AST- GOT LR liquid reagent

REF C3700650 6x50ml

CE **C3700650A** 6x50ml

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

Reagents are liquid and ready to use. About using as monoreagent ("sample-starter" procedure) add the entire contents of one bottle of AST **R2** in the AST **R1** bottle. For minor use add to every 4 ml of **R1** reagent, 1 ml of **R2** reagent. Keep out the reagents from refrigerator only for the 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.
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

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