γ-GT (GGT)

L-γ-Glutamyltransferase
IFCC
RX SERIES

INTENDED USE

A γ-GT test system is a device intended for the quantitative *in vitro* determination of L-γ-Glutamyltransferase (γ-GT) activity in serum and plasma. This product is suitable for use on the RX **series** instruments, which includes the RX **daytona** and the RX **imola**.

Cat. No.		
GT 3874	R1a. Buffer	6 x 17.5 ml
	R1b. Substrate	6 x 3.5 ml

GTIN: 05055273203462

CLINICAL SIGNIFICANCE

Gamma-Glutamyltransferase (γ-GT) and isoenzymes measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumours.

COLORIMETRIC METHOD [1]

This is an optimised standard method according to the European Committee for Clinical Laboratory Standards (ECCLS).

PRINCIPLE

The substrate L-γ-glutamyl-3-carboxy-4-nitroanilide, in the presence of glycylglycine is converted by γ-GT in the sample, to 5-amino-2-nitro-benzoate which absorbs at 405 nm.

L-γ-glutamyl-3-carboxy-4-nitroanilide + glycylglycine

$$\xrightarrow{\gamma\text{-GT}}$$

L-γ-glutamylglycylglycine + 5-amino-2-nitro-benzoate

SAMPLE COLLECTION AND STORAGE [3]

Serum: Use only non haemolysed serum.

Plasma: Only use EDTA plasma or Li Heparinised plasma that is free from haemolysis. Other anticoagulants interfere with this test.

GGT in serum is stable for 7 days at +2 to +8°C or 3 months at –20°C.

REAGENT COMPOSITION

Contents	Concentrations in the Test
R1a. Buffer	
Glycylglycine	150 mmol/l, pH 7.7
R1b. Substrate	
L-γ-glutamyl-3-carboxy-4-nitroanilide	6.0 mmol/l

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Safety Data Sheets are available on request.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

R1a. Buffer

Contents ready for use. Stable up to the expiry date when stored at +2 to +8°C.

R1b. Substrate

Contents ready for use. Stable up to the expiry date when stored at +2 to +8°C.

STABILITY AND PREPARATION OF WORKING REAGENT

Pour the contents of 1 vial of R1b in bottle R1a. Mix by inversion. Reagent is stable for 28 days at +2 to +8°C.

MATERIALS PROVIDED

γ-GT Buffer
γ-GT Substrate

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multisera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)
RX **series** Saline (Cat. No. SA 3854)

PROCEDURE NOTES

The Chemistry parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the barcode. If the barcode cannot be read by the analyser, then enter manually the series of numbers given beneath the barcode. If the problems continue, contact Randox Laboratories Technical Services, Northern Ireland + 44 (0) 28 9445 1070.

CALIBRATION

The use of Saline and Randox Calibration Serum Level 3 is recommended for calibration. A 2-point calibration is recommended.

STANDARDISATION [4]

Randox Calibration Serum Level 3 is traceable to γ-GT reference materials AD452 (IFCC) and JSCC TS01.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water. Contaminants, i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland + 44 (0) 28 9445 1070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

INTERFERENCE

The analytes below were tested up to the following levels and were found not to interfere:

Haemoglobin	1000 mg/dl
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	12.5 mg/dl
Triglycerides	1000 mg/dl
Intralipid®	1000 mg/dl

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances[5]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

NORMAL VALUES [6]

	25°C	30°C	37°C
Men	6-28 U/l	8-38 U/l	11-50 U/l
Women	4-18 U/l	5-25 U/l	7-32 U/l

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained using an RX **daytona** analyser at 37°C.

LINEARITY

The method is linear up to 1397 U/l. In the event of a rerun, the linearity is extended to 5588 U/l.

SENSITIVITY

The minimum detectable concentration of γ-GT with an acceptable level of precision was determined as 3.90 U/l.

PRECISION

Within run precision

	Level 1	Level 2	Level 3
Mean (U/l)	16.2	58.8	199
SD	0.745	1.33	1.70
CV (%)	4.61	2.27	0.856
n	20	20	20

Between run precision

	Level 1	Level 2	Level 3
Mean (U/l)	16.3	58.8	197
SD	0.851	1.77	2.50
CV (%)	5.24	3.00	1.27
n	20	20	20

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 0.98 X + 0.08

and a correlation coefficient of r = 1.00

51 patient samples were analyzed spanning the range 9 to 1389 U/l.

REFERENCES

1. ECCLS document Number **3-4:** 1988.
2. Szasz, G., Bergmeyer H.U., ed. Method of Enzymatic analysis. Weinheim Verlag Chemie, 1974.
3. Ladenson J M, Gradwohl's Clinical Laboratory Methods and Diagnosis, 8th ed, Sonnenwirth A C and Jarett L, eds, St Louis MO: C V Mosby Co, 1980.
4. IFCC Reference procedure for the measurement of Catalytic Concentrations of K-Glutamyltransferase. Clin. Chem Lab Med 2002; 40: 734-738.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.
6. Thomas, L. Labor und Diagnose. Die Medizinische Verlagsgesellschaft Marburg/Lahn. 1984; 70-73.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP

Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Revised 05 Sep 22 ld