GPT (ALT, SGPT)

IFCC

Diagnostic reagent for determination of ALT activity.

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
A2220	5 x 100 mL	DM2220	960 Tests	BY2220	7670 Tests	K2221	4000 Tests
A2221	5 x 50 mL	R2220	2885 Tests	BY2221	5114 Tests	M2220	2512 Tests
A2222	5 x 25 mL	R2221	962 Tests	N2220	800 Tests	M2221	1675 Tests
T2220	4000 Tests	S2220	3077 Tests	N2221	400 Tests	L2220	3750 Tests
T2221	2121 Tests	S2221	1477 Tests	K2220	6000 Tests	L2221	2000 Tests

INTENDED USE

The test is applied for the quantitative determination of GPT in serum.

TEST PRINCIPLE

The enzyme alanine aminotransferase (EC 2.6.1.2; L-Alanine: 2-Oxoglutarate Aminotransferase, ALT or A1aAT; Glutamate Pyruvate Transaminase, GPT) catalyzes the transaminase reaction between L-Alanine and 2-Oxoglutarate. The pyruvate formed, is reduced to lactate in the presence of LDH. As the reactions proceed, NADH is oxidized to NAD. The disappearance of NADH per unit time is followed by measuring the decrease in absorbance at 340 nm.

The present method has been made by according to IFCC (2002).

TEST PARAMETERS

Method	: UV, Kinetic, Decreasing Reaction, modified IFCC
Wavelength	: 340 nm
Temperature	: 37°C
Sample	: Serum, EDTA-Plasma, heparinized Plasma
Linearity	: 3 U/L - 440 U/L (340 nm, 37°C, Sample Start)

REAGENT COMPOSITION

Tris buffer	≤ 120 mM pH 7.15,
L-Alanine	≤ 550 mM,
2-Oxoglutarate	≤ 18 mM,
NADH	≤ 0.18 mM,
LDH	≥ 1700 U/L.

REAGENT PREPARATION

Working reagent

Mix 4 parts of Reagent 1 (Buffer, Enzymes) with 1 part of Reagent 2 (Substrate). For example: 4 ml Reagent 1 and 1 ml Reagent 2.

Working reagents are stable at 2-8ºC in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

REAGENT STABILITY AND STORAGE

Protect from light. Note expiration date on the label. Close immediately after use.
Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions and away from light sources. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum (preferred) is collected by standard procedures. Plasma is not recommended.
GPT in serum is stable for 4 days at 2-8ºC and 1 month at -20°C.

TEST PROCEDURE

Sample Start

There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

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 1746
Activity in µkat/L: U/l x 0.0167 = µkat/L

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Men : < 45 U/L (< 0.74 µkat/L)
Women: < 34 U/L (< 0.56 µkat/L)

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

All control sera with GPT values determined by this method can be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The use of a GPT Calibrator (for automated Systems) is optional. We recommend:
ARCAL Calibrator **Cat. No.** A39050

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is about 30 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 3 U/L

High Linearity: The method is linear up to 440 U/L. If a ΔA/min of 0.200 is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
38.58 U/L	0.53	1.40%	10
114.95 U/L	0.78	0.70%	10

Reproducibility (run to run) (Inter-assay)

Mean conc.	SD	CV	n
39.65 U/L	1.02	2.60%	20
119.53 U/L	3.77	3.20%	20

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 3.37 U/L.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences: No interference was observed by the presence of:
Hemoglobin ≤ 400 mg/dL
Bilirubin ≤ 17 mg/dL
Lipids ≤ 600 mg/dL

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

GPT Archem = x
GPT competitor = y
n = 112
y = 1.032x - 1.344 r2= 0.997

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

ALT : Alanine Aminotransaminase
CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
GPT : Glutamate Pyruvate Transaminase
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

1. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press (1990).
2. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis- Ashwood (1994).
3. J. Clin.Chem.Clin.Biochem 8 (1970) 658; 10 (1972) 182
4. Wallhofer H., Schmidt E., Schmidt U.F. W.: Synopsis Der Laberkrankhetien. G.Thieme Verlag, Stuttgart (1974)
5. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
6. CCLM 2002; 40(7):725-733, Schumann et al. - IFCC reference procedure for aspartate aminotransferase.
7. HU Bergmeyer - Methods of enzymatic analysis, (1987).
8. International Federation of Clinical Chemistry, Committee on Reference Systems for Enzymes, Chem Clin Lab Med 2002; 40 (7):718–724.

SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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