Serum

Sampling: Duplicate

Check Interval: 63 days

Auto: Change Lot | Full Calibration

Auto Interval: hours

Type: Linear Lot: New

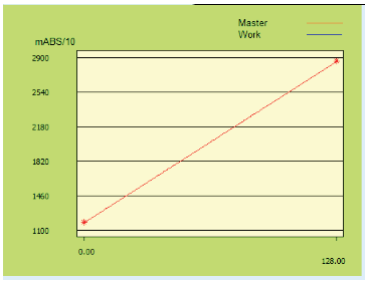
Material Name: TruCal U

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K: Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1: * R2: * Last:



The calibration curve is lot dependent

Reagent blank: mAbs/10 Last:

Blank: Automatic entry mAbs/10 Last:

Type: Conc.:

Absorbance: mAbs/10 Recalculation