BIOLABO
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AST GOT (IFC)

Reagent for quantitative determination of Aspartate amino transferase activity (AST) [EC 2.6.1.1] in human serum and plasma

REF K1505	**R1** 2 x 16 mL	**R2** 1 x 8 mL
REF K2505	**R1** 2 x 32 mL	**R2** 2 x 8 mL
REF K4505	**R1** 2 x 40 mL	**R2** 1 x 20 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made In France
I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
I It allows the quantification of global activity of the aspartate amino transferase (AST) enzyme in human serum and plasma.

GENERALITIES (1) (2)

AST is distributed in all body tissues, but greatest activity occurs in liver, heart, skeletal muscle and in erythrocytes. Minimal activity occurs in skin, kidney and pancreas. Although serum levels of both AST and ALT become elevated whenever diseases processes affecting liver cells integrity (viral hepatitis, liver necrosis and cirrhosis), an increased AST activity in serum or plasma appears in more than 97% of cases of myocardial infarction. AST levels (and occasionally ALT) are also elevated in progressive muscular dystrophy, pulmonary emboli, acute pancreatitis…

PRINCIPLE (4) (5)

Method developed by Karmen and Al and optimised by Henry and al. (according to modified IFCC recommendations).

Reaction scheme is as follows:

L-Aspartate + 2-Oxoglutarate $\xrightleftharpoons{\text{AST}}$ Oxaloacetate + L-Glutamate

Oxaloacetate + NADH + H^+ $\xrightleftharpoons{\text{MDH}}$ L-Malate + NAD^+

The decrease in absorbance proportional to AST activity in the secimen is measured at 340 nm.
Absence of P_5P allows a better stability of working reagent.

REAGENTS COMPOSITION

R1 AS2	Buffer Enzymes	
L-Aspartate	275	mmol/L
MDH	≥1000	UI/L
LDH	≥ 500	UI/L
EDTA	6	mmol/L
Tris Buffer	105	mmol/L
pH à 30°C	7,80 ± 0.1	
Stabilizer		

R2 AS2	Coenzyme	
Tris Buffer	20	mmol/L
NADH	≤ 1,4	mmol/L
2-Oxoglutarate	80	mmol/L
Stabilizer		

According to 1272/2008/EC Regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 2-8°C, reagents are stable when stored and used as described in the insert:

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened:
- 2 separated reagents are stable at least 6 months.
- Discard any cloudy reagent or if reagent blank at 340 nm is < 1.000.

SPECIMEN COLLECTION AND HANDLING (2)

Unhemolysed serum. Do not use heparinised plasma

AST is stable in serum or plasma for:
- 24 hours at room temperature
- 28 days at 2-8°C
- At least for 1 year at –20°C.

Adding pyridoxal phosphate (0.1 mM) improves stability at room temperature to 7 days.

LIMITS (3) (6)

LDH contained in reagent allows, during pre-incubation step, reduction of endogenous pyruvate which would positively interfere.

Likewise, oxaloacetate, product of the reaction, is carboxilated into pyruvate. This one will also be consumed by LDH contained in reagent and will not interfere with AST determination.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

REFRENCE INTERVALS (1) (2)

	(IU/L) 37°C
Newborn	39-117
Infant	23-94
Adult	13-31

Each laboratory should establish its own normal ranges for the population it serves.

PERFORMANCES

On Kenza One, 37°C, 340 nm.

Linearity Range: between 16 and 650 IU/L

Detection limit: approx. 3 IU/L

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	27	55	229
S.D. IU/L	1.1	1.3	1.2
C.V. %	4.0	2.3	0.5

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (IU/L)	28	57	229
S.D. IU/L	1.4	1.7	4.6
C.V. %	4.8	3.1	2.0

Analytical sensitivity: approx. 0.0053 abs/min for 10 IU/L

Interferences:

Total bilirubin	Negative interference from 380 µmol/L
Direct bilirubin	No interference up to 697 µmol/L
Ascorbic acid	Positive interference from 1235 mg/dL
Glucose	No interference up to 1120 mg/dL
Turbidity	No interference up to 0.273 OD
Haemoglobin	Positive interference from 228 µmol/L

Other substances may interfere (see § Limits)

Comparison studies with commercially available reagent:
Studies on Kenza 240TX with human specimens (n=100) between 10 and 350 IU/L

y = 0.9527 x + 1.6243 r = 0.9985

On-board stability: 2 separate reagents are stable 60 days

Calibration Frequency: 14 days

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

Performances and stability data on Kenza 450TX/ISE and Kenza One are available on request

CALIBRATION

- REF 95015 Multicalibrator traceable *to ERM-D457/IFCC*

The calibration frequency depends on proper instrument functions and on the preservation of reagent.

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- External quality control program

It is recommended to control in the following cases:

- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly result in IU/L.
Refer to the instruction of use of Kenza analyzer.

REFERENCES

(1) *TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 652-657*
(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 154-159*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-68 to 3-79*
(4) *HENRY R. J. and al., Am J clin Path (1960), 34, 381-398*
(5) *IFCC Method for L-Aspartate aminotransferase. J Clin. Chem. Clin. Biochem.(1986), 24, p.497-510.*
(6) *M. MATHIEU and col. SFBC. Comité de Standardisation. Recommandations pour la mesure de l'activité catalytique de l'Aspartate aminotransférase dans le sérum à 30°C. Ann. Biol. Clin. 1976. 34. 291-297*

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute wih