

GAMMA GT

(γ -Glutamyl Transferase)

En

REF T2172 3498 Tests

REF T2173 1795 Tests

FOR USE WITH
ARCHITECT

Diagnostic reagent for determination of Gamma GT concentration.

Liquid. Dual reagents. Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.
T2172/T2173 Ref Number Products are Produced Specifically for Architect Chemistry Analyzer Series.

Changes made in the instructions for use are marked as grey.

INTENDED USE

The test is applied for the quantitative determination of Gamma-GT in serum and plasma.

TEST SUMMARY AND PROCEDURE ^{1, 2, 3, 4, 5}

The enzyme γ -GT (EC 2.3.2.2, γ -glutamyl-peptide:amino acid γ -glutamyltransferase; GGT) hydrolyzes the GLUPA-C to release p-nitroaniline. The p-nitroaniline formation is detected spectrophotometrically at 405 nm to detect GGT activity in the sample.

TEST PARAMETERS

Method : Colorimetric, Kinetic, Increasing Reaction, IFCC
Wavelength : 405 nm
Linearity : 500 U/L

REAGENT COMPONENTS

Tris buffer ≤ 100 mM
pH 8.25,
Glycylglycine ≤ 100 mM,
L-Glutamyl-3-carboxy-4-nitroanilide ≤ 5 mM.

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE ⁶

Reagents are stable at +2/+8°C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 60 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SAMPLE

Serum and plasma are collected according to standard procedures. Avoid hemolysis.

GGT is stable for:

7 days at +2/+8°C,
7 days at +20/+25°C,
1 year at -20°C.

REFERENCE INTERVAL (NORMAL VALUES) ⁷

Men : < 50 U/L (< 0.83 μ kat/L)
Women : < 30 U/L (< 0.50 μ kat/L)

It is recommended that each laboratory establish its own normal range.

Reference interval has been verified by using CLSI EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used. We recommend:

Arcon N (Level I Control) Lyophilized
Ref.No: A3910

Arcon P (Level II Control) Lyophilized
Ref.No: A3920

The assay requires the use of a Multiconstituent Calibrator. We recommend:

Multiconstituent Calibrator
Ref.No: A39053

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 60 days.

If controls are not within acceptable limits, calibration is required and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures.

Quality control is recommended every morning. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of detection is 1 U/L.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) \leq 20%]:⁸ 4 U/L.

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 500 U/L.

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:⁹

Repeatability (Within Run)

Mean Concentration	SD*	CV%	n
27,42 U/L	0,30	1,12	40
168,22 U/L	0,88	0,52	40

Repeatability (Day to Day)

Mean Concentration	SD	CV%	n
56,73 U/L	1,68	2,96	84
159,51 U/L	4,21	2,64	84

*SD: Standard Deviation

*CV: Variation Coefficient

\pm 10% CV% deviations between devices can be observed.

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison:^{10, 11}

Correlation with a comparative method is: $r = 0.997$

According to Passing-Bablok Fit:

Slope: 1.10

Intercept: -1.11

Interference:^{3, 4, 12}

No significant interactions were observed for conjugated bilirubin up to the interferent concentration given in the table.

Interferant and Concentration	Gamma GT Target (U/L)	N	%Observed Recovery
Bilirubin 7,12 mg/dL	25,3	3	91

Non-hemolysis and non-lipemic samples should be used.

The acceptable interference limit is set 10% below the highest interference concentration within \pm 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only.

Do not use expired reagents.

Reagents with two different lot numbers should not be interchanged.

For professional use.

Follow Good Laboratory Practice (GLP) guidelines.

Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

EUH032 :Releases a very toxic gas if contacts with acid.

H317 :May cause allergic skin reaction.

Precaution

P280 :Use protective gloves / clothes / glasses / mask.

P264 :Wash your hands properly after using.

P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352 :Wash with plenty of water and soap if it contacts with skin.

P333+P313 :Seek medical help if it irritates your skin or develops rash.

P362+P364 :Remove contaminated clothes and wash properly before using.






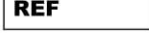
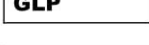








Disposal

P501 :Dispose the vials and contents according to the local regulations.

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SYMBOLS	
	In Vitro Diagnostic Medical Device
	Lot Number
	Reagent 1
	Reagent 2
	Global Trade Item Number
	Reference Number
	Good Laboratory Practices
	Identifies Products to Be Used Together
	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests


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