BECKMAN COULTER

SYNCHRON CX® System(s) Chemistry Information Sheet

TG
Triglycerides GPO

Kit Reorder # 445850

For *In Vitro* Diagnostic Use

ANNUAL REVIEW

Reviewed by:	Date	Reviewed by:	Date

PRINCIPLE

INTENDED USE

TG reagent, when used in conjunction with SYNCHRON CX® System(s) and SYNCHRON CX MULTI™ Calibrator, is intended for the quantitative determination of total triglycerides (TG) concentration in human serum or plasma.

CLINICAL SIGNIFICANCE

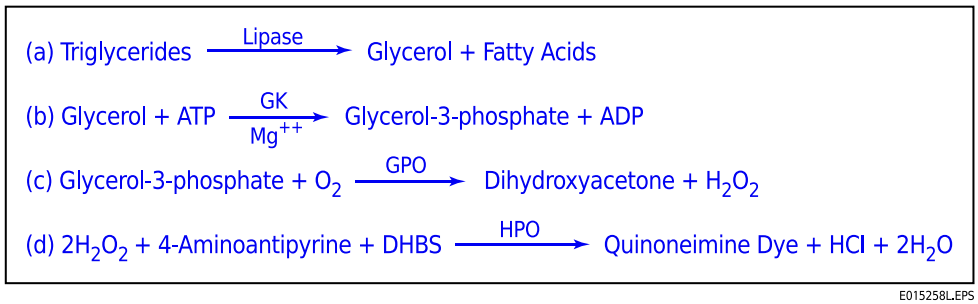
Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

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 SYNCHRON CX® 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. This change in absorbance is directly proportional to the concentration of TG in the sample and is used by the System to calculate and express TG 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.[3] 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.[4]
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.[4]

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

SAMPLE VOLUME

A filled 0.5 mL sample cup is the optimum volume. For optimum volume in primary tube samples, refer to Primary Sample Tube Chart Template (P/N 248511) for minimum volume requirements.

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 Reagent Cartridges (2 x 300 tests)
One Instruction Insert

VOLUMES PER TEST

Sample Volume	3 µL
Total Reagent Volume	300 µL
Cartridge Volumes	
A	285 µL
B	15 µL
C	– –

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

Lipase	93 U/L
Adenosine triphosphate (ATP)	2.52 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)	1.54 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 National Institute for Occupational Safety and Health Bulletin: Explosive Azide Hazards (8/16/76).

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

SYNCHRON CX MULTI™ Calibrator
At least two levels of control material
Saline

REAGENT PREPARATION

1. Qualitatively transfer all the contents of compartment C (smallest compartment) into compartment A (largest compartment).
2. Replace cartridge caps and gently invert the cartridge several times to ensure adequate mixing.

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 reagent, when stored unopened at +2°C to +8°C, will remain stable until the expiration date printed on the cartridge label. Once prepared, the reagent 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 CX MULTI™ Calibrator

CALIBRATOR PREPARATION

No preparation is required.

CALIBRATOR STORAGE AND STABILITY

If unopened, the SYNCHRON CX MULTI™ Calibrator may be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and 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.[5]

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 reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the SYNCHRON CX *Operating Instructions* manual. This assay has within-lot calibration available. Refer to Section 6 of the SYNCHRON CX *Operating Instructions* manual for information on this feature.
3. For detailed calibration instructions refer to Section 6 of the SYNCHRON CX *Operating Instructions* 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. The explanation of these error codes can be found in Appendix G of Section 10 in the SYNCHRON CX *Operating Instructions* 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 SYNCHRON CX *Operating Instructions* manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on work load and work flow.

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 prepare reagent cartridge as defined in the Reagent Preparation section of this chemistry information sheet and load the reagent onto the system as directed in Section 6 of the SYNCHRON CX *Operating Instructions* manual.
2. After reagent load is completed, calibration may be required. Refer to Section 6 of the SYNCHRON CX *Operating Instructions* manual for details of the calibration procedure.
3. Program samples and controls for analysis as directed in Section 6 of the SYNCHRON CX *Operating Instructions* manual.
4. After loading samples and controls onto the system, follow the protocols for system operation as directed in Section 6 of the SYNCHRON CX *Operating Instructions* manual.

CALCULATIONS

The system performs all calculations internally to produce the final reported result. SYNCHRON CX4/5 Systems do not calculate the final result for sample dilutions made by the operator. In these cases, the result produced by the instrument must be multiplied by the dilution factor before reporting the final result. SYNCHRON CX4CE/5CE/7 Systems (including the CX DELTA and CX PRO Systems) 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

REFERENCE INTERVALS

The Adult Treatment Panel of the Center for Disease Control (CDC) recommends triglyceride values for cardiovascular risk to be:[6,7]

Table 2.0 Reference intervals

CARDIOVASCULAR RISK	CONVENTIONAL UNITS	S.I. UNITS
Normal	Less than 150 mg/dL	Less than 1.95 mmol/L
Borderline high	150 – 199 mg/dL	1.95 – 2.59 mmol/L
High	200 – 500 mg/dL	2.60 – 6.49 mmol/L
Very high	Greater than 500 mg/dL	Greater than 6.50 mmol/L

Refer to Reference (8) 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 (9,10,11) 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

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	AVERAGE PLASMA-SERUM BIAS (mg/dL) @ +37°C
Ammonium Heparin	29 Units/mL	NSI[a]
Lithium Heparin	29 Units/mL	NSI
Sodium Heparin	29 Units/mL	NSI
EDTA	3.0 mg/mL	NSI

a 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

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	PLASMA-SERUM BIAS (mg/dL) @ +37°C[a]
Sodium Citrate	1.7 mg/mL	≤±30.0
Potassium Oxalate/Sodium Fluoride	4.0 / 5.0 mg/mL	≤-80.0

a Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

LIMITATIONS

1. It is recommended that this test be run at +37°C only.
2. If observed visible lipemia is 4+ or greater, a preliminary dilution of the sample (1:10) is recommended in order to prevent falsely decreased results due to excessive turbidity.

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	(4+) 500 mg/dL	≤±5.0 mg/dL
Bilirubin	Bovine	5 mg/dL	≤-8.0 mg/dL

Table 5.0 Interferences, Continued

SUBSTANCE	SOURCE	LEVEL	OBSERVED EFFECT[a]
Dextrose	NA[b]	1200 mg/dL	≤+5.0 mg/dL
Creatinine	NA	30 mg/dL	≤+3.0 mg/dL
Urea	NA	500 mg/dL	≤+9.0 mg/dL
Ascorbic Acid	NA	1.5 mg/dL	≤-4.8 mg/dL
Acetoacetate	NA	0.2 mg/mL	≤+0.7 mg/dL
		1.08 mg/mL	≤+3.7 mg/dL

a Plus (+) or minus (-) signs in this column signify positive or negative interference.
b NA = Not applicable.

2. Refer to References (12,13,14) for other interferences caused by drugs, disease and preanalytical variables.

PERFORMANCE CHARACTERISTICS

ANALYTIC RANGE

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

Table 6.0 Analytical Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum or Plasma	10 – 1000 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

EQUIVALENCY

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

Serum or plasma:

Y (SYNCHRON CX Systems)[a]	= 1.065X + 9.89
N	= 94
MEAN (SYNCHRON CX Systems)[a]	= 314.2
MEAN (BMD Trig/GPO on COBAS-BIO)[b]	= 285.7
CORRELATION COEFFICIENT (r)	= 0.999

a Data shown was collected using the SYNCHRON CX4/CX5 Systems. Equivalency between SYNCHRON CX Systems has been established by Deming regression analysis to SYNCHRON CX4/CX5 Systems.
b BMD is a registered trademark of Boehringer Mannheim Corporation. COBAS-BIO is a registered trademark of Roche Analytical Instruments, Inc.

Refer to References (15) for guidelines on performing equivalency testing.

PRECISION

A properly operating SYNCHRON CX® 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]		
		mg/dL	mmol/L	mg/dL	mmol/L	% CV
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.

Refer to References (16) for guidelines on performing on-site precision testing.

NOTICE

These degrees of precision and equivalency were obtained in typical testing procedures on the SYNCHRON CX® System(s) and are not intended to represent the performance specifications for this reagent.

ADDITIONAL INFORMATION

For more detailed information on SYNCHRON CX Systems, refer to the appropriate SYNCHRON CX manual.

SHIPPING DAMAGE

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

REFERENCES

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