AST- GOT LR

REF 3700650 6x50 ml
3701230 12x30 ml

CE IVD For in vitro medical device

Use
Kit for measurement of aspartate-aminotransferase in serum or plasma - Kinetic UV optimized method IFCC*
* International Federation of Clinical Chemistry and Laboratory Medicine

Summary
AST measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

Principle
The enzyme aspartate-aminotransferase (AST) (or glutamic-oxaloacetic transaminase/GOT) catalyzes reaction between alpha-ketoglutarate and L-aspartate giving glutamate and oxaloacetate.
In presence of malate dehydrogenase (MDH), oxaloacetate reacts with NADH giving malate and NAD+. The rate of decrease of absorbance due to oxidation of NADH to NAD+ is directly proportional to sample AST activity.

Reagents

R1	Goods buffer pH 7.8	80.0 mmol/l
	L-aspartate	240.0 mmol/l
	LDH	≥ 1800 U/l
	MDH	≥ 800 U/l
R2	Goods buffer pH 7.8	80.0 mmol/l
	alpha-ketoglutarate	65.0 mmol/l
	NADH	≥ 1.18 mmol/l

Preparation of Reagents
The reagents are liquid and ready to use. For use as monoreagent (procedure "sample starter"), put the contents of R2 into R1. For smaller usage add to every 4 ml of reagent R1, 1 ml of reagent R2. Remove the reagents from refrigerator only as long as necessary for their use and recap them immediately.

Storage and Stability
- Store the kit at 2-8°C.
- After opening, the vials **R1** and **R2** are stable 90 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.
- Working solution stability (**R1+ R2**): 20 days at 2-8°C.

Precaution in Use
The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998. The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances. However the reagent should be handled with care, according to good laboratory practice.
Caution: the reagents contain Sodium Azide (0.095%) as preservative. Avoid swallowing and contact with skin, eyes and mucous membranes.
In case of contact with eyes rinse immediately with plenty of water and seek medical advice.

Waste Management
Please refer to the local legal requirements.

Speciments Collection and Preparation
- Serum-heparinized plasma or EDTA plasma.
- Do not use samples with haemolysis because this one could cause results wrongly positive. The anticoagulants containing ammonium salt (es. ammonium heparinate) should not be used.
- The AST activity tends to decrease (< 8%) after 3 days at 2-8°C.

Note
- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

Procedures

Wavelength	340 (334-365) nm
Working temperature	37°C
Optical path	1 cm
Reaction	kinetic (decreasing)

Bring the reagents at 15-25°C before using them.

- Monoreagent Procedure"sample starter"

	BLANK	SAMPLE
Working Reagent	1000 µl	1000 µl
Distilled Water	100 µl	--
Sample	---	100 µl

Mix, then incubate for 1' a 37°C. Measure the absorbance of sample (EC) at time 0 and after 1, 2, 3 minutes. Then, calculate the absorbance variation ΔE/min obtained by performed readings.

- Bireagent Procedure "substrate starter"

	BLANK	SAMPLE
Reagent R1	800 µl	800 µl
Distilled water	100 µl	--
Sample	--	100 µl

Mix, incubate at 37°C for 1' And then add: **Reagent R2** 200 µl 200 µl
Mix, then incubate for 1' a 37°C. Measure the absorbance of sample (EC) at time 0 and after 1, 2, 3 minutes. Then, calculate the absorbance variation ΔE/min obtained by performed readings.

Calculation
AST [U/l] = ΔE/min x 1746

The factor and the reagent performances are related to 37°C , 1 cm and 340 nm.

Reference Values to 37°C

Serum – plasma	[U/l]	37°C
Women	≤	31 [U/l]
Men	≤	37 [U/l]

Reference values are considered indicative since each laboratory should establish references ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity
Reaction is linear up to a concentration of 400 U/l. Samples with values exceeding this range must be diluted with saline solution. Multiply, then, the result for diluting factor.

Analytical sensitivity
The test sensitivity in terms of detection limit is 2.4 U/l.

"Intra-Assay" precision (within-Run)
Determined on 20 samples for each control (N-H) (Normal-High). Results:

MEAN (U/l)	N = 39.70	H = 130.35
D.S.	N = 1.45	H = 2.17.
C.V.%	N = 3.66	H = 1.67

"Inter-Assay" precision (between-run)
Determined on 20 samples for each control (N-H). Results:

MEAN (U/l)	N = 41.32	H= 131.63
D.S.	N = 1.34	H = 2.17
C.V.%	N = 3.25	H = 1.63

Correlation
A study based comparing this method with a similar method on 20 samples has given a correlating factor
r = 0.99
y = 0.9227x + 1.399

Interferences
No interference was observed by the presence of :

Triglycerides	≤ 1000	mg/dl
Bilirubin	≤ 30	mg/dl
Ascorbic acid	≤ 25	mg/dl

Hemoglobin interferes also at minimum concentrations.

Quality Controls
It's necessary, each time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should estabilish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

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Symbols

CE	CE Mark (requirement of 98/79 regulation)
IVD	in vitro medical device
LOT	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Gesan Production srl
	Shelter from sunlight
UDI	Unique Identified Number
	Production data