Triglyceride in Plasma/Serum or Body Fluid

Purpose

This procedure provides instructions for performing TRIGLYCERIDE IN PLASMA/SERUM or BODY FLUID. The TRIG method is an *in vitro* diagnostic test for the quantitative measurement of triglycerides in human serum and plasma on the Dimension Vista System.

Policy Statements

This procedure applies to all personnel responsible for testing Triglyceride on the Siemens Dimension Vista.

Principle

The triglycerides method is based on an enzymatic procedure using a combination of enzymes. The sample is incubated with lipoprotein lipase (LPL) enzyme reagent that converts triglycerides into free glycerol and fatty acids. Glycerol kinase (GK) catalyzes the phosphorylation of glycerol by adenosine-5-triphosphate (ATP) to glycerol-3-phosphate. Glycerol-3-phosphate-oxidase oxidizes glycerol-3-phosphate to dihydroxyacetone phosphate and hydrogen peroxide. The catalytic action of peroxidase forms quinoneimine from H_2O_2, aminoantipyrine and 4-chlorophenol. The change in absorbance due to the formation of quinoneimine is directly proportional to the total amount of glycerol and its precursors in the sample and is measured using a bichromatic (510, 700 nm) endpoint technique. See product insert for additional information.

Clinical Significance

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

Triglycerides are water-insoluble lipids consisting of three fatty acids linked to one glycerol molecule. Triglycerides are transported in the blood as core constituents of all lipoproteins, but the greatest concentration of these molecules is carried in the triglycerides-rich chylomicrons and very low density lipoproteins (VLDL). Through the action of lipases and bile acids, triglycerides are hydrolyzed into glycerol and fatty acids which are absorbed by adipose tissue for storage or by other tissues requiring a source of energy.

A peak concentration of chylomicron-associated triglycerides occurs within 3–6 hours after ingestion of a fat-rich meal; however, the rate of absorption of fats is highly variable, depending on the individual and dietary composition of the fat. After absorption, triglycerides are resynthesized in the epithelial cells and combined with cholesterol and a number of apolipoproteins to form chylomicrons.

Analyzer

PRIMARY METHOD: *Siemens Dimension Vista 500*

SECONDARY (BACKUP) METHOD: Siemens Dimension Vista (opposite campus)

Test Codes

TRIG	Triglyceride in serum or plasma
FTRG	Body fluid triglyceride

Specimen

Patient preparation: The patient should be fasting for 10-14 hours and on a stable diet for 3 weeks prior to collection. Avoid alcohol for 3 days, and strenuous exercise for 24 hours prior to collection.

- Venipuncture should occur prior to administration of N-Acetylcysteine (NAC) or Metamizole due to the potential for falsely depressed results[8]. NAC is the accepted antidote for acetaminophen toxicity. Metamizole is an anti-pyretic banned in most countries.
- Blood collection tubes containing glycerol lubricated stoppers should be avoided since they will cause erroneously elevated result.
- Plasma (lithium heparin) preferred
- Serum
- Body fluid, free of clots and fibrin strands

Minimum volume: 200 µL, 100 µL minimum, Actual test volume: 1.6 µL

Stability: 2-8 °C / 7 days, < -20°C / 3 months

Rejection criteria:
- Unlabelled specimens.
- Body fluid specimens too highly viscous to assure accurate test results on the Dimension Vista.

Preparation:
1. Whole blood specimens should be centrifuged following complete clot formation, according to Specimen Processing procedures prior to analysis.
2. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
3. Do *not* ultrafuge lipemic samples.
4. Specimens should be free of particulate matter.
5. Transfer serum/ plasma or prepared urine to a properly labeled RXL SSC or tube. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.

Reagents

PRIMARY METHOD:

Product Description	***Product Code***	***Stability***
TRIG Flex® reagent cartridge, All reagents are liquid and ready to use.	K2069	**Store at:** 2 – 8 °C **Unopened:** Refer to carton for expiration date. **On-board:** Sealed wells on the instrument are stable for 30 days. **Open well stability:** 7 days for wells 1-12
CHEM 2 CAL (Vista)	KC120	**Store at:** 2 - 8 °C. **Unopened:** Refer to carton for expiration date. **On-board:** Once the vial stopper is punctured, assigned values are stable for 24 hours when stored on board the Dimension Vista® System. **Opened**: Once the cap is removed, assigned values are stable for 30 days when recapped and stored at 2-8 C. Do not use on board the Vista.

Risk and Safety

Precautions:

- Contains sodium azide (< 0.1%) as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Flush with adequate water.
- Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.
- Follow laboratory safety policies and procedures.
- Safety data sheets (MSDS/SDS) available on www.siemens.com/diagnostics

Calibration

Analytical Measuring Range	2–1000 mg/dL
Reference Material:	CHEM 2 CAL (KC120)
Suggested Calibration Levels:	Level 1 (Calibrator A): 0 mg/dL Level 2 (Calibrator B): 1064 mg/dL
Calibration Scheme:	2 levels (n=5)
Calibration Frequency:	Every 90 days for any one lot For each new lot of Flex® reagent cartridges After major maintenance or service, if indicated by quality control results As indicated in laboratory quality control procedures
Analytical Measuring Range and Calibration Verification	• Cal Verification and AMR verification are performed at least once every six (6) months. • Touch Advanced → Calibrations → Calibrations by Lot, select method TRIG and "Order a Linearity Study" • See iGuide "Calibration by Lot" for more information.

Quality Control (Plasma/Serum)

Biorad Multiqual (Human) Levels 1 & 3

Frequency: Two levels each day of use

Stability: Stable until the date on vial when stored at -20 to -50 °C protect from light. Thawed and unopened, 7 days at 2 -8 °C. 7 days on board the Vista, and 5 days opened and stored at 2 – 8 °C

Preparation: Allow the control to stand at 18 – 25 °C for 30 minutes until completely thawed. Gently mix the vials until homogeneous to dissolve any precipitate.

Sunquest Control names: Level 1 = C-MQ1, Level 2 = C-MQ3

Acceptable ranges:

- Ranges are current in Sunquest and the instrument. Refer to the Quality Control Procedure for QC exception codes.
- If a control value is outside the confidence interval, the determination must be repeated. If the repeated determination confirms the deviation, a new reference curve should be established.
- Do not release patient results until the cause of deviation has been identified and corrected
- When a new lot of control is received, validate the manufacturer's insert range by running the new lot in parallel with the current lot, and confirming that the results obtained are within the stated range

Interferences

Hemolysis, Icterus & Lipemia (HIL) Index Values:

H	I	L
-	3	-

- Small amounts of free glycerol may be found in blood samples from healthy individuals due to natural lipolysis. The concentration of free glycerol may be increased by stress, disease states or administration of intravenous infusates. Free glycerol or other polyols may cause a positive interference.
- Glycerol-based quality control products should not be used with this method
- Bilirubin (unconjugated) of 10 mg/dL will increase a triglycerides result of 180 mg/dL by 11%
- Ascorbic acid at a concentration of 5 mg/dL decreases triglyceride results by 11.8% at a triglyceride concentration of 180 mg/dL.

Refer to the product insert for a list of substances that have been shown to have no measurable effect on the TRIG result at typical concentrations.

Reference Range

Serum/Plasma:

Age	Acceptable	Borderline	High
0 – 9	0 – 75	75 - 99	≥ 100
10 – 17	< 90	90 – 129	≥ 130
> 18 years	< 150	150 – 199	≥ 200

Critical Values

None defined

Limitations

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension Operator's Guide for troubleshooting.

Dilutions

Maximum Dilution:	1:4
Surplus Rack:	Samples with results >1000 mg/dL reflex to a 1:4 dilution.
Limited Rack:	Samples with results >1000 mg/dL should be repeated as an Add-On Test with a 1:4 dilution.
Manual Dilution:	Do not dilute manually.

Result Reporting

- Results between 2-1000 mg/dL without error messages are released
- Serum/Plasma results below 2 mg/dL: report as < 2 mg/dL.
- Results >1000 mg/dL without error messages are reported following a maximum dilution of 1:4
- Results that exceed the assay range following a maximum dilution of 1:4: Report as >4000 mg/dL
- Append appropriate HIL comments. Refer to CH5.101 HIL on Dimension Vista

The following comments are automatically appended to:

Patients < 9 years

National Cholesterol Education Program (NCEP) guidelines:
<9 y:
Normal: <75
Borderline high: 75-99
High: ≥100

Patients < 18 years

National Cholesterol Education Program (NCEP) guidelines:
<18 y:
Normal: <90
Borderline high: 90-129
High: ≥130

Patients ≥ 18 years

National Cholesterol Education Program (NCEP) guidelines:
≥18 y:
Normal: <150
Borderline high: 150-199
High: >200-499
Very high: ≥500

Specimen Storage

Promptly stopper tested specimen and store upright in specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer.

References

1. TRIG Flex® reagent cartridge insert sheet Siemens Healthcare Diagnostics Inc, PN 781069.001 2013-08-20 E
2. Tietz Textbook of Clinical Chemistry, 3rd Edition, WB Saunders Company, 1999
3. Jacobs & DeMott Laboratory Test Handbook, Lexi-Comp, Inc, Hudson, OH, 5th Edition, 2001
4. Biorad Multiqual Chemistry Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618
5. US Department of Health and Human Services, National Institutes of Health Publication # 01-3305, May 2001
6. US Department of Health and Human Services, Summary Report of the Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents:
7. Mayo Medical Laboratories, online test catalogue, 1/06/2012
8. Medical Device Correction Notice DC-16-02.A.US – March 17, 2016

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1.	Unknown	Unknown	Triglyceride on Dimension AR
2.	Deane L Riedel	11/21/2000	Triglycerides on Dade Dimension RXL,
3.	L. Lichty	8/12/03	Replaces version 2
4.	L. Lichty	8/21/2005	Revision, minor
5.	L. Lichty	1/11/06	Revision, manufacturer revised reagent
6.	L. Lichty	12/22/06	Revision, update QC material
7.	L. Lichty	June 1, 2011	New format, updates from product insert, renumbered from CH 3.43
8.	L. Lichty	February 21, 2012	Change reference ranges to NCEP
9.	L. Lichty	April 16, 2013	Clarify maximum dilution reporting, add hemolysis comment
10.	L. Lichty	12/17/2013	Siemens TRIG CLSI procedure for Vista, 2013-08-20 Rev E
11.	D. Helfinstine	June 15, 2015	Updated for Dimension Vista
12.	L. Lichty	March 28, 2016	NAC/Metamizole warning