GPT (ALT)-LO

GPT (ALT)-LQ

NADH. Kinetic UV. IFCC rec. Liquid.

Quantitative determination of alanine aminotransferase GPT (ALT)
IVD

Store at 2-8ºC

PRINCIPLE OF THE METHOD

Alanine aminotranferase (ALT) or Glutamate pyruvate transaminase (GPT) catalyses the reversible transfer of an amino group from alanine to α-ketoglutarate forming glutamate and piruvate.
The piruvate produced is reduced to lactate by lactate dehydrogenase (LDH) and NADH:

$$\text{L-Alanine} + \alpha\text{-Ketoglutarate} \xrightarrow{\text{ALT}} \text{Glutamate} + \text{Piruvate}$$

$$\text{Piruvate} + \text{NADH} + \text{H}^+ \xrightarrow{\text{LDH}} \text{Lactate} + \text{NAD}^+$$

The rate of decrease in concentration of NADH, measured photometrically, is proportional to the catalytic concentration of ALT present in the sample[1].

CLINICAL SIGNIFICANCE

The ALT is a cellular enzyme, found in highest concentration in liver and kidney.
High levels are observed in hepatic disease like hepatitis, diseases of muscles and traumatisms; its better application is in the diagnosis of the diseases of the liver.
When they are used in conjunction with AST aid in the diagnosis of infarcts in the myocardium, since the value of the ALT stays within the normal limits in the presence of elevated levels of AST[1,4,5].
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENTS

R 1 Buffer	TRIS pH 7.8 Lactate dehydrogenase (LDH) L-Alanine	100 mmol/L 1200 U/L 500 mmol/L
R 2 Substrate	NADH α-Ketoglutarate	0,18 mmol/L 15 mmol/L

PRECAUTIONS

R1: H290-May be corrosive to metals.
Follow the precautionary statements given in MSDS and label of the product.

PREPARATION

All the reagents are ready to use.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.
Signs of reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 340 nm < 1,00.

ADDITIONAL EQUIPMENT

- Autoanalyzer Spintech 240.
- General laboratory equipment.

SAMPLES

Serum or plasma[1]: Stability 7 days at 2-8ºC.

Temperature conversion factors
To correct results to other temperatures multiply by:

Assay temperature	Conversion factor to		
	25ºC	30ºC	37ºC
25ºC	1,00	1,32	1,82
30ºC	0,76	1,00	1,39
37ºC	0,55	0,72	1,00

REFERENCE VALUES[4,5]

	25ºC	30ºC	37ºC
Men	up to 22 U/L	29 U/L	40 U/L
Women	up to 18 U/L	22 U/L	32 U/L

Normal newborns have been reported to show a reference range of up to double the adult, attributed to the neonate's hepatocytes. These values decline to adult levels by approximately 3 months of age.
These values are for orientation purpose; each laboratory should establish its own reference range.

APPLICATION SPINTECH 240

Item Name GPT

DATA INFORMATION
Units U/L
Decimals 0

ANALYSIS
Type RATE
W.Length 1 340
W. Length 2
Method KINETIC

CORR
SLOPE INTER
1,000 x + 0

CALIBRATION
TYPE Linear

STANDARD
#1 * #4
#2 #5
#3 #6

NORMAL RANGE (37ºC)
LOW HIGH
SERUM MALE
FEMALE
URINE

Item Name GPT

ASPIRATION
KIND Single ✔ Double

VOLUME
SAMPLE 25 µL
REAGENT 1 200 µL
REAGENT 2 50 µL

Third Mix ✔ OFF ON
R1 Blank ✔ Water R1-B

MONITOR
0 LEVEL POINT 1
SPAN 3,000

DATA PROCESS
READ
START END
MAIN 37 49
SUB

ABSORBANCE LIMIT
LOW -3,000
HIGH 3,000

ENDPOINT LIMIT
LINEAR CHECK (%) 90

FACTOR
Blank Correction 1,000

PROZONE CHECK
START END LIMIT (%)
FIRST
SECOND ✔ Low High
THIRD ✔ Low High

Blank parameter must be performed in order to get good results in CALIB screen from main menu.

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures: SPINTROL H Normal and Pathologic (Ref. 1002120 and 1002210).
If control values are found outside the defined range, check the instrument, reagents and technique for problems.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

PERFORMANCE CHARACTERISTICS

Measuring range: From *detection limit* of 0 U/L to *linearity limit* of 400 U/L.
If the results obtained were greater than linearity limit, dilute the sample 1/10 with NaCl 9 g/L and multiply the result by 10.
Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (U/L)	42,0	116	41,1	115
SD	0,47	0,42	0,76	1,61
CV (%)	1,11	0,36	1,85	1,40

Sensitivity: 1 U/L = 0,00052 ΔA / min.
Accuracy: Results obtained using SPINREACT reagents (y) did not show systematic differences when compared with other commercial reagents (x).
The results obtained using 50 samples were the following:
Correlation coefficient (r)[2]: 0,99597.
Regression equation: y=1,1209x + 1,390.
The results of the performance characteristics depend on the analyzer used.

BIBLIOGRAPHY

1. Murray R. Alanine aminotransferase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1088-1090.
2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
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4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
5. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

PACKAGING

Ref: TK41274	Cont.	R 1: 10 x 25 mL R 2: 10 x 7 mL

SPINREACT,S.A./S.A.U. Ctra.Santa Coloma, 7 E-17176 SANT ESTEVE DE BAS (GI) SPAIN
Tel. +34 972 69 08 00 Fax +34 972 69 00 99. e-mail: spinreact@spinreact.com

GPT (ALT)-LO

GPT (ALT)-LQ

NADH. Kinetic UV. IFCC rec. Liquid.

Quantitative determination of alanine aminotransferase GPT (ALT)
IVD

Store at 2-8ºC

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ADDITIONAL EQUIPMENT

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- General laboratory equipment.

SAMPLES

Serum or plasma[1]: Stability 7 days at 2-8ºC.

Temperature conversion factors
To correct results to other temperatures multiply by:

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APPLICATION SPINTECH 240

Item Name GPT

DATA INFORMATION
Units U/L
Decimals 0

ANALYSIS
Type RATE
W.Length 1 340
W. Length 2
Method KINETIC

CORR
SLOPE INTER
1,000 x + 0

CALIBRATION
TYPE Linear

STANDARD
#1 * #4
#2 #5
#3 #6

NORMAL RANGE (37ºC)
LOW HIGH
SERUM MALE
FEMALE
URINE

Item Name GPT

ASPIRATION
KIND Single ✔ Double

VOLUME
SAMPLE 25 µL
REAGENT 1 200 µL
REAGENT 2 50 µL

Third Mix ✔ OFF ON
R1 Blank ✔ Water R1-B

MONITOR
0 LEVEL POINT 1
SPAN 3,000

DATA PROCESS
READ
START END
MAIN 37 49
SUB

ABSORBANCE LIMIT
LOW -3,000
HIGH 3,000

ENDPOINT LIMIT
LINEAR CHECK (%) 90

FACTOR
Blank Correction 1,000

PROZONE CHECK
START END LIMIT (%)
FIRST
SECOND ✔ Low High
THIRD ✔ Low High

Blank parameter must be performed in order to get good results in CALIB screen from main menu.

QUALITY CONTROL

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PERFORMANCE CHARACTERISTICS

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PACKAGING

Ref: TK41274	Cont.	R 1: 10 x 25 mL R 2: 10 x 7 mL

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Tel. +34 972 69 08 00 Fax +34 972 69 00 99. e-mail: spinreact@spinreact.com

GPT (ALT)-LO

GPT (ALT)-LQ

NADH. Cinético UV. IFCC rec. Líquido

Determinación cuantitativa de alanina aminotransferasa GPT (ALT)
IVD

Conservar a 2-8ºC

PRINCIPIO DEL MÉTODO

La alanina aminotrasferasa (ALT) inicialmente llamada transaminasa glutámico pirúvica (GPT) cataliza la transferencia reversible de un grupo amino de la alanina al α-cetoglutarato con formación de glutamato y piruvato. El piruvato producido es reducido a lactato en presencia de lactato deshidrogenasa (LDH) y NADH:

$$\text{L-Alanina} + \alpha\text{-Cetoglutarato} \xrightarrow{\text{ALT}} \text{Glutamato} + \text{Piruvato}$$

$$\text{Piruvato} + \text{NADH} + \text{H}^+ \xrightarrow{\text{LDH}} \text{Lactato} + \text{NAD}^+$$

La velocidad de disminución de la concentración de NADH en el medio, determinado fotometricamente, es proporcional a la concentración catalítica de ALT en la muestra ensayada[1].

SIGNIFICADO CLÍNICO

La ALT es una enzima intracelular, se encuentra principalmente en las células del hígado y el riñón.
Su mejor aplicación es en el diagnóstico de las enfermedades del hígado.
Se observan niveles elevados en enfermedades hepáticas como la hepatitis, enfermedades de los músculos y traumatismos.
Cuando se emplean en conjunción con la AST ayuda en el diagnóstico de infartos de miocardio, ya que el valor de la ALT se mantiene dentro de los límites normales y aumenta en los niveles de AST[1,4,5].
El diagnostico clínico debe realizarse teniendo en cuenta todos los datos clínicos y de laboratorio.

REACTIVOS

R 1 Tampón	TRIS pH 7,8 Lactato Deshidrogenasa (LDH) L-Alanina	100 mmol/L 1200 U/L 500 mmol/L
R 2 Substrato	NADH α-Cetoglutarato	0,18 mmol/L 15 mmol/L

PRECAUCIONES

R1: H290-Puede ser corrosivo para los metales.
Seguir los consejos de prudencia indicados en la FDS y etiqueta del producto.

PREPARACIÓN

Todos los reactivos están listos para su uso.

CONSERVACIÓN Y ESTABILIDAD

Todos los componentes del kit son estables, hasta la fecha de caducidad indicada en la etiqueta, cuando se mantienen los frascos bien cerrados a 2-8ºC, protegidos de la luz y se evita su contaminación.
No usar reactivos fuera de la fecha indicada.
Indicadores de deterioro de los reactivos:
- Presencia de partículas y turbidez.
- Absorbancias del Blanco a 340 < 1,00.

MATERIAL ADICIONAL

- Autoanalizador Spintech 240.
- Equipamiento habitual de laboratorio.

MUESTRAS

Suero o plasma[1]. Estabilidad de la muestra: 7 días a 2-8ºC.

Factores de conversión de temperaturas

Los resultados pueden transformarse a otras temperaturas multiplicando por:

Temperatura de medición	Factor para convertir a		
	25ºC	30ºC	37ºC
25ºC	1,00	1,32	1,82
30ºC	0,76	1,00	1,39
37ºC	0,55	0,72	1,00

VALORES DE REFERENCIA[5]

	25ºC	30ºC	37ºC
Hombres	hasta 22 U/L	29 U/L	40 U/L
Mujeres	hasta 18 U/L	22 U/L	32 U/L

En recién nacidos normales se han descrito valores de referencia hasta el doble del de los adultos, debido a su inmadurez hepática, estos valores se normalizan aproximadamente a los tres meses.
Estos valores son orientativos. Es recomendable que cada laboratorio establezca sus propios valores de referencia

APLICACIÓN AL SPINTECH 240

Item Name	GPT		
DATA INFORMATION		CALIBRATION	
Units	U/L	TYPE	Linear
Decimals	0		
ANALYSIS		STANDARD	
Type	RATE	#1 *	#4
		#2	#5
W.Length 1	340	#3	#6
W. Length 2			
		NORMAL RANGE (37ºC)	
Method	CINETICO	LOW	HIGH
		SERUM MALE	
CORR		FEMALE	
SLOPE	INTER	URINE	
1,000 x +	0		

Item Name	GPT		
ASPIRATION		DATA PROCESS	ABSORBANCE LIMIT
KIND	Single ✔ Double	READ	LOW -3,000
	VOLUME	START END	HIGH 3,000
SAMPLE	25 µL	MAIN 37 49	
REAGENT 1	200 µL	SUB	
REAGENT 2	50 µL		ENDPOINT LIMIT
			LINEAR CHECK (%) 90
		FACTOR	
Third Mix	✔ OFF ON	Blank Correction	1,000
R1 Blank	✔ Water R1-B		
MONITOR		PROZONE CHECK	
0 LEVEL POINT	1	START END	LIMIT (%)
SPAN	3,000	FIRST	
		SECOND	✔ Low High
		THIRD	✔ Low High

Es necesario solicitar el blanco en este parámetro para obtener resultados correctos en la pantalla principal de CALIB.

CONTROL DE CALIDAD

Es conveniente analizar junto con las muestras de sueros control valorados: SPINTROL H Normal y Patológico (Ref. 1002120 y 1002210).
Si los valores hallados se encuentran fuera del rango de tolerancia, revisar el instrumento, los reactivos y el calibrador.
Cada laboratorio debe disponer su propio Control de Calidad y establecer correcciones en el caso de que los controles no cumplan con las tolerancias.

CARACTERÍSTICAS DEL MÉTODO

Rango de medida: Desde el *límite de detección* 0 U/L hasta el *límite de linealidad* 400 U/L.
Si la concentración de la muestra es superior al límite de linealidad, diluir 1/10 con NaCl 9 g/L y multiplicar el resultado final por 10.
Precisión:

	Intraserie (n= 20)		Interserie (n= 20)	
Media (U/L)	42,0	116	41,1	115
SD	0,47	0,42	0,76	1,61
CV (%)	1,11	0,36	1,85	1,40

Sensibilidad analítica: 1 U/L = 0,00052 ΔA / min.
Exactitud: Los reactivos SPINREACT (y) no muestran diferencias sistemáticas significativas cuando se comparan con otros reactivos comerciales (x).
Los resultados obtenidos con 50 muestras fueron los siguientes:
Coeficiente de regresión $(r)^2$: 0,99597.
Ecuación de la recta de regresión: y=1,1209x + 1,390.
Las características del método pueden variar según el analizador utilizado.

BIBLIOGRAFÍA

1. Murray R. Alanine aminotransferase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1088-1090.
2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
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PRESENTACIÓN

Ref: TK41274	Cont.	R 1: 10 x 25 mL R 2: 10 x 7 mL

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