Gamma-Glutamyl Transferase2

FOR USE WITH ARCHITECT

Read Highlighted Changes: Revised June 2022.

REF 04T0020

REF 04T0030

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

NAME

Gamma-Glutamyl Transferase2 (also referred to as GGT2)

INTENDED USE

The Gamma-Glutamyl Transferase2 assay is used for the quantitation of gamma-glutamyl transferase in human serum or plasma on the ARCHITECT c Systems.

The Gamma-Glutamyl Transferase2 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.

SUMMARY AND EXPLANATION OF THE TEST

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.[1] GGT is encoded by seven different genes, although only one produces an active enzyme[2] that plays an essential role in regulation of oxidative stress, redox signaling, and detoxification of xenobiotics through glutathione cleavage.[3]

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.[4] GGT is also one of the markers for chronic alcoholic liver disease.[5]

Elevated levels of GGT were found to be associated with poor outcomes in breast, ovarian, and other types of tumors;[3] increased risk for cardiovascular disease, stroke, and related mortality;[1] pre-disposition to metabolic syndrome and resistance to insulin in type 2 diabetics; chronic kidney disease; and increased iron levels in aging individuals.[6] Accordingly, elevated GGT should not be considered a highly-specific marker of hepatobiliary disease.

PRINCIPLES OF THE PROCEDURE

The Gamma-Glutamyl Transferase2 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 412 nm (ARCHITECT c8000) or 416 nm (ARCHITECT c4000 and ARCHITECT c16000) is directly proportional to the GGT activity in the sample.[7, 8]

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

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

Gamma-Glutamyl Transferase2 Reagent Kit 04T00

NOTE: Some kit sizes may not be available. Please contact your local distributor.

Volumes (mL) listed in the following table indicate the volume per cartridge.

REF	04T0020	04T0030
Tests per cartridge set	150	650
Number of cartridge sets per kit	4	4
Tests per kit	600	2600
R1	12.2 mL	43.7 mL
R2	14.7 mL	53.9 mL

R1 Active ingredient: Glycylglycine (39.640 g/L). Preservatives: ProClin 950 and sodium azide.

R2 Active ingredient: Glupac (glupa-carboxylate monoammonium salt) (5.000 g/L). Preservatives: ProClin 950 and sodium azide.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[9-12]

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.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not pool reagents within a kit or between kits.
- Do not use components from one lot with components from another lot.
- Do not reuse containers, caps or plugs due to the risk of contamination and the potential to compromise reagent performance.
- When either the R1 or R2 reagent cartridge becomes empty, replace both cartridges.
- Upon receipt, reagent cartridges can be used immediately or stored in an upright position.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position.

Reagents may be stored on or off the ARCHITECT c System. If reagents are removed from the system, store at 2 to 8°C (with replacement caps) in their original boxes.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Gamma-Glutamyl Transferase2 assay file must be installed on the ARCHITECT c System prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

Alternate Result Units

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
U/L	0.01667	µkat/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types and collection tube types have not been verified with this assay.

Specimen Types	Collection Tubes
Serum	Serum
	Serum separator
Plasma	Lithium heparin
	Lithium heparin separator
	Sodium heparin

- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens.

The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
  - heat-inactivated specimens
  - pooled specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low-speed vortex or by inverting 10 times prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low-speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	Room temperature (20 to 25°C)	7 days[13]
	2 to 8°C	7 days[13]
	-20°C	3 months[14]

Avoid multiple freeze/thaw cycles.[14]

It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.

For additional information on sample handling and processing, refer to CLSI GP44-A4.[15] The storage information provided here is based on references.

Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Stored specimens must be inspected for particulates. If present, mix with a low-speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

04T00 Gamma-Glutamyl Transferase2 Reagent Kit

Materials Required but not Provided

- Gamma-Glutamyl Transferase2 assay file found on www.corelaboratory.abbott
- 04V1501 Consolidated Chemistry Calibrator
- Controls containing gamma-glutamyl transferase
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the ARCHITECT System Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the ARCHITECT System Operations Manual, Section 5 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 effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 3.2 µL.

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the ARCHITECT System Operations Manual, Section 5.
- Refer to the Consolidated Chemistry Calibrator package insert REF 04V1501 and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Sample dilutions have not been evaluated for the Gamma-Glutamyl Transferase2 assay. Samples with a gamma-glutamyl transferase value exceeding 7782 U/L (129.73 µkat/L) are flagged with code "> 7782 U/L" ("> 129.73 µkat/L").

For details on configuring automated dilutions, refer to the ARCHITECT System Operations Manual, Section 2.

Calibration

For instructions on performing a calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Calibration is stable for approximately 30 days (720 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- At least 2 levels of controls (low and high) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to "Basic QC Practices" by James O. Westgard, Ph.D. for guidance on laboratory quality control practices.[16]

RESULTS

Calculation

The Gamma-Glutamyl Transferase2 assay utilizes the Linear data reduction method to generate a calibration and results.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

Reportable Interval

Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.[17]

	U/L	µkat/L
Analytical Measuring Interval (AMI)[a]	5 - 7782	0.08 - 129.73
Reportable Interval[b]	3 - 7782	0.05 - 129.73

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in U/L (µkat/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] The reportable interval extends from the LoD to the upper limit of the AMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the reportable interval of 3 U/L (0.05 µkat/L). To flag values using the lower limit of the analytical measuring interval of 5 U/L (0.08 µkat/L), the operator must edit the Low Linearity value.

For detailed information on editing the result settings of assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- The Gamma-Glutamyl Transferase2 assay can exhibit both positive and negative hemoglobin interference. No significant interference (within ± 10%) was observed with samples containing up to 250 mg/dL hemoglobin.
- There is potential for interference by paraproteins, particularly in patients with IgM gammopathies.[18, 19]
- Substances that demonstrated interference with the Gamma-Glutamyl Transferase2 assay are listed in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.

EXPECTED VALUES

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Reference Ranges[20]

Adult	U/L	µkat/L*
Female	< 38	< 0.63
Male	< 55	< 0.92

* Alternate result units were calculated by Abbott.

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.[21] Testing was conducted using 3 lots of the Gamma-Glutamyl Transferase2 reagents, 3 lots of the Consolidated Chemistry Calibrator, and 1 lot of commercially available controls, and 3 instruments. Two controls and 5 human serum panels were tested in a minimum of 2 replicates twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot are paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (U/L)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	37	0.4	1.2	0.7 (0.6 - 0.7)	1.9 (1.5 - 1.9)
Control Level 2	80	168	1.3	0.8	2.8 (2.0 - 2.8)	1.7 (1.3 - 1.7)
Panel A	80	7	0.6	8.2	0.8 (0.7 - 0.8)	11.1 (10.1 - 11.1)
Panel B	80	74	0.7	0.9	1.3 (1.3 - 2.0)	1.8 (1.8 - 2.8)
Panel C	80	1115	9.3	0.8	23.1 (18.5 - 23.1)	2.1 (1.6 - 2.1)
Panel D	80	3647	53.2	1.5	88.4 (66.2 - 88.4)	2.4 (1.8 - 2.4)
Panel E	80	7202	48.9	0.7	176.1 (159.8 - 220.4)	2.4 (2.2 - 3.0)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD and %CV across the 3 reagent lot/calibrator lot/instrument combinations.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (µkat/L)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	0.62	0.007	1.1	0.012 (0.008 - 0.012)	1.9 (1.4 - 1.9)
Control Level 2	80	2.80	0.022	0.8	0.045 (0.034 - 0.045)	1.6 (1.3 - 1.6)
Panel A	80	0.11	0.007	6.2	0.012 (0.011 - 0.012)	10.6 (9.9 - 10.6)
Panel B	80	1.23	0.012	0.9	0.022 (0.022 - 0.033)	1.8 (1.8 - 2.8)
Panel C	80	18.59	0.156	0.8	0.385 (0.308 - 0.385)	2.1 (1.6 - 2.1)
Panel D	80	60.79	0.886	1.5	1.473 (1.103 - 1.473)	2.4 (1.8 - 2.4)
Panel E	80	120.06	0.814	0.7	2.935 (2.663 - 3.675)	2.4 (2.2 - 3.0)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD and %CV across the 3 reagent lot/calibrator lot/instrument combinations.

Reproducibility

A study was performed based on guidance from CLSI EP05-A3.[21] Testing was conducted using 1 lot of Gamma-Glutamyl Transferase2 reagent, 1 lot of Consolidated Chemistry Calibrator, 1 lot of each commercially available control, and 3 instruments. Each instrument was operated by a different technician, and each technician prepared an individual sample set. Five levels of controls were tested in a minimum of 3 replicates (from separate sample cups), at 2 times per day (separated by a minimum of 2 hours) on at least 5 different days.

			Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	n	Mean (U/L)	SD	%CV	SD	%CV	SD	%CV
Control Level 1	90	38	0.4	1.2	0.6	1.5	0.6	1.5
Control Level 2	90	169	1.2	0.7	1.4	0.8	1.9	1.1
Control Level A	90	22	0.4	1.8	0.4	1.9	0.5	2.1
Control Level B	90	72	0.5	0.8	0.6	0.8	0.7	0.9
Control Level C	90	152	0.8	0.5	1.0	0.7	1.0	0.7

[a] Includes repeatability (within-run), between-run, and between-day variability.

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

			Repeatability		Within-Laboratory[a]		Reproducibility[b]	
Sample	n	Mean (µkat/L)	SD	%CV	SD	%CV	SD	%CV
Control Level 1	90	0.63	0.006	1.0	0.008	1.3	0.009	1.4
Control Level 2	90	2.82	0.021	0.7	0.025	0.9	0.032	1.1
Control Level A	90	0.37	0.005	1.5	0.006	1.8	0.007	1.9
Control Level B	90	1.21	0.007	0.6	0.010	0.8	0.011	0.9
Control Level C	90	2.53	0.014	0.5	0.018	0.7	0.018	0.7

[a] Includes repeatability (within-run), between-run, and between-day variability.

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

Accuracy

A study was performed to estimate the bias of the Gamma-Glutamyl Transferase2 assay relative to material standardized to the Certified Reference Material ERM-AD452/IFCC.

Testing was conducted using 3 lots of the Gamma-Glutamyl Transferase2 reagents, 2 lots of the Consolidated Chemistry Calibrator, and 3 instruments. The bias ranged from -0.9% to 3.9% across all instruments, calibrator and reagent lots.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[22] Testing was conducted using 3 lots of the Gamma-Glutamyl Transferase2 reagents on each of 2 instruments over a minimum of 3 days. The limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below. These representative data support the lower limit of the analytical measuring interval.

	U/L	µkat/L
LoB[a]	1	0.02
LoD[b]	3	0.05
LoQ[c]	5	0.08

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ presented in the table is in alignment with the low end of the AMI for the Gamma-Glutamyl Transferase2 assay on the ARCHITECT c System.

Linearity

A study was performed based on guidance from CLSI EP06-A.[23]

This assay is linear across the analytical measuring interval of 5 to 7782 U/L (0.08 to 129.73 µkat/L).

Analytical Specificity

Interference

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[24] Each substance was tested at 2 levels of the analyte (approximately 40 U/L and 150 U/L).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)		
	Interferent Level	
Potentially Interfering Substance	Default Units	Alternate Units
Apolipoprotein A1	600 mg/dL	6 g/L
Bilirubin - conjugated	60 mg/dL	712 µmol/L
Bilirubin - unconjugated	60 mg/dL	1026 µmol/L
Hemoglobin	250 mg/dL	2.5 g/L
Paraproteins (kappa)	0.5 g/dL	5 g/L
Total protein	15 g/dL	150 g/L
Triglycerides	1500 mg/dL	17 mmol/L

Interference beyond ± 10% (based on 95% Confidence Interval [CI]) was observed at the concentrations shown below for the following substance.

Interference beyond ± 10% (based on 95% Confidence Interval [CI]))					
Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Hemoglobin	500 mg/dL	5 g/L	40 U/L	0.67 µkat/L	14% (12%, 16%)

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[24] Each substance was tested at 2 levels of the analyte (approximately 40 U/L and 150 U/L).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)

	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
Acetaminophen	160 mg/L	1059 µmol/L
Acetylcysteine	150 mg/L	920 µmol/L
Acetylsalicylic acid	30 mg/L	167 µmol/L
Ampicillin-Na	80 mg/L	215 µmol/L
Ascorbic acid	60 mg/L	341 µmol/L
Biotin	4250 ng/mL	17 µmol/L
Ca-dobesilate	60 mg/L	143 µmol/L
Cefotaxime	53 mg/dL	1166 µmol/L
Cefoxitin	6600 mg/L	15 mmol/L
Cyclosporine	2 mg/L	1.7 µmol/L
Doxycycline	20 mg/L	45 µmol/L
Ibuprofen	220 mg/L	1067 µmol/L
Levodopa	8 mg/L	41 µmol/L
Methyldopa	25 mg/L	118 µmol/L
Metronidazole	130 mg/L	759 µmol/L
Phenylbutazone	330 mg/L	1069 µmol/L
Rifampicin	50 mg/L	61 µmol/L
Sodium heparin	4 U/mL	N/A
Theophylline (1,3-dimethylxanthine)	60 mg/L	333 µmol/L

N/A = Not applicable

Interferences from medication or endogenous substances may affect results.[25]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3[26] using the Passing-Bablok regression method.

Gamma-Glutamyl Transferase2 vs Gamma-Glutamyl Transferase on the ARCHITECT c System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	133	U/L	1.00	1	1.08	5 - 6913
		(µkat/L)		(0.02)		(0.08 - 115.23)

BIBLIOGRAPHY

1. Ndrepepa G, Kastrati A. Gamma-glutamyl transferase and cardiovascular disease. *Ann Transl Med* 2016;4(24):481.
2. Pawlak A, Lahuna O, Suzuki A, et al. Gamma-glutamyl transpeptidase: a single copy gene in the rat and a multigene family in the human genome. *J Biol Chem* 1988;263:9913-9916.
3. Hanigan MH. Gamma-glutamyl transpeptidase: redox regulation and drug resistance. *Adv Cancer Res* 2014;122:103-141.
4. Ruhl CE, Everhart JE. Elevated serum alanine aminotransferase and γ-glutamyltransferase and mortality in the United States population. *Gastroenterology* 2009;136:477-485.
5. Neumann T, Spies C. Use of biomarkers for alcohol use disorders in clinical practice. *Addiction* 2003;98(suppl 2):81-91.
6. Koenig G, Seneff S. Gamma-glutamyltransferase: A predictive biomarker of cellular antioxidant inadequacy and disease risk. *Dis Markers* 2015;2015.
7. Theodorsen L, Stromme JH. Gamma-glutamyl-3-carboxy-4-nitroanilide: the substrate of choice for routine determinations of gamma-glutamyl-transferase activity in serum? *Clin Chim Acta* 1976:72(2):205-210.
8. Schumann G, Bonora R, Ceriotti F, et al. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37°C. Part 6. Reference procedure for the measurement of catalytic concentration of γ-glutamyltransferase. *Clin Chem Lab Med* 2002;40(7):734–738.
9. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
10. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories.* 6th ed. Washington, DC: US Government Printing Office; June 2020.
11. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
12. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition.* CLSI Document M29-A4. Wayne, PA: CLSI; 2014.
13. Cuhadar S, Atay A, Koseoglu M, et al. Stability studies of common biochemical analytes in serum separator tubes with or without gel barrier subjected to various storage conditions. *Biochem Med* 2012;22(2):202-214.
14. Cuhadar S, Koseoglu M, Atay A, et al. The effect of storage time and freeze-thaw cycles on the stability of serum samples. *Biochem Med* 2013;23(1):70-77.
15. Clinical and Laboratory Standards Institute (CLSI). *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition.* CLSI Document GP44-A4. Wayne, PA: CLSI; 2010.
16. Westgard JO. *Basic QC Practices; Training in Statistical Quality Control for Medical Laboratories.* 4th ed. Westgard QC, Inc.; 2016.
17. Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking.* 1st ed. CLSI Guideline EP34. Wayne, PA: CLSI; 2018.
18. Tichy M, Friedecky B, Budina M, et al. Interference of IgM-lambda paraprotein with biuret-type assay for total serum protein quantification. Letter. *Clin Chem Lab Med* 2009;47(2):235-236.
19. Dimeski G, Carter A. Rare IgM interference with Roche/Hitachi Modular glucose and gamma-glutamyltransferase methods in heparin samples. *Clin Chem* 2005;51(11):2202-2204.
20. Burtis CA, Bruns DE. *Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics.* 7th ed. St Louis, MO: Saunders Elsevier; 2014:965.
21. Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline—Third Edition.* CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.
22. Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition.* CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.
23. Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. CLSI Document EP06-A. Wayne, PA: CLSI; 2003.
24. Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry.* 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.
25. Young DS. Laboratory test listings. In: *Effects of Drugs on Clinical Laboratory Tests.* 5th ed. AACC Press; 2000:chap 3.

Abbott

26. Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition.* CLSI Document EP09-A3. Wayne, PA: CLSI; 2013.

Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
DISTRIBUTED IN THE USA BY	Distributed in the USA by
FOR USE WITH	Identifies products to be used together
INFORMATION FOR USA ONLY	Information needed for United States of America only
PRODUCT OF IRELAND	Product of Ireland
R1	Reagent 1
R2	Reagent 2
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

The ARCHITECT c System family of instruments consists of c4000, c8000, and c16000 instruments.

Abbott Ireland
Diagnostics Division
Lisnamuck, Longford
Co. Longford
Ireland
+353-43-3331000

CE
0123

DISTRIBUTED IN THE USA BY

Abbott Laboratories
Abbott Park, IL 60064 USA

Customer Service: Contact your local representative or find country-specific contact information on www.corelaboratory.abbott

For customers in the European Union: if, in the course of using this device, you have reason to believe that a serious incident has occurred, report it to the manufacturer and to your national authority.

A summary of safety and performance (SSP) for this device is available at https://ec.europa.eu/tools/eudamed. This is the SSP location after the launch of European Database on Medical Devices. Search for the device using the UDI-DI provided on the outer packaging of the device.

Revised June 2022.

Abbott