DXC 800 (TG) TRIGLYCERIDES

☒ St. Joseph Medical Center, Tacoma, WA	☐ St. Anthony Hospital Gig Harbor, WA	☐ Harrison Medical Center, Bremerton, WA
☐ St. Francis Hospital, Federal Way, WA	☐ St. Elizabeth Hospital Enumclaw, WA	☐ Harrison Medical Center, Silverdale, WA
☐ St. Clare Hospital Lakewood, WA	☐ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To provide instructions for the quantitative determination of triclycerides on the DXC 800.

PRINCIPLE

TG reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Multi Calibrator, is intended for quantitative determination of total Triglycerides concentration in human serum or plasma.

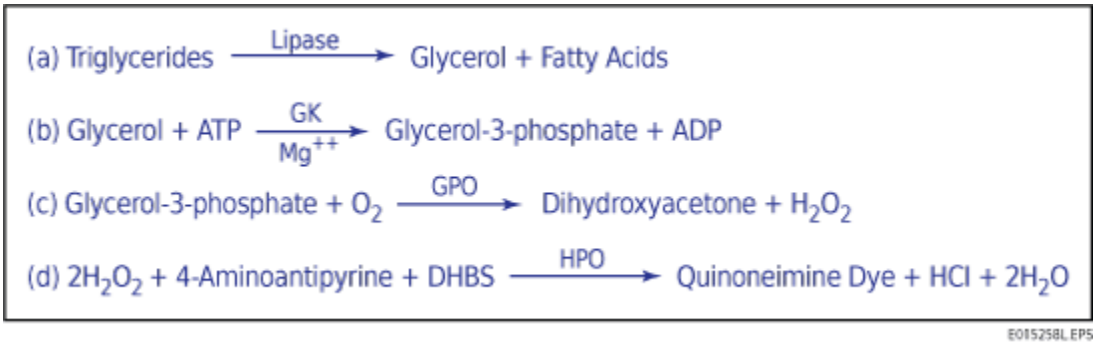
BACKGROUND

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. 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® 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 the TG concentration.



RELATED DOCUMENTS

R-PO-CH-0810 Quality Control Program General Laboratory

R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
J-F-CH-0820	DXC 800 Controls
J-F-CH-0826	DXC 800 Calibrators
J-F-CH-1940	DXC Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. 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.

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.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• Separate serum from cells within 2 hours • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 months

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

Patient Preparation

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

REAGENTS

Contents

Each kit contains the following items:
Two TG Reagent Cartridges (2 x 300 tests)
One Instruction Insert

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

Reactive Ingredients	
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.

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 cartridge is stable for 30 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE.

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.

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 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

See Related Documents J-F-CH0820 DXC 800 Controls.

STEPS

1. If necessary prepare reagent as defined in the Reagent Preparation section of this chemistry information sheet and 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 operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. .For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform 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.

ANTICOAGULANT TEST RESULTS

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:

Anticoagulant	Level Tested for In Vitro Interference
Ammonium Heparin	29 Units/mL
Lithium Heparin	29 Units/mL
Sodium Heparin	29 Units/mL

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

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias (mg/dL)
Sodium Citrate	1.7 mg/mL	≤±30.0
Potassium Oxalate/Sodium Fluoride	4.0 / 5.0 mg/mL	≤-80.0

PERFORMANCE CHARACTERISTICS

Reference Range

Normal	Less than 150 mg/dL
Borderline high	150 – 199 mg/dL
High	200 – 499 mg/dL
Very high	Greater than 500 mg/dL

Analytic Range

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

Sample Type	Conventional Units
Serum or Plasma	10 – 1000 mg/dL

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

Reporting results outside of analytical range

Lower limit of detection	10 mg/dL	Results below 10, report as <10mg/dL
Upper limit of detection	1000 mg/dL	Results >1000mg/dL, should be diluted with 0.9% saline, reanalyzed and dilution factor applied. For Lipemic index <9, maximum dilution is X5. For Lipemic index of >9, maximum dilution is X10. Results >5000 on Lipemic index <9 are reported as >5000 mg/dL. Results >10,000 for Lipemic index >9 are reported as >10,000 mg/dL.

Sensitivity

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

LIMITATIONS

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.

Interferences

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

Substance	Source	Level Tested	Observed Effect
Hemoglobin	RBC hemolysate	325 mg/dL INDEX of 9	≤-15 mg/dL or 10%
Bilirubin	Bovine	30 mg/dL INDEX of 20	≤-10 mg/dL or 10%
Dextrose	NA	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

ADDITIONAL INFORMATION

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

REFERENCES

1. Bucolo, G., David, H., *Clin. Chem.*, 19:476 (1973).
2. Pinter, J. K., Hayashi, J. A., Watson, J. A., *Arch. Biochem. Biophys.*, 121:404 (1965).
3. Tietz, N. W., "Specimen Collection and Processing; Sources of Biological Variation", *Textbook of Clinical Chemistry*, 2nd Edition, W. B. Saunders, Philadelphia, PA (1994).
4. National Committee for Clinical Laboratory Standards, *Procedures for the Handling and Processing of Blood Specimens*, Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).
5. CDC-NIH manual, *Biosafety in Microbiological and Biomedical Laboratories*, U.S. Government Printing Office, Washington, D.C. (1984).
6. NIH Publication No. 01 3305, *ATP III Guidelines At-A-Glance*, Quick Desk Reference, May (2001).
7. NIH Publication No. 01 3670, Third Report of National Cholesterol Education Program (NCEP) Expert Panel on Detection, *Evaluation and Treatment of High Cholesterol in Adults (Adult Treatment Panel III)*, May (2001).
8. Tietz, N. W., *Clinical Guide to Laboratory Tests*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1995).
9. National Committee for Clinical Laboratory Standards, *How to Define, Determine, and Utilize Reference Intervals in the Clinical Laboratory*, Approved Guideline, NCCLS publication C28-A, Villanova, PA (1995).
10. Tietz, N. W., ed., *Fundamentals of Clinical Chemistry*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1987).
11. Henry, J. B., *Clinical Diagnosis and Management by Laboratory Methods*, 18th Edition, W. B. Saunders Company, Philadelphia, PA (1991).
12. Young, D. S., *Effects of Drugs on Clinical Laboratory Tests*, 4th Edition, AACC Press, Washington, D. C. (1995).
13. Friedman, R. B., Young, D. S., *Effects of Disease on Clinical Laboratory Tests*, 3rd Edition, AACC Press, Washington, D.C. (1997).
14. Young, D. S., *Effects of Preanalytical Variables on Clinical Laboratory Tests*, 2nd Edition, AACC Press, Washington, D. C. (1997).
15. National Committee for Clinical Laboratory Standards, *Method Comparison and Bias Estimation Using Patient Samples*, Approved Guideline, NCCLS publication EP9-A, Villanova, PA (1995).
16. National Committee for Clinical Laboratory Standards, *Precision Performance of Clinical Chemistry Devices*, Tentative Guideline, 2nd Edition, NCCLS publication EP5-T2, Villanova, PA (1992).

DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
Formatting, added max dilutions, changes in interfering substances.			
☐ *No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.*			
Committee Approval Date	☐ Date: ☒ N/A – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 9/25/15