

R1: 4 x 47 mL - R2: 4 x 5,5 mL • [REF] A-R0200001001

R1: 3 x 12,6 mL – R2: 1 x 4 mL • [REF] R3330000008



**INTENDED USE**

Product for use in the quantitative determination in vitro of the GPT activity in human serum or plasma. The results of the test must always be interpreted in conjunction with the clinical context. For professional use only.

**CLINICAL SIGNIFICANCE**

Alanine aminotransferase (ALT/GPT) and aspartate aminotransferase (AST/GOT) are part of the group of aminotransferases or transaminases. These catalyze the reversible transformation of  $\alpha$ -cheto-acids into aminoacids through the transfer of amino groups. AST and ALT are present in human plasma, bile, cerebrospinal fluid and saliva. In viral hepatitis and other forms of hepatic disease, the serum ALT level increases even before the appearance of clinical signs and pathological symptoms. The ALT activity can reach values 100-times higher than the upper reference range limit, although in most cases the increase corresponds to 20-25 times the normal values.

**PRINCIPLE**

In the presence of 2-oxoglutarate, alanine is transformed into pyruvate and glutamate by the GPT present in the sample. In the presence of NADH and Lactate-D-hydrogenase (LDH), Pyruvate is transformed into lactate and NAD. The consumption of NADH over a given period of time, determined at  $\lambda$  340 nm, is proportional to the GPT concentration in the test sample.

**Abbreviations:**

ALT: Alanine aminotransferase  
LDH: Lactate dihydrogenase  
NADH: Reduced Nicotinamide-adenine dinucleotide  
NAD+: Oxidated Nicotinamide-adenine dinucleotide

**REAGENTES**

A-R0200001001- R1: 4 x 47 – R2: 4 x 5,5 mL  
**Reagent 1:** n° 4 vials x 47,0 mL ready for use  
**Reagent 2:** n° 4 vials x 5,5 mL ready for use  
R3330000008 - R1: 3 x 12,6 – R2: 1 x 4 mL  
**Reagent 1:** n° 3 vials x 12,6 mL ready for use  
**Reagent 2:** n° 1 vials x 4,0 mL ready for use

**Concentrations**

Reagent 1:		
	Conc.	U.M.
TRIS buffer pH 7.8 ± 0.2	110	mM
L-Alanine	550	mM
LDH	≥ 1320	U/L
2-Oxoglutarate	16.5	mM
Sodium azide	30.0	mM
Reagent 2:		
	Conc.	U.M.
TRIS buffer pH 10.2 ± 0.2	10.0	mM
NADH	2.60	mM
Sodium azide	30.0	mM

**Precautions**

Kit for professional laboratory use, used only by qualified and properly trained technical personnel, under the supervision of a doctor in charge of the laboratory. In addition to risk indications related to the active components, reagents may contain inactive components such as preservatives and detergents. The total concentration of these components is lower than the limits reported in the EC 1272/2008 Regulation and subsequent amendments and additions. However, it is recommended to handle reagents according to the standards of good laboratory practice

**Reports of serious incidents**

In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

**Storage and stability**

Store at 2 - 8 °C away from direct light. When stored as described above, reagents are stable until the expiry date stated on the label. A slight variation in the composition of the reagents can occur from batch to batch, without affecting the test results. After opening, they are stable for 30 days if closed immediately and protected from contamination, evaporation, direct light and stored at the correct temperature.

**SAMPLE COLLECTION**

**Type of sample and storage**

Fresh non-haemolysed serum or heparinised plasma samples should be used. GPT is stable in serum or plasma for 7 days at 4 - 8°C and 12 months at - 20°C (3) .

**Precautions**

All human samples must be handled and disposed of as potentially infectious materials.

**PROCEDURE**

**Quality control**

Control sera with a known titer of ALT are commercially available for quality control, including certificates of analysis showing values and confidence limits. Normal and abnormal control sera are available as "Normal control serum" code R0400000006 and "Pathological control serum" code R0400000106. The values obtained must be contained within the acceptability range. In case of incorrect results check the following points:

- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

**Automation**

Although this device has been developed and manufactured to be used by manual method and instrumental systems, it can also be used in combination with other instrumental devices that are able to meet the requirements indicated in the paragraph "Reaction conditions / Technique".

All applications not explicitly approved by, cannot be guaranteed in terms of performance and will therefore have to be evaluated by the user.

**Calibration**

For calibration use the kit "Multicalibrator" code R0300000006. For the use on ISE srl instruments Calibration every 10 days is recommended.

**Traceability:**

The ALT value is visible in the insert of the calibration serum package.

**Reaction conditions**

Wavelength (primary): 340 nm  
Wavelength (secondary): 380 nm  
Temperature: 37°C

**Technique - Procedure with Reagent B as starter**

Bring the reagents to the reaction temperature.

	U.M.	Calib. Serum	Sample
Reagent A	µL	1000	1000
Calib. Serum	µL	85	-
Sample	µL	-	85
Mix, after 2 minutes add:			
Reagent B	µL	100	100

Mix gently and incubate at 37°C. After incubation, add reagent B and read absorbance at 340 nm after 30 seconds. Repeat readings every 30 seconds or every 60 seconds. At least 3 repetitions of reading in the chosen times are recommended. Mean between  $\Delta$  D.O./min.

**The reaction volumes can be varied proportionately, the calculation remaining unchanged.**

**Results**

The concentration of ALT-GPT is obtained through the following formula:

$$\frac{\Delta \text{D.O. Simple}}{\Delta \text{D.O. Calib. Serum}} \times \text{Calib.Serum. (U/L)} = \text{U/L di ALT-GPT}$$

**Calculation of results obtained against multiplication factor**

$$\Delta \text{D.O./min} \times \text{K-factor}^* = \text{U/L di ALT-GPT}$$

Explanation of the formula:

$$\frac{Vt \times 1000}{C.M.E. \times P.O. \times Vc} \text{K-Factor}^* \times \Delta \text{D.O./min.} = \text{U/L di ALT-GPT}$$

\*K-factor (monoreagent method) = 2090

\*K-factor (bireagent method) = 1961

where:



# ALT GPT – Instructions for use (IFU)

Manufactured exclusively for:

**ISE S.r.l.**

CUSTOMISED SOLUTIONS  
FOR YOUR LABORATORY

R1: 4 x 47 mL - R2: 4 x 5,5 mL • [REF] A-R0200001001

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U/L = activities in international units per liter  
 $\Delta$  D.O./min. = change in absorbance per minute  
Vt = total reaction volume ( $\mu$ L)  
1000 = conversion of concentration per litre  
C.M.E = coeff. NADH extinction micromolar 6.22 cm<sup>2</sup>/l/mol at 340 nm  
P.O = optical path (1.0 cm)  
Vc = sample volume in the final reaction mixture ( $\mu$ L)

## Reagents included in the kit

The reagents are described above.

## Materials required but not supplied in the kit

Controls and calibrators.

## NORMAL VALUES

Serum or Plasma:

- Male: < 40.0 U/L
- Female: < 35.0 U/L

Each laboratory must establish its own normal values on the basis of its local catchment area.

## ANALYTICAL CHARACTERISTICS/PERFORMANCE

### Linearity

The method is linear up to the following values of 400 U/L at 340 nm.

### Specificity

The method is specific for the determination of ALT/GPT. Any eventual nonspecific reaction terminates within the delay period before taking the reading.

### Accuracy – Recovery

The recovery of ALT/GPT added to a normal sample at known concentrations showed a result of 92.6%.

### Interferences

Triglycerides below 2000 mg/dL does not interfere in the reaction. Ascorbic Acid influences the reaction at concentrations over 30 mg/dL.

### Precision of the method

Within-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	U/L	24.8	2.284	9.21%	20
High	U/L	196	2.262	1.15%	20
Between-run precision					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	U/L	24.8	1.056	4.26%	20
High	U/L	196	7.886	4.02%	20

### Sensitivity

At  $\lambda$  340 nm a concentration of about 5.41 U/L of ALT/GPT in the conditions established for this test.

### Comparative method

The method was compared with a similar method, as described in the IFCC optimization. Samples tested = no. 120; y intercept = 1.0877 + 2.49; Correlation Coefficient r = 0.9815.

### Disposal of reagents

Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

## Manufacturer:

### Sclavo Diagnostics International

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## Distributor:

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## Symbols used in IFU and Packaging

[IVD]	In vitro diagnostic medical device vitro	[M]	Manufacturer
[REF]	Catalogue Number	[i]	Instruction for use
[LOT]	Lot Number	[T]	Temperature limitation
[E]	Expiration date		

## Reference

1. Recommendation on I.F.C.C. methods for measurement of catalytic concentrations of enzymes, Clin Chem, 23:5 (1977).
2. Wroblewsky F., Ladue J.S., Proc. Soc. Exper. Biol and Med, 91:569 (1965).
3. NCCLS Document, "Procedures for the collection of arterial blood specimens", Approved Standard, 3rd Ed. (1999).
4. EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC.

REVISION	DATE	CHANGE
Rev.C	01/2023	Edit header and "Reagents" paragraph.



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