GAMMA-GT FL

GT F080 CH	4 x 20 ml
GT F245 CH	12 x 20 ml
GT F400 CH	8 x 50 ml
GT F600 CH	5 x 120 ml

INTENDED USE

Reagent for quantitative in vitro determination of γ-GT in biological fluids.

SUMMARY OF TEST

Even though renal tissue has the highest level of GGT, the enzyme present in serum appears to originate primarily from the hepatobiliary system, and GGT activity is elevated in any and all forms of liver disease. It is highest in cases of intra- or posthepatic biliary obstruction, reaching levels some 5 to 30 times normal.

PRINCIPLE OF THE METHOD

The enzyme γ-GT (EC 2.3.2.2, γ-glutamyl-peptide:amino acid γ-glutamyltransferase; GGT) hydrolizes the GLUPA-C to release p-nitroaniline. The p-nitroaniline formed is detected spectrophotometrically at 405 nm to give a measurement of GGT activity in the sample.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

GGT R1 **F080: 4 x 16 ml (liquid) blue cap**
F245: 12 x 16 ml (liquid) blue cap
F400: 8 x 40 ml (liquid) blue cap
F600: 4 x 120 ml (liquid) blue cap

GGT R2 **F080: 1 x 16 ml (liquid) red cap**
F245: 3 x 16 ml (liquid) red cap
F400: 2 x 40 ml (liquid) red cap
F600: 1 x 120 ml (liquid) red cap

Composition in the test: Tris buffer 100 mM pH 8.25, glycilglycine 100 mM, L-Glutamyl-3-carboxy-4-nitroanilide 4 mM.

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Serum as starter procedure:
Codes F080/F245: add 4 ml of reagent R2 to a bottle of reagent R1.
Code F400: add 10 ml of reagent R2 to a bottle of reagent R1.
Code F600: mix 1 part of reagent R2 with 4 parts of reagent R1.
Stability of working reagent: preferably within 60 days at 2-8°C, away from light sources.

Reagent as starter procedure:
use separate reagents ready to use.
Stability: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: preferably within 60 days at 2-8°C.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Serum, plasma EDTA. Avoid hemolysis.
GGT is stable up to 7 days at both room temperature and 2-8°C. Store at -20°C for prolonged storage.

TEST PROCEDURE (sample as starter)

Wavelenght: 405 nm
Ligthpath: 1 cm
Temperature: 37°C

dispense in cuvette working reagent:	1 ml
preincubate at 37°C for 5 minutes.	
add sample:	100 µl

Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the ΔA/min.

TEST PROCEDURE (reagent as starter)

Wavelenght: 405 nm
Ligthpath: 1 cm
Temperature: 37°C

dispense in cuvette reagent R1:	1 ml
add sample:	100 µl
incubate at 37°C for 5 minutes.	
dispense in cuvette reagent R2:	250 µl

Mix, execute a first reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the ΔA/min.

RESULTS CALCULATION

Perform calculation in units per litre, multiplying the ΔA/min by the factor as it is indicated.

Calculation in U/l: ΔA/min x 1280 (sample starter)
Calculation in U/l: ΔA/min x 1571 (reagent starter)

Activity in µkat/l: U/l x 0.0167 = µkat/l

EXPECTED VALUES

Men: < 50 U/l (< 0.83 µkat/l)
Women: < 30 U/l (< 0.50 µkat/l)

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
QUANTINORM CHEMA
with normal or close to normal control values
QUANTIPATH CHEMA
with pathological control values.
If required, a multiparametric, human based calibrator is available:
AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity
the method is linear up to 800 U/l.
If a ΔA/min of 0.400 is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)
the limit of detection is 2 U/l.

Interferences
no interference was observed by the presence of:

hemoglobin	≤ 200 mg/dl
bilirubin	≤ 25 mg/dl
lipids	≤ 500 mg/dl

Precision

intra-assay (n=10)	mean (U/l)	SD (U/l)	CV%
sample 1	44.96	0.41	0.90
sample 2	187.72	1.15	0.60

inter-assay (n=20)	mean (U/l)	SD (U/l)	CV%
sample 1	44.37	0.51	1.10
sample 2	186.70	1.07	0.60

Methods comparison
a comparison between Chema and a commercially available product gave the following results:

GGT Chema = x
GGT competitor = y
n = 112

y = 1.10x - 1.11 U/l r^2 = 0.997

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Szasz G. - Clin. Chem. 22, 2051 (1976)
Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
HU Bergmeyer - Method of enzymatic analysis (1987)

MANUFACTURER

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

CE