GGT, Serum or Plasma

Purpose

This procedure provides instructions for GGT on Abbott Instrumentation. The Alinity c GGT2 assay is used for the quantification of Gamma-Glutamyl Transferase (GGT) in human serum or plasma on the Alinity c analyzer.

Policy Statements

This procedure applies to all personnel responsible for operating the Abbott Alinity c at Children's Minnesota Laboratory.

Principle

Methodology: L-gamma-glutamyl-3-carboxy-4-nitroanilide substrate

The Gamma-Glutamyl Transferase2 (GGT2) assay is an automated clinical chemistry assay. GGT catalyzes the transfer of the gamma-glutamyl group from the donor substrate (L-gamma-glutamyl-3-carboxy-4-nitroanilide) to the glycylglycine acceptor to yield 3-carboxy-4-nitroaniline (also known as 5-amino-2-nitrobenzoate). The rate of change in absorbance at 416 nm is directly proportional to the GGT activity in the sample.[1]

Clinical Significance

The GGT2 assay is to be used primarily as an aid in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.[1]

Gamma-glutamyl transferase (GGT) is a glycoprotein comprised of two subunits. It is located at the cell surface and is highly abundant in luminal surfaces of kidney, biliary system, intestine, and epididymis. GGT is encoded by seven different genes, although only one produces an active enzyme that plays an essential role in regulation of oxidative stress, redox signaling, and detoxification of xenobiotics through glutathione cleavage. Traditionally, a serum GGT test is used in conjunction with the patient's history, clinical findings, and additional diagnostic testing for differential diagnosis of hepatobiliary disease (including liver, bile ducts, and gallbladder), intrahepatic or posthepatic biliary obstruction, and acute and chronic pancreatitis due to posthepatic biliary obstruction. GGT is also one of the markers for chronic alcoholic liver disease. Elevated levels of GGT were found to be associated with poor outcomes in breast, ovarian, and other types of tumors; increased risk for cardiovascular disease, stroke, and related mortality; pre-disposition to metabolic syndrome and resistance to insulin in type 2 diabetics; chronic kidney disease; and increased iron levels in aging individuals. Accordingly, elevated GGT should not be considered a highly-specific marker of hepatobiliary disease.[1]

Materials

Product Description	*Product Code*	*Stability*
GGT2 Reagent (600 tests per box; each box contains 4 reagent sets of 150 tests). Each reagent set consists of an R1 and R2 component.	**MFR#** 04T9620 **CHC#** 33993	**Store at:** 2-8 °C **Unopened:** Until Expiration **Opened:** Stable 30 days onboard the analyzer. Stable until expiration if returned to 2-8 °C storage with replacement

R1: Active Ingredient: glycylglycine. Preservatives: ProClin 950 and sodium azide. **R2:** Active ingredient: Glupac. Preservatives ProClin 950 and sodium azide. Abbott Diagnostics		caps tightly secured and in upright position.
Consolidated Chemistry Calibrator (ConCC) Each calibrator set consists of 6 lyophilized calibrator vials and 6 empty barcode labeled vials. Abbott Diagnostics	**MFR#** 04V6201 **CHC#** TBD	**Store at:** 2-8 °C **Unopened:** Until Expiration **Reconstituted:** Stable 7 days if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.
Biorad MultiQual Controls Levels 1 and 3 Each box contains 12 5mL vials of control material. Biorad Laboratories	**Level 1 MFR#** 697 **Level 1 CHC#** 34574 **Level 3 MFR#** 699 **Level 3 CHC#** 34575	**Store at:** 2-8 °C **Unopened:** Until Expiration **Opened:** Stable 30 days onboard the analyzer. Stable until expiration if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.

Special Safety Precautions

The following warnings and precautions apply to: R1 and R2. **WARNING** Contains methylisothiazolones and sodium azide. H317 May cause an allergic skin reaction. EUH032 Contact with acids liberates very toxic gas. **Prevention** P261 Avoid breathing mist / vapors / spray. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves / protective clothing / eye protection. **Response** P302+P352 IF ON SKIN: Wash with plenty of water. P333+P313 If skin irritation or rash occurs: Get medical advice / attention. P362+P364 Take off contaminated clothing and wash it before reuse. **Disposal** P501 Dispose of contents / container in accordance with local regulations.[1]

Calibration material contains human-sourced and/or potentially infectious components.[3]

Sample

Sample: Plasma collected with lithium heparin with or without gel barrier is preferred. Alternatively, serum collected with or without gel barrier is also accepted.

Stability: 7 days at room temperature, 7 days at 2-8 C, or up to 3 months frozen at –20 C or colder.

Test Code

LIS Test code: GGT for GGT in Serum or Plasma.

Analyzer

Primary Analyzer or Method: MACC (Minneapolis Alinity c), SALIC (St. Paul Alinity c).
Backup: Each primary analyzer will act as a backup for the other.

Calibration

Calibration Information

Reference Material	ConCC; 04V6201
Calibration Frequency	Calibration is due every 30 days and with each new reagent lot.
Calibration Scheme	1-Point Calibration; 3 replicates per level. The Gamma-Glutamyl Transferase2 assay utilizes the Linear data reduction method to generate calibration and results.

Quality Control

Material: Biorad Multiqual, Levels 1 and 3
Frequency: Run 2 levels, once per day.
Acceptable Ranges: Acceptable ranges are set in Unity Real Time software.

Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, section 4 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report.
- To minimize the effect of evaporation, verify that adequate sample cup volume is present prior to running the test.
- Maximum number of replicates sampled from the same sample cup: 10
    - Sample volume for the first test: 3.2 uL + 50 uL for over-aspiration and dead volume
    - Sample volume for each additional test from the same sample cup: 3.2 uL

Dilutions

Do not dilute.

Calculations

Not applicable.

Interpretation and Resulting

Results will be reported to the whole number.

Results between 5 and 7782 U/L without error messages are released.
Results below 5 U/L without error messages are reported as <5 U/L.
Results greater than 7782 U/L without error messages are reported as >7782 U/L.

Reference Intervals

Critical Values: Not applicable

Reference Ranges[2]

Age	*Sex*	*Reference Interval (U/L)*
0 to <15 days	All	23-219
15 days to 1 year	All	8-127
1 to <11 years	All	6-16
11 to 18 years	All	7-21
Adult	Female Male	9-36 12-64

Method Performance Specifications

Analytical Measuring Range: 5-7782 U/L
AMR/Calibration Verification Frequency: every 6 months, or as needed
AMR recommended verification product: Maine Standards GC3
AMR proximity budget: 6 U/L or 20%
AMR systematic error budget: 50%
Allowable Error: 5 U/L or 15% (CAP)
Precision: 1.5 U/L SD or 4% CV, whichever is greater

Limitations

HIL Indices Cutoff Values[1,4]				At HIL levels at or above the specified cutoff value, append the appropriate comment AFTER visually confirming presence of interferent: -HP for "Hemolysis present, may affect results." -BIN for "Bilirubin Interference" -LINT for "Lipid Interference"
Interpretation	H	I	L	
Quant (mg/dL)	500	N/A	N/A	
Semi Quant	4+	N/A	N/A	

Interference beyond ±10% was observed at the following concentrations.[1]

- Hemoglobin, 500 mg/dL

Additional interference information can be found in reagent package insert, page 5.

References

1. GGT2 for Alinity c Reagent Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised July 2021
2. CALIPER Reference Interval Studies, accessed October 27, 2020
3. ConCC for Alinity c Calibrator Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised December 2020

4. Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis. CLSI guideline C56-A, 1st Ed, Wayne, PA: CLSI, 2012

Appendices

Not applicable.

Training Plan/Competency Assessment

CH 1.04.T1 Abbott Alinity Training
QP 2.30 Orientation and Training
QP 2.40 Competency Assessment

Historical Record

Version	Author	Effective Date	Summary
1	Matt Johnson	11/14/2025	Initial Version