Adventist HealthCare

TRAINING UPDATE

Lab Location:	SGMC	**Date Distributed:**	7/31/23
Department:	Chemistry	**Due Date:**	8/31/23
		Implementation:	**8/3/23**

DESCRIPTION OF PROCEDURE REVISION – New Method

Name of procedure:

New Method SOP:
SGMC.C 3073 Triglycerides - 2 (Trig - 2) by Atellica CH Analyzer

Description of change(s):

Siemens changed the method for Triglyceride on the Atellica. The new method is TRIG-2

Reagents	Supplier & Catalog Number
Triglycerides - 2 (Trig - 2)	Siemens, Atellica CH, Cat. No. 11537222

The onboard stability is 90 days (vs previous method 30 days). QC and calibrators remain the same. The AMR and CRR have changed. (See highlighted in attached SOP).

Much of the procedure remains the same.

Document your compliance with this training update by taking the quiz in the MTS system.

SGMC.C 3073 Triglycerides - 2 (Trig - 2) by Atellica CH Analyzer

Copy of version 1.0 (approved and current)

Last Approval or Periodic Review Completed	7/3/2023
Next Periodic Review Needed On or Before	7/3/2025
Effective Date	7/4/2023

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Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	7/3/2023	1.0	Nicolas Cacciabeve MD Nicolas Cacciabeve	
Approval	Core lab approvals	7/3/2023	1.0	Robert SanLuis Robert SanLuis	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	6/12/2023	7/4/2023	Indefinite

Technical SOP

Title	**Triglycerides - 2 (Trig - 2) by Atellica CH Analyzer**
Prepared by	Ashkan Chini Date: 6/12/23
Owner	Robert SanLuis Date: 6/12/23

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Triglycerides	Atellica CH Analyzer	TRIG

Synonyms/Abbreviations
TGL, TRIG, Included in Batteries/Packages: LPNL

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The Atellica CH Trig-2 assay is based on an enzymatic procedure in which a combination of enzymes are employed for the measurement of serum or plasma triglycerides. The sample is incubated with lipoprotein lipase enzyme reagent that converts triglycerides into free glycerol and fatty acids. Glycerol kinase catalyzes the phosphorylation of glycerol by adenosine-5-triphosphate 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 H2O2, 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 (505/694 nm) endpoint technique.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	Fasting specimens preferred. Patient should be fasting for 12 hours before collection.
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Plasma (Lithium Heparin)
-Other Acceptable	Serum

Criteria	
Collection Container	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: To be determined
	Refrigerated: 7 days
	Frozen: 30 days
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	**Lipemic Samples:** Ultra-centrifugation removes lipemia. Thus, if lipid testing (CHOL, TRIG, HDL, or LDL) is requested, testing for lipids must be performed prior to ultra-centrifugation. **Note:** Saved aliquot must be clearly marked at ultra-centrifuged. Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Allow Red Top or SST to clot completely prior to centrifugation. Before placing on system, ensure samples are free of: • Bubbles or foam • Fibrin or other particulate matter

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Triglycerides - 2 (Trig - 2)	Siemens, Atellica CH, Cat. No. 11537222

4.2 Reagent Preparation and Storage

Reagent	**Triglycerides - 2 (Trig - 2)**
Storage	- Store at 2-8° C - Store in an upright position, away from light
Stability	Onboard per well: 90 days
Preparation	Reagent is liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Chemistry Calibrator (CHEM CAL)	Siemens Atellica CH, Cat. No. 11099411

5.2 Calibrator Preparation and Storage

Calibrator	Chemistry Calibrator (CHEM CAL)
Preparation	1. Shake to break up lyophilized cake. 2. Open each vial carefully. 3. Using a calibrated pipette, add exactly 3.0 mL of reagent grade water into the vial. Replace the stopper. 4. Manually mix by inverting 10 times every 10 minutes for a period of 30 minutes, or until reconstitution is complete. 5. Prior to use, mix by inversion at least 5 times to ensure homogeneity. 6. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.
Storage/Stability	• Protect from heat and light sources. • Store at 2-8°C • **Unopened:** stable until expiration date stamped on the box. • **Reconstituted:** remains stable for 48 hours

5.3 Calibration Parameter

Criteria	**Special Notations**
Reference Material	Chemistry Calibrator (CHEM CAL)

Assay Range	See Package Insert for specific assay ranges.
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mg/dL
Frequency	• When changing lot numbers of primary reagent packs. • At the end of the lot calibration interval (30 days), for a specified lot of calibrated reagent on the system. • At the end of pack calibration interval (15 days), for calibrated reagent packs on the system. • When indicated by quality control results. • After major maintenance or service. At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.
Calibration Scheme	See Package Insert for specific calibration scheme.
Procedure	Refer to the Atellica Solution Operation, QC, Calibration and Maintenance procedure for specific instructions.

5.3 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
InteliQ Assayed Multiqual Control Levels 1 & 3	Bio-Rad Laboratories Cat. No. 12008256, 12008258

6.2 Control Preparation and Storage

Control	InteliQ Assayed Multiqual Control Levels 1 & 3
Preparation	Allow the frozen product to thaw at room temperature (18 to 25°C) for 60 minutes or until completely thawed prior to use. Once thawed, gently invert the tube several times to ensue homogeneity.

Storage/Stability	**Frozen:** until the expiration date if unopened at -20 to -70°C **Thawed and Unopened**: 7 days at 2 to 8°C for Trig – 2. **Thawed and Opened**: 7 days at 2 to 8°C for Trig – 2. Note: stabiligy varies by assay

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing (notated on the QC frequency sheets posted on the instruments).

Refer to the Siemens Atellica QC Schedule and in the Siemens Atellica Quick Reference Guide.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Siemens Atellica CH Analyzer

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -50°C.
- Centrifuge

7.3 Supplies

- System Fluids
- Assorted calibrated pipettes (MLA or equivalent) and disposable tips

8. PROCEDURE

Atellica CH Triglycerides - 2 (Trig - 2) is required to perform this test.

Triglycerides is performed on the Atellica CH Analyzer after the method is calibrated and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-up Protocol
1.	Perform any required instrument maintenance.
2.	Ensure that the instrument has sufficient primary and ancillary reagents.
3.	Check status of cuvettes and tips. Check waste levels. Fill or empty as appropriate.
4.	Check calibration status and re-calibrate as needed.

8.2	Specimen Testing
1.	Centrifuge the specimens.
2.	Load the sample in the Atellica rack and place the rack into the Sample Handler to initiate testing. **NOTE: If not equipped with an in-line decapper unit, samples must be de-capped prior to loading on the Atellica system
3.	Refer to the general operating procedure for detailed steps.
4.	Follow protocol in section 10.6 “Repeat Criteria and Resulting” for samples with results above the analytical measurement range (AMR). Investigate any flagged results and repeat as necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

The instrument automatically calculates the concentration of Triglycerides in mg/dL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results as a whole number.

10.3 Units of Measure

mg/dL

10.4 Clinically Reportable Range (CRR)

15 – 10,000 mg/dL

10.5 Review Patient Data

Each result is reviewed for error messages. Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall below or within the AMR or CRR may be reported without repeat. Values that exceed the upper ranges must be repeated.

IF the result is …	THEN…
< 15 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 15 mg/dL
≥ 1000 mg/dL	**On Board Automated Dilution:** Results ≥ 1000 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 10. No multiplication is necessary.
> 10,000 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 10,000 mg/dL -REP" Bring to the attention of Tech in Charge (TIC) or Group Lead to check for integrity issues prior to release of results.

Message	Code
Verified by repeat analysis	Append –REP to the result.

11. EXPECTED VALUES

11.1 Reference Ranges

Age	Female	Male
Adult (>18 yesrs):	0 – 149 mg/dL	0 – 149 mg/dL
Pediatric:		
16 – 18 years	35 – 134	32 – 134
14 – 15 years	36 – 129	32 – 158
12 – 13 years	35 – 124	22 – 138
10 – 11 years	37 – 134	22 – 131
7 – 9 years	26 – 123	26 – 123
4 – 6 years	30 – 110	30 – 110
1 – 3 years	25 – 119	25 – 119
1 – 11 months	34 – 340	42 – 279
8 – 30 days	33 - 270	37 – 279
0 – 7 days	26 – 159	19 - 174

11.2 Critical Values

None established

11.3 Standard Required Messages

The following comment is automatically added to the report by the LIS when a lipid panel is ordered:

Lipid Interpretation:

Risk of Coronary Heart Disease		
Total Chol. / HDL-Chol. Ratio		
	Men	Women
½ average risk	3.4	3.4
average risk	5.0	4.4
2 times average risk	9.6	7.1
3 times average risk	23.4	11.0

12. CLINICAL SIGNIFICANCE

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

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

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.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

15 – 1000 mg/dL

14.2 Precision

Material	Mean mg/dL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
QC1	144	0.7	5.7
Serum 1	398	1.2	4.6
Serum 2	693	1.9	6.6

14.3 Interfering Substances

HIL Interference:
Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2.

Substance tested	Substance Concentration	mg/dL	Bias %
Hemoglobin	300 mg/dL	199	3
Bilirubin (unconjugated)	5 mg/dL	200	3
Bilirubin (conjugated)	15 mg/dL	196	-6

14.4 Clinical Sensitivity/Specificity/Predictive Values

Detection Capability
The assay is designed to have an LoQ ≤ 15 mg/dL. The LoQ was determined using multiple patient samples in the interval 5–35 mg/dL.

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

16. RELATED DOCUMENTS

1. Atellica Solution Operation, QC, Calibration and Maintenance procedure
2. Laboratory Quality Control Program
3. QC Schedule for Siemens Atellica Solution
4. Laboratory Safety Manual
5. Safety Data Sheets (SDS)
6. Atellica Solution Limits Chart
7. Quest Diagnostics Records Management Procedure
8. Atellica Solution System Error Messages Chart
9. Centrifuge Use, Maintenance and Function Checks (Lab policy)
10. Specimen Acceptability Requirements (Lab policy)
11. Repeat Testing Requirement (Lab policy)
12. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
13. Current package insert of Triglycerides - 2 Reagent

17. REFERENCES

1. Ghoshal, Amit K. and Soldin, Steven J., Evaluation of the Dade Behring Dimension® RxL: Integrated chemistry system-pediatric reference ranges. Clinica Chimica Acta 2003; 331:144.
2. Package Insert, Triglycerides - 2 Reagent, Siemens Healthcare Diagnostics Inc., 03/2022.
3. Package Insert, Chemistry Calibrator (CHEM CAL), Siemens Healthcare Diagnostics Inc., 04/2022.
4. Package Insert, InteliQ Assayed Multiqual Controls, Bio-Rad Laboratories, 02/2023.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

None