

ABX Pentra GGT CP

REF	A11A01630
REAGENT 1	56 mL
REAGENT 2	14 mL



IVD Rx Only

■ Pentra C200

HORIBA ABX SAS
Parc Euromédecine
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34184 Montpellier Cedex 4
FRANCE

Diagnostic reagent for quantitative *in vitro* determination of Gamma-GlutamylTransferase (GGT) in serum or plasma by colorimetry.

Application Release

Serum, plasma: GGT

01.xx

Intended Use

ABX Pentra GGT CP reagent is intended for the quantitative *in vitro* diagnostic determination of Gamma-GlutamylTransferase (GGT) in serum or plasma. Gamma-glutamyltranspeptidase measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.

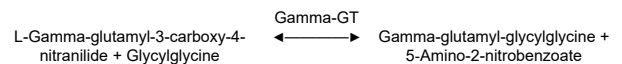
Clinical Interest (1)

Gamma-glutamyltransferase (Gamma-GT or GGT), also called gamma-glutamyltranspeptidase, is an enzyme present in liver and bile duct which is the most sensitive indicator of hepatobiliary diseases. Because of a high negative predictive value for these diseases the measurement of gamma-GT is widely used to rule out an hepatic or biliary origin. Together with other enzymes such as alanine aminotransferase (ALAT), aspartate aminotransferase (ASAT) and cholinesterase gamma-GT is a valuable tool for the differential diagnosis in liver diseases.

Method (2)

Kinetic photometric test according to Szasz modified (1974). Gamma-GT catalyzes the transfer of glutamic acid to acceptors like glycylglycine in this case. This process releases 5-amino-2-nitrobenzoate, which can be

measured at 405 nm. The increase in absorbance at this wavelength is directly related to the activity of gamma-GT.



Reagents

ABX Pentra GGT CP is ready-to-use.

Reagent 1:

TRIS pH 8.25	137 mmol/L
Glycylglycine	137 mmol/L
Sodium azide	< 1 g/L

Reagent 2:

L-Gamma-glutamyl-3-carboxy-4-nitroanilide	22 mmol/L
Sodium azide	< 1 g/L

ABX Pentra GGT CP should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Remove both caps of the cassette.
2. If present, remove foam by using a plastic pipette.
3. Place the cassette into the refrigerated Pentra C200 reagent compartment.

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Calibrator

For calibration, use:

ABX Pentra Multical (A11A01652) (not included)
10 x 3 mL (lyophilisate)

Control ^a

For internal quality control, use:

- **ABX Pentra N MultiControl** (1300054414) (not included)
10 x 5 mL (lyophilisate)
- **ABX Pentra P MultiControl** (1300054415) (not included)
10 x 5 mL (lyophilisate)

Each control should be assayed daily and/or after a calibration.

The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. You should follow federal, state and local guidelines for testing quality control materials. The results must be within the range of the defined confidence limits. Each laboratory should establish a procedure to follow if the results exceed these confidence limits.

Materials Required but not Provided ^a

- Automated clinical chemistry analyzer: Pentra C200
- Calibrator: **ABX Pentra Multical** (A11A01652)
- Controls:
 - ABX Pentra N MultiControl** (1300054414)
 - ABX Pentra P MultiControl** (1300054415)
- Standard laboratory equipment.

Specimen ^b

This device intended testing population is general population.

Specimen types

- Serum.
- Plasma in lithium heparin.

Anticoagulants other than those listed have not been tested by HORIBA Medical and are therefore not recommended for use with this assay.

Stability (3)

- At 20-25°C: 7 days
- At 4-8°C: 7 days
- At -20°C: 1 year

Reference Range (4) ^c

Each laboratory should establish its own reference ranges. The values given here are used as guidelines only.

37°C
Women: ≤ 38 U/L
Men: ≤ 55 U/L

Clinical sensitivity and specificity, positive predictive value and negative predictive value are not commonly reported for this analyte. This is largely attributed to the fact that this analyte is not sole indicator for the intended purpose and patient treatment decision making. To arrive at a diagnosis and a course of treatment, results from others routine clinical chemistry tests should be used in conjunction with other diagnostic information and the attending health-care professional's evaluation of the patient's condition.

Storage and Stability ^d

Stability before opening:

Stable up to the expiry date on the label if stored at 2-8°C. Store protected from light.

Stability after opening:

Refer to the paragraph "Performance on Pentra C200".

Do not freeze.

^aModification: control removed.

^bModification: modification of "Specimen".

^cModification: information added.

^dModification: modification of storage and stability.

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Waste Management

- Please refer to local legal requirements.
- This reagent contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

General Precautions ^e

- This reagent is for professional *in vitro* diagnostic use only.
For laboratory use.
- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- Do not pipette by mouth.
- Do not replenish the reagents.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The reagent cassettes are disposable and should be disposed of in accordance with the local legal requirements.
- Please refer to the SDS associated with the reagent.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA Medical representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the reagent used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

Performance on Pentra C200

Lot to Lot Variability ^f

The recovery of samples (serum and plasma) done during QC release of three consecutive lots of reagent shows that the lot to lot variability is within specification: < 10%.

^eModification: general precautions modification.

^fModification: chapter added.

^gModification: data added.

^hModification: modification of quantitation limit.

Serum, plasma

The performance data listed below have been obtained on the Pentra C200 analyzer.

Number of tests: approximately 279 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Pentra C200 compartment is stable for 39 days.

Sample volume: 7.5 µL/test

Detection Limit ^g

The detection limit is determined according to CLSI (NCCLS), EP17-A2 protocol (5) and equals 1.65 U/L.

Limit of Quantitation ^h

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (5) and equals 6.0 U/L.

Accuracy and Precision

Repeatability (*within-run precision*)

Repeatability according to the recommendations found in the Valtec protocol (6) with samples tested 20 times:

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value U/L	CV %
Control specimen 1	43	1.32
Control specimen 2	214	0.49
Specimen 1	21	3.87
Specimen 2	51	1.33
Specimen 3	431	0.91

Reproducibility (*total precision*)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP5-A2 protocol (7) with samples tested in duplicate for 20 days (2 series per day):

- 2 controls
- 3 specimens (low / medium / high levels)

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	Mean value U/L	CV %
Control specimen 1	43.51	2.9
Control specimen 2	216.03	1.7
Specimen 1	21.18	4.1
Specimen 2	52.74	2.7
Specimen 3	445.28	1.8

Measuring Range

The assay confirmed a measuring range from 6.0 U/L to 1000 U/L.

The measuring range is extended up to 3000 U/L with the automatic post-dilution.

The reagent linearity has been assessed up to 1000 U/L according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (8).

Correlationⁱ

Patient samples: Serum

Number of patient samples: 101

Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (9).

Values ranged from 10.0 U/L to 931.0 U/L.

The equation for the allometric line obtained using Passing-Bablok regression procedure (10) is:

$$Y = 0.9412 X - 0.2353 \text{ (U/L)}$$

with a correlation coefficient $r^2 = 0.999$.

Interferences

Haemoglobin: No significant influence is observed up to 300 µmol/L (517 mg/dL).

Triglycerides: No significant influence is observed up to a triglyceride concentration of 4.71 mmol/L (412 mg/dL).

Total Bilirubin: No significant influence is observed up to 500 µmol/L (29.3 mg/dL).

Direct Bilirubin: No significant influence is observed up to 350 µmol/L (20.5 mg/dL).

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (11, 12).

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.

The calibration stability is 20 days.

Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Reference

1. Thomas L. Gamma glutamyltransferase (GGT). In: Thomas L. editor. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft (1998): 80-86.
2. Persijn JP, Van der Silk W. A new method for the determination of gamma-glutamyltransferase in serum. J. Clin. Chem. Clin. Biochem. (1976) **14**: 421-427.
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4. IFCC Primary Reference Procedures for the Measurement of Catalytic Activity Concentrations of Enzymes at 37°C; Part 6; Clin. Chem. Lab. Med. (2002) **40** (7): 734-738.
5. Evaluation of detection capability for clinical laboratory measurement procedures. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP17-A2 (2012) **32** (8).
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7. Evaluation of Precision Performance of Quantitative Measurement Method. Approved Guideline, CLSI (NCCLS) document EP5-A2 (2004) **24** (25).
8. Evaluation of Linearity of Quantitative Measurement Procedures. 2nd Edition, CLSI (NCCLS) guideline EP06-Ed2 (2020) **40** (16).
9. Measurement Procedure Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 3rd ed., CLSI (NCCLS) document EP09c (2018) **38** (12).
10. Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J. Clin. Chem. Clin. Biochem. (1983) **21**: 709-720.
11. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th Edition, Washington, DC, AACC Press (2000).
12. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd Edition, Washington, DC, AACC Press (1997) **3**: 120-132.

ⁱModification: modification of correlation.