GAMMA-GT

IFCC

Intended use:
Reagent for quantitative in vitro determination of y-GT in biological fluids.

Summary:
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 eleva- ted in any and ali forms of liver disease. İt is highest in cases of intra- or posthepatic biliary obstruction, reaching levels some 5 to 30 times normal.

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

Reagent concentration:

Tris buffer 100 mM pH 8.25, glycil- glycine 100 mM, L-Glutamyl-3-carboxy-4-nitroanilide 4 mM.

Preparation and stability:
Sample start:
Mix 4 volumes of R1 with 1 volume of R2. This working solution is stable:
28 days at + 2°C to + 8°C
7 days at +20°C to +25°C
Substrate start:
R1: ready for use
R2: ready for use
Unopened reagents are stable up to the expiry date on the label when stored at +2°C to +8°C.
Onboard stability: R1: 28 days
R2: 28 days

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
Stability: 7 days at +20°C to +25°C
7 days at + 2°C to + 8°C

Notes:
For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.

Limitations - interference:
no interference was observed by the presence of:
hemoglobin < 200 mg/dl
bilirubin < 25 mg/dl
lipids < 500 mg/dl

Testing procedure:
Applications for automated systems are available on request.
Materials provided
• Working solutions as described above
Additional materials required
• Calibrators and controls as indicated below
• 0.9% NACl

Manual procedure for serum start	
Wavelength:	Hg 405 nm (400-420nm)
Temperature:	+25 / +30 / +37°C
Cuvette:	1 cm light path
Zero adjustment:	air or distilled water
	Normal Cuvette
R1	1000 ul
Sample	100 µl
Mix, incubate 1-5 min. Then Add;	
R2	250 ul
Mix, execute afirst reading of absorbance after 1 minute, incubating at 37°C. Perform other 3 readings at 60 seconds intervals. Calculate the AA/min.	

Measuring /reportable range:
The method is linear up to 800 U/l.
If a AA/min of 0.400 is exceeded, it is suggested to dilute sample 1+9 with şaline and to repeat the test, multiplying the result by 10.

Expected values:
Men 37°C < 50 U/l
Women 37°C < 30 U/l
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes the GGT results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

Analytical sensitivity (lower detection limit)
Detection limit: 2 U/l
The lower detection limit represents the lowest measurable GGT activity that can be distinguished from zero.

Precision:
Reproducibility was determined using controls. The following results were obtained:

	Betwen day		
Sample	Mean U/l	SD U/l	% CV
Sample 1	39,5	0,66	1,67
Sample 2	87,1	1,42	1,63
Sample 3	215	2,91	1,35
	Within run		
Sample	Mean U/l	SD U/l	% CV
Sample 1	41,6	0,60	1,44
Sample 2	105	0,65	0,62
Sample 3	169	0,62	0,37

Method comparison:
A comparison of the BIOANALYTIC GGT (y) with a commercial obtainable assay (x) gave with samples the following result:
y = 1.10x - 1.11 U/l; r = 0.997

Waste Disposal:

This product is made to be used in professional labora- tories.
P501: Dispose of contents according to national/interna- tional regulations.

Quality Control:
Control Serum:
BIOCON N 5 x 5 ml #B10814
BIOCON P 5 x 5 ml #B10817
The control intervals and limits must be adapted to the individual laboratory and country-specific requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Calibration:
S1: 0.9% NaCl
S2: BIOCAL H 5 x 3 ml #B11895

Calibration frequency:
A two-point-calibration is recommended in case of:
1-change of lot
2- quality control requirements

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Literature:

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Order information (Cat No.) :

CC410	BGGT250	B25161	B31160	B36160
SH410	BGGT500	B27160	B32160	B36161
CR410	B21160	B27161	B32161	B37160
OL410	B21161	B28160	B33160	B37161
KL410	B22160	B28161	B33160	B80160
BGGT500	B24160	B30160	B34160	B80161
AB410	B25160	B30161	B35160	B80162

Manufacturer

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SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions

CE IVD
ISO 9001:2015
ISO 13485:2016