BECKMAN COULTER CE

SYNCHRON System(s)

Chemistry Information Sheet

TG-B

Triglycerides GPO Blanked

REF 445850

For *In Vitro* Diagnostic Use

Rx Only

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

Triglycerides GPO reagent, when used in conjunction with UniCel DxC 600/800 System(s), Synchron Systems Multi Calibrator and the Triglycerides Gpo Blanked assay parameters, is intended for quantitative determination of triglycerides concentration in human serum or plasma.

CLINICAL SIGNIFICANCE

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.

METHODOLOGY

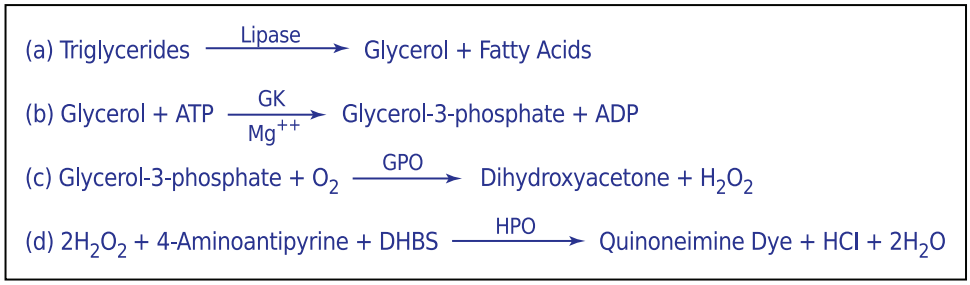
Triglycerides GPO reagent is used to measure the triglycerides concentration by a timed endpoint method.[1,2] Triglycerides in the sample are hydrolyzed to glycerol and free fatty acids by the action of lipase. A sequence of three coupled enzymatic steps using glycerol kinase (GK), glycerophosphate oxidase (GPO), and horseradish peroxidase (HPO) causes the oxidative coupling of 3,5-dichloro-2-hydroxybenzenesulfonic acid (DHBS) with 4-aminoantipyrine to form a red quinoneimine dye.

The triglycerides-blanked assay parameters are an alternate parameter set designed to be used with the Triglycerides GPO (TG) reagent. The triglycerides-blanked assay reduces the effects of free glycerol in serum which may be seen with the triglycerides assay parameters. The triglycerides-blanked assay employs the use of a reaction trigger cycle for glycerol blanking. The blanking step in the triglycerides-blanked assay reduces the sample throughput when compared to the nonblanked triglycerides assay. In some cases, free glycerol can have a clinically significant effect on the final result.[3,4]

The SYNCHRON System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 100 parts reagent. The System monitors the change in absorbance at 520 nanometers

just prior to the addition of lipase and for a fixed time interval after lipase addition. This change in absorbance is directly proportional to the concentration of triglycerides in the sample and is used by the System to calculate and express the triglycerides concentration.

CHEMICAL REACTION SCHEME



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SPECIMEN

TYPE OF SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.[5] Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine are not recommended for use as a sample.

SPECIMEN STORAGE AND STABILITY

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.[6]
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.[6]

Additional specimen storage and stability conditions as designated by this laboratory:

SAMPLE VOLUME

The optimum volume, when using a 0.5 mL sample cup, is 0.3 mL of sample. For optimum primary sample tube volumes and minimum volumes, refer to the Primary Tube Sample Template for your system.

CRITERIA FOR UNACCEPTABLE SPECIMENS

Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on unacceptable specimens.

Criteria for sample rejection as designated by this laboratory:

PATIENT PREPARATION

It is recommended that blood specimens be drawn after the patient has fasted for 12 hours.

Special instructions for patient preparation as designated by this laboratory:

SPECIMEN HANDLING

Special instructions for specimen handling as designated by this laboratory:

REAGENTS

CONTENTS

Each kit contains the following items:

Two TG-B Reagent Cartridges (2 x 300 tests)

VOLUMES PER TEST

Sample Volume	3 µL
Total Reagent Volume	300 µL
Cartridge Volumes	
A	275 µL
B	15 µL
C	10 µL

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

Lipase	68 U/L
Adenosine triphosphate (ATP)	2.56 mmol/L
Glycerol kinase (GK)	4 KIU/L
Glycerophosphate oxidase (GPO)	1.1 KIU/L
4-Aminoantipyrine	0.71 mmol/L
3,5-Dichloro-2-Hydroxybenzenesulfonic Acid (DHBS)	1.56 mmol/L
Horseradish peroxidase (HPO)	9 KIU/L

Also non-reactive chemicals necessary for optimal system performance.

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS	Safety Data Sheet is available at techdocs.beckmancoulter.com

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

Synchron Systems Multi Calibrator
At least two levels of control material
Saline

REAGENT PREPARATION

No preparation is required, but the cartridge must be manually loaded.

ACCEPTABLE REAGENT PERFORMANCE

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility's acceptance criteria.

REAGENT STORAGE AND STABILITY

TG-B reagent, when stored unopened at +2°C to +8°C, will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent cartridge is stable for 30 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE.

Reagent storage location:

CALIBRATION

CALIBRATOR REQUIRED

Synchron Systems Multi Calibrator

CALIBRATOR PREPARATION

No preparation is required.

CALIBRATOR STORAGE AND STABILITY

Synchron Systems Multi Calibrator is stable until the expiration date printed on the calibrator bottle if stored unopened at -15°C to -20°C. Once opened, resealed calibrators stored at +2°C to +8°C are stable for 20 days unless the expiration date is exceeded.

⚠ CAUTION

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HbsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples to be handled as specified in Centers for Disease Control's Biosafety Level 2 guidelines.[7]

Calibrator storage location:

CALIBRATION INFORMATION

1. The system must have a valid calibration curve in memory before control or patient samples can be run.
2. Under typical operating conditions the TG-B reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.
4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

TRACEABILITY

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new calibration, with each new reagent cartridge, and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

The following controls should be prepared and used in accordance with the package inserts. Discrepant quality control results should be evaluated by your facility.

Table 1.0 Quality Control Material

CONTROL NAME	SAMPLE TYPE	STORAGE

TESTING PROCEDURE(S)

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration may be required.
3. Program samples and controls for analysis.
4. After loading samples and controls onto the system, follow the protocols for system operations.

For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

The SYNCHRON System(s) performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

REPORTING RESULTS

Equivalency between the SYNCHRON LX and UniCel DxC 600/800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

REFERENCE INTERVALS

The Adult Treatment Panel of the Center for Disease Control (CDC) recommends triglyceride values for cardiovascular risk to be:[8,9]

Table 2.0 Triglyceride Reference Intervals

CARDIOVASCULAR RISK	CONVENTIONAL UNITS	S.I. UNITS
Normal	Less than 150 mg/dL	Less than 1.69 mmol/L
Borderline high	150 – 199 mg/dL	1.69 - 2.25 mmol/L
High	200 – 500 mg/dL	2.26 - 5.64 mmol/L
Very high	Greater than 500 mg/dL	Greater than 5.65 mmol/L

Refer to Reference (10) for additional reference intervals according to age and sex. Each laboratory should establish its own reference intervals based upon its patient population.

Refer to References (11, 12, 13) for guidelines on establishing laboratory-specific reference intervals.

Additional reporting information as designated by this laboratory:

PROCEDURAL NOTES

ANTICOAGULANT TEST RESULTS

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Table 3.0 Acceptable Anticoagulants[a]

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	AVERAGE PLASMA-SERUM BIAS (mg/dL)
Ammonium Heparin	29 Units/mL	NSI[b]
Lithium Heparin	29 Units/mL	NSI
Sodium Heparin	29 Units/mL	NSI

a Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

b NSI = No Significant Interference (within ±10.0 mg/dL or 6%).

2. The following anticoagulants were found to be incompatible with this method:

Table 4.0 Incompatible Anticoagulants[a]

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	MAXIMUM BIAS BETWEEN PLASMA-SERUM (mg/dL)[b]
Sodium Citrate	1.7 mg/mL	≤-39.0
Potassium Oxalate/Sodium Fluoride	4.0 / 5.0 mg/mL	≤-78.0

a Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.
b Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

LIMITATIONS

Triglycerides-blanked samples must be run in the Batch Mode in which triglycerides-blanked samples are programmed in a run separately from all other samples and assays. The triglycerides-blanked runs must be started when the system is in Standby.

INTERFERENCES

1. The following substances were tested for interference with this methodology:

Table 5.0 Interferences

SUBSTANCE	SOURCE	LEVEL	OBSERVED EFFECT[a]
Hemoglobin	RBC hemolysate	500 mg/dL	≤-10 mg/dL or 10%
Bilirubin	Bovine	30 mg/dL	≤-10 mg/dL or 10%
Dextrose[b]	NA[c]	1,200 mg/dL	≤+2.0 mg/dL
Creatinine[b]	NA	30 mg/dL	≤+2.0 mg/dL
Urea[b]	NA	500 mg/dL	≤±3.0 mg/dL
Ascorbic Acid[b]	NA	3.0 mg/dL	≤-5.0 mg/dL

a Plus (+) or minus (-) signs in this column signify positive or negative interference.
b Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.
c NA = Not applicable.

2. Samples at a Lipemia Index Level of 9 and above should be diluted one part sample plus nine parts saline prior to analysis. The result should be multiplied by ten or the factor entered into the system during sample programming. This should prevent falsely decreased results due to excessive turbidity.
3. Venipuncture immediately after or during the administration of Metamizole (Dipyrone) may lead to falsely low results for TG-B. Venipuncture should be performed prior to the administration of Metamizole.
4. *N-acetyl-p-benzoquinone imine* (NAPQI), a metabolite of acetaminophen (paracetamol), may generate erroneously low results in samples for patients that have taken toxic doses of acetaminophen (paracetamol).
5. Refer to References (14,15,16) for other interferences caused by drugs, disease and preanalytical variables.

PERFORMANCE CHARACTERISTICS

ANALYTIC RANGE

The SYNCHRON System(s) method for the determination of this analyte provides the following analytical ranges:

Table 6.0 Analytical Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum or Plasma	10 – 1,000 mg/dL	0.1 – 11.3 mmol/L

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

REPORTABLE RANGE (AS DETERMINED ON SITE):

Table 7.0 Reportable Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS

SENSITIVITY

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for TG-B determination is 10 mg/dL (0.1 mmol/L).

EQUIVALENCY

Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

Serum or plasma (in the range of 21 to 936 mg/dL):

Y (SYNCHRON LX Systems)	= 0.989X + 5.69
N	= 73
MEAN (SYNCHRON LX Systems)	= 236.2
MEAN (SYNCHRON CX7 DELTA)	= 233.1
CORRELATION COEFFICIENT (r)	= 0.9888

Refer to References (17) for guidelines on performing equivalency testing.

PRECISION

A properly operating SYNCHRON System(s) should exhibit precision values less than or equal to the following:

Table 8.0 Precision Values

TYPE OF PRECISION	SAMPLE TYPE	1 SD		CHANGEOVER VALUE[a]		% CV
		mg/dL	mmol/L	mg/dL	mmol/L	
Within-run	Serum/Plasma	5.0	0.1	166.7	2.0	3.0
Total	Serum/Plasma	7.5	0.2	166.7	2.0	4.5

a When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

Comparative performance data for a SYNCHRON LX System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below.[18] Each laboratory should characterize their own instrument performance for comparison purposes.

Table 9.0 NCCLS EP5-T2 Precision Estimate Method

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points[a]	Test Mean Value (mg/dL)	EP5-T2 Calculated Point Estimates	
						SD	%CV
Within-run	Serum	Control 1	1	80	51.1	1.0	2.0
	Serum	Control 2	1	80	82.0	1.5	1.8
	Serum	Control 3	1	80	113.5	1.9	1.6
Total	Serum	Control 1	1	80	51.1	1.0	2.0
	Serum	Control 2	1	80	82.0	1.6	2.0
	Serum	Control 3	1	80	113.5	2.0	1.7

a The point estimate is based on the pooled data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer's instructions.

NOTICE

These degrees of precision and equivalency were obtained in typical testing procedures on a SYNCHRON LX System and are not intended to represent the performance specifications for this reagent.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

SHIPPING DAMAGE

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

REVISION HISTORY

Revision AF

Revised Reagent Preparation section.

Revision AG

Updated corporate address; removed insert reference from content description and removed EDTA as an Acceptable Anticoagulant claim.

Revision AH

Added Revision History

Revision AJ

Revised Interferences section.

Revision AK

Added new language requirement: Czech, and Korean.

Revision AL

Revised Reference Intervals S.I. Units.

Revision AM

Removed references to CX and LX systems as they are discontinued effective 12/2013.

Added Beckman Coulter trademark statement and disclaimer.

Revision AN

Added GHS Classification information

Revision AP

Updates to comply with requirements per Beckman Coulter Global Labeling Policy.

New statement (item #3) added under INTERFERENCES section.

Revision AR

Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.

Revision AT

New statement (item #4) added under INTERFERENCES section.

Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.

Revision AU

Added new language requirement: Bulgarian, Romanian, Serbian, and Vietnamese.

SYMBOLS KEY

Table 10.0

REF	Catalogue Number	IVD	In Vitro Diagnostic
CONTENTS	Contents		Temperature limit
	Manufacturer		Expiration Date
LOT	Batch code	SDS	Safety Data Sheet
CE	CE Mark		Consult Instructions for Use
EC REP	Authorized Representative in the European Community		Date of Manufacture
	Caution		Biological risks
	Do Not Freeze		Do not reuse
Made in USA of US and Foreign Components		Made in USA of US and Foreign Components	

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