Cat. No 4-524

DIAGNOSTIC KIT FOR DETERMINATION OF γ-GLUTAMYLTRANSFERASE ACTIVITY

HC – GGT

INTRODUCTION

γ-Glutamyltransferase (GGT, GGTP) is a membrane localized enzyme that catalyzes the transfer of glutamyl groups from glutathione to amino acids or peptides. Large GGT amounts are present in secretory organs: kidney, liver, bile duct, pancreas. Although the GGT activity is highest in renal tissue, serum GGT is generally elevated as a result of liver disease. Since alcohol induces GGT production, measurement of GGT activity is used for monitoring of abstinence in withdrawal treatment.

METHOD PRINCIPLE

Kinetic method with L-γ-glutamyl-3-carboxy-4-nitroanilide.

L-γ-glutamyl-3-carboxy-4-nitroanilide + glycylglycine $\xrightarrow{\gamma\text{-GT}}$ L-γ-glutamyloglycylglycine + 5-amino-2-nitrobenzoate

The rate of 5-amino-2-nitrobenzoate creation measured colorimetrically is directly proportional to γ-glutamyltransferase activity.

REAGENTS

Package

1-Reagent	6 x 76 ml
2-Reagent	6 x 19.5 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

Tris (pH 8.25)	100 mmol/l
glycylglycine	100 mmol/l
L-γ-glutamyl-3-carboxy-4-nitroanilide	4 mmol/l

Warnings and notes

- Product for in vitro diagnostic use only.

SPECIMEN

Serum, EDTA plasma free from haemolysis.
Do not use citrate, oxalate and fluoride as anticoagulants because of GGT activity inhibition!
Heparin causes turbidity in the reaction mixture!
GGT activity remains stable in specimen up to 2 days at 15-25ºC or 1 week at 2-8ºC or 1 month at -25ºC. Freezing of sample causes a loss of enzyme activity. Frozen specimens should be thawed and kept at room temperature for 18 to 24 hours before measurement to achieve full enzyme reactivation.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagents are ready to use.
These reagents may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [6]

serum / plasma	37ºC
female	7 – 32 U/l (0.117 – 0.533 µkat/l)
male	11 – 49 U/l (0.183 – 0.817 µkat/l)

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) and LEVEL 2 (Cat. No 5-175; 5-177) is recommended. **Calibrators and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 1.8 U/l (0.03 µkat/l).
- **Linearity:** up to 1300 U/l (21.71 µkat/l).
- **Specificity / Interferences**
  Haemoglobin up to 0.16 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.
- **Precision**

Repeatability (run to run) n = 20	Mean [U/l]	SD [U/l]	CV [%]
level 1	60.60	0.92	1.51
level 2	147.55	2.25	1.52

Reproducibility (day to day) n = 80	Mean [U/l]	SD [U/l]	CV [%]
level 1	52.35	0.55	1.04
level 2	138.01	1.16	0.84

- **Method comparison**

A comparison between GGT activity determined at Hitachi 912 (y) and at COBAS INTEGRA 400 (x) using 65 samples gave following results:
y = 0.8996 x + 4.1645 U/l;
R = 0.9998 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Szasz G., Weimann G., Suhler F., Wahlefrld A.W., Persijn J.P. : Z. Klin. Chem. Klin. Biochem. 12, 228 (1974).
2. Persijn J.P., van der Silk W.: J. Clin. Chem. Clin. Biochem. 14, 421-427 (1976).
3. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders, 850-1, (1994).
4. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders, 286 (1995).
5. Kaplan L.A., Pesce A.J.: Clinical Chemistry. Theory, analysis and correlation 3rd Ed., the C.V. Mosby Company, St. Louis 1996, p.1072.
6. Alan H.B. Wu: Tietz Clinical Guide to Laboratory Tests, 4th ed. WB Saunders, 470, (2006).

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