CE

CK-NAC- LO

CK-NAC-LQ (Creatine kinase)

NAC. Kinetic UV. Liquid

Quantitative determination of creatine kinase liquid (CK)
IVD
Store at 2-8ºC

PRINCIPLE OF THE METHOD

Kinetic determination of the creatine kinase based upon IFCC and DGKC recommendations.
Creatine kinase (CK) catalyses the reversible transfer of a phosphate group from phosphocreatine to ADP. This reaction is coupled to those catalysed by hexokinase (HK) and glucose-6-phosphate dehydrogenase (G6P-DH):

$$\text{Creatine phosphate} + \text{ADP} \xrightarrow{\text{CK}} \text{Creatine} + \text{ATP}$$

$$\text{ATP} + \text{D-Glucose} \xrightarrow{\text{HK}} \text{ADP} + \text{Glucose-6-phosphate}$$

$$\text{G6P} + \text{NADP}^+ \xrightarrow{\text{G6P-DH}} \text{6-Phosphogluconate} + \text{NADPH} + \text{H}^+$$

The rate of NADPH formation, measured photometrically, is proportional to the catalytic concentration of CK present in the sample[1,2].

CLINICAL SIGNIFICANCE

Creatine kinase is a cellular enzyme with wide tissue distribution in the body. Its physiological role is associated with adenosine triphosphate (ATP) generation for contractile or transport systems.
Elevated CK values are observed in diseases of skeletal muscle and after myocardial infarction[1,5,6].
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENTS

R 1	Imidazol, pH 6.7	125 mmol/L
	D-Glucose	25 mmol/L
	N-Acetyl-L-Cysteine	25 mmol/L
	Magnesium acetate	12.5 mmol/L
	NADP	2.52 mmol/L
	EDTA	2.02 mmol/L
	Hexokinase	≥6 800 U/L
R 2	ADP	15.2 mmol/L
	AMP	25 mmol/L
	di-Adenosine-5- penta-P	103 mmol/L
	Glucose-6-phosphate DH	≥8 800 U/L
	Creatine phosphate	250 mmol/L

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 the tablets if appears broken.
Signs of reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 340 nm ≥ 1.60.

ADDITIONAL EQUIPMENT

- Autoanalyzer Spintech 240.
- General laboratory equipment.

SAMPLES

Serum free of hemolysis or heparin plasma.
Stability 7 days at 2-8ºC, protected from light.
The creatin kinase activity decreases 10% after 1 day at 2-5ºC or after 1 hour at 15-25ºC.

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

Assay temperature	Conversion factor to		
	25ºC	30ºC	37ºC
25ºC	1.00	1.56	2.44
30ºC	0.64	1.00	1.56
37ºC	0.41	0.63	1.00

REFERENCE VALUES[1]

	25ºC	30ºC	37ºC
Men, up to	80 U/L	130 U/L	195 U/L
Women, up to	70 U/L	110 U/L	170 U/L

These values are for orientation purpose; each laboratory should establish its own reference range.

APPLICATION SPINTECH 240

Item Name CKNAC

DATA INFORMATION
Units U/L
Decimals 0

ANALYSIS
Type RATE
W.Length 1 340
Method Kinetic UV.Liquid

CORR
SLOPE INTER
1.000 x + 0

CALIBRATION
TYPE Linear

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

NORMAL RANGE

		LOW	HIGH
SERUM	MALE	24	195
	FEMALE	24	170

Item Name CKNAC

ASPIRATION
KIND Single ✔ Double

VOLUME
SAMPLE 5 µL
REAGENT 1 240 µL
REAGENT 2 60 µL

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

MONITOR
0 LEVEL POINT 1
SPAN 3.000

DATA PROCESS

READ
START END
MAIN 40 52
SUB

FACTOR
Blank Correction 1.000

ABSORBANCE LIMIT
LOW -0.1
HIGH 3.000

ENDPOINT LIMIT
LINEAR CHECK (%) 90

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. This parameter calibration is stable for more than **7days**.*

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 2,12 U/L to linearity limit of 2000 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		Inter-assay	
Mean (U/L)	147	494	145	485
SD	1,23	3,60	2,91	8,97
CV (%)	0,84	0,73	2,01	1,85

Sensitivity: 1 U/L = 0,00012 ΔA/min.
Accuracy: Results obtained using SPINREACT reagents (y) did not show systematic differences when compared with other commercial reagents (x).
The results obtained were the following:
Correlation coefficient $(r)^2$: 0,9995
Regression equation: y= 1,0846x – 0,3512.
The results of the performance characteristics depend on the analyzer used.

BIBLIOGRAPHY

1. Abbot B et al. Creatinine kinase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984: 1112-116.
2. Gerhardt W et al. Creatine kinase B-Subunit activity in serum after immunohinhibition of M-Subunit activity. Clin Chem 1979;(25/7): 1274-1280.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
4. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.
7. Mathieu M. et coll. Recommandation pour la mesure de la concentration catalytique de la créatinine kinase dans la sérum humain. Ann. Biol. Clin.,40, (1482), 87.

PACKAGING

Ref: TK41250	Cont.	R1: 10 x 25 mL, R2: 10 x 7 mL
Ref: TK41251		R1: 2 x 25 mL, R2: 2 x 7 mL

SPINREACT,S.A/S.A.U Ctra.Santa Coloma, 7 E-17176 SANT ESTEVE DE BAS (GI) SPAIN
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CK-NAC-LQ (Creatina quinasa)

NAC. Cinético UV. Líquido

Determinación cuantitativa de creatina quinasa (CK)
IVD
Conservar a 2-8ºC

PRINCIPIO DEL MÉTODO

Determinación cinética de la creatina quinasa siguiendo las recomendaciones IFCC y DGKC.
La creatina quinasa (CK) cataliza la transferencia reversible de un grupo fosfato de la fosfocreatina al ADP. Esta reacción se acopla con otras catalizadas por la hexoquinasa (HK) y por la glucosa-6-fosfato deshidrogenasa (G6F-DH):

$$\text{Fosfocreatina + ADP} \xrightarrow{CK} \text{Creatina + ATP}$$

$$\text{ATP + Glucosa} \xrightarrow{HK} \text{ADP + Glucosa-6-fosfato}$$

$$\text{G6P + NADP}^+ \xrightarrow{G6F-DH} \text{6-Fosfogluconato + NADPH + H}^+$$

La velocidad de formación de NADPH, determinado fotometricamente, es proporcional a la concentración catalítica de CK en la muestra ensayada[1,2].

SIGNIFICADO CLÍNICO

La creatina quinasa es una enzima intracelular, distribuida por todo el organismo humano. Su función fisiológica está asociada con la adenosina trifosfato (ATP) producida cuando el músculo se contrae.
El nivel de CK en suero esta elevado en pacientes con alteraciones del músculo esquelético y en infartos de miocardio[1,5,6].
El diagnóstico clínico debe realizarse teniendo en cuenta todos los datos clínicos y de laboratorio.

REACTIVOS

R 1	Imidazol pH 6.7	125 mmol/L
	D-Glucosa	25 mmol/L
	N-Acetyl-L-Cysteine	25 mmol/L
	Acetato de magnesio	12.5 mmol/L
	NADP	2.52 mmol/L
	EDTA	2.02 mmol/L
	Hexokinase	≥6 800 U/L
R 2	ADP	15.2 mmol/L
	AMP	25 mmol/L
	di-Adenosina-5- pentafosfato	103 mmol/L
	G6F-DH	≥8 800 U/L
	Fosfato de creatina	250 mmol/L

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 ≥ 1,60.

MATERIAL ADICIONAL

- Autoanalizador Spintech 240.
- Equipamiento habitual de laboratorio.

MUESTRAS

Suero libre de hemólisis o plasma heparinizado[1]. Estabilidad: 7 días a 2-8ºC, protegida de la luz. La actividad de la creatin quinasa disminuye un 10% tras 1 día a 2-5ºC ó tras 1 hora a 15-25ªC.

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	1,56	2,44
30ºC	0,64	1,00	1,56
37ºC	0,41	0,63	1,00

VALORES DE REFERENCIA[1]

	25ºC	30ºC	37ºC
Hombres, hasta	80 U/L	130 U/L	195 U/L
Mujeres, hasta	70 U/L	110 U/L	170 U/L

Estos valores son orientativos. Es recomendable que cada laboratorio establezca sus propios valores de referencia.

APLICACIÓN AL SPINTECH 240

Item Name CKNAC	
DATA INFORMATION	CALIBRATION
Units U/L	TYPE Linear
Decimals 0	
ANALYSIS	STANDARD
Type RATE	#1 * #4
	#2 #5
W.Length 1 340	#3 #6
	NORMAL RANGE
Method Kinetic UV.Liquid	LOW HIGH
	SERUM MALE 24 195
CORR	FEMALE 24 170
SLOPE INTER	
1.000 x + 0	
Item Name CKNAC	
ASPIRATION	DATA PROCESS ABSORBANCE LIMIT
KIND Single ✔ Double	READ LOW -0.1
VOLUME	START END HIGH 3.000
SAMPLE 5 µL	MAIN 40 52
REAGENT 1 240 µL	SUB
REAGENT 2 60 µL	ENDPOINT LIMIT
	LINEAR CHECK (%) 90
Third Mix ✔ OFF ON	FACTOR
R1 Blank ✔ Water R1-B	Blank Correction 1.000
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. La Calibración de este parámetro es estable más de ***7 días****.*

CONTROL DE CALIDAD

Es conveniente analizar junto con las muestras 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 2,12 U/L hasta el límite de linealidad 2000 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		Interserie	
Media (U/L)	147	494	145	485
SD	1,23	3,60	2,91	8,97
CV (%)	0,84	0,73	2,01	1,85

Sensibilidad analítica: 1 U/L = 0,00012 ΔA/min.
Exactitud*:* Los reactivos SPINREACT (y) no muestran diferencias sistemáticas significativas cuando se comparan con otros reactivos comerciales (x).
Coeficiente de correlación (r^2): 0,9995.
Ecuación de la recta de regresión: y= 1,0846x – 0,3512.
Las características del método pueden variar según el analizador utilizado.

BIBLIOGRAFÍA

1. Abbot B et al. Creatinine kinase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984: 1112-116.
2. Gerhardt W et al. Creatine kinase B-Subunit activity in serum after immunohinhibition of M-Subunit activity. Clin Chem 1979;(25/7): 1274-1280.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
4. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
5. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
6. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.
7. Mathieu M. et coll. Recommandation pour la mesure de la concentration catalytique de la créatinine kinase dans la sérum humain. Ann. Biol. Clin.,40, (1482), 87.

PRESENTACIÓN

Ref: TK41250	Cont.	R1: 10 x 25 mL, R2: 10 x 7 mL
Ref: TK41251		R1: 2 x 25 mL, R2: 2 x 7 mL

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CE **CK-NAC- LQ**

CK-NAC-LQ (Créatine kinase)

CK-NAC. Cinétique UV. Liquide

Détermination quantitative de créatine kinase (CK)

IVD

A conserver entre 2-8ºC

PRINCIPE DE LA MÉTHODE

Détermination cinétique de la créatine kinase en suivant les recommandations IFCC et DGKC.

La créatine kinase (CK) catalyse le transfert réversible d'un groupe phosphate de la phosphocréatine vers l'ADP. Cette réaction s'ajoute à d'autres catalysées par l'hexokinase (HK) et par le glucose-6-phosphate déshydrogénase (G6P-DH) :

$$\text{Phosphocréatine + ADP} \xrightarrow{CK} \text{Créatine + ATP}$$

$$\text{ATP + Glucose} \xrightarrow{HK} \text{ADP + Glucose-6-phosphate}$$

$$\text{Glucose-6-phosphate + NADP}^+ \xrightarrow{G6F-DH} \text{6-Phosphogluconate + NADPH + H}^+$$

La vitesse de formation de NADPH, déterminé par photométrie, est proportionnelle à la concentration catalytique de CK dans l'échantillon testé[1,2].

SIGNIFICATION CLINIQUE

La créatine kinase est une enzyme intracellulaire, distribuée dans tout l'organisme humain. Sa fonction physiologique est associée à l'adénosine triphosphate (ATP) produite lorsque le muscle se contracte.

Le niveau de CK sérique est élevé chez les patients présentant des altérations du muscle squelettique et lors d'infarctus du myocarde[1,5,6].

Le diagnostic clinique doit être réalisé en tenant compte de toutes les données cliniques et de laboratoire.

RÉACTIFS

R 1	Imidazole pH 6,7	125 mmol/L
	D-Glucose	25 mmol/L
	N-Acétyl-L-Cystéine	25 mmol/L
	Acétate de magnésium	12,5mmol/L
	NADP	2,52 mmol/L
	EDTA	2,02 mmol/L
	Hexokinase	≥6 800 U/L
R 2	ADP	15,2 mmol/L
	AMP	25 mmol/L
	di-Adénosine-5- pentaphosphate	103 mmol/L
	Glucose-6-phosphate déshydrogénase (G6F-DH)	≥8 800 U/L
	Phosphate de créatine	250 mmol/L

PRÉPARATION

Tous les réactifs sont prêts à l'emploi.

CONSERVATION ET STABILITÉ

Toutes les composantes du kit sont stables jusqu'à l'expiration de la date mentionnée sur l'étiquette en cas de conservation hermétique sous 2-8ºC et de protection contre la lumière et les contaminations évitées lors de leur utilisation.

Ne pas utiliser de réactifs en dehors de la date indiquée.

Indicateurs de détérioration des réactifs :

- Présence de particules et turbidité.
- Absorbance (A) du témoin à 340 nm ≥1,60.

MATERIEL SUPPLEMENTAIRE

- Auto-analyseur SPINTECH 240.
- Equipement classique de laboratoire.

ÉCHANTILLONS

Sérum sans hémolyse ou plasma hépariné[1]. Stabilité : 7 jours à 2-8ºC, protégé de la lumière.

L'activité de la créatine kinase diminue de 10 % après une journée à 2-5ºC ou après une heure à 15-25ºC.

VALEURS DE RÉFÉRENCE[1]

	25ºC	30ºC	37ºC
Hommes, jusqu'à	80 U/L	130 U/L	195 U/L
Femmes, jusqu'à	70 U/L	110 U/L	170 U/L

Ces valeurs sont orientatives. Il est conseillé que chaque laboratoire établisse ses propres valeurs de référence.

CONTRÔLE DE QUALITÉ

Il convient d'analyser des sérums de contrôle estimés en même temps que les échantillons : SPINTROL H normal et pathologique (réf. 1002120 et 1002210).

Si les valeurs trouvées sont en dehors de la gamme de tolérance, il faut réviser l'instrument, les réactifs et la technique.

Chaque laboratoire doit établir son propre système de contrôle de qualité et des actions correctives au cas où les contrôles n'atteignent pas les tolérances acceptables.

APPLICATION AU SPINTECH 240

Item Name CKNAC DATA INFORMATION Units U/L Decimals 0 ANALYSIS Type RATE W.Length 1 340 Method Kinetic UV.Liquid CORR SLOPE INTER 1.000 x + 0	CALIBRATION TYPE Linear STANDARD #1 * #4 #2 #5 #3 #6 NORMAL RANGE LOW HIGH SERUM MALE 24 195 FEMALE 24 170
Item Name CKNAC ASPIRATION KIND Single ✔ Double VOLUME SAMPLE 5 µL REAGENT 1 240 µL REAGENT 2 60 µL Third Mix ✔ OFF ON R1 Blank ✔ Water R1-B MONITOR 0 LEVEL POINT 1 SPAN 3.000	DATA PROCESS READ START END MAIN 40 52 SUB ABSORBANCE LIMIT LOW -0.1 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

*Dans ce paramètre, le blanc est nécessaire pour obtenir des résultats corrects à l'écran principal de CALIB. L'étalonnage avec le blanc réactif est stable jusqu'à **7 jours**.*

CARACTÉRISTIQUES DE LA MÉTHODE

Gamme de mesure : De la limite de la détection de 2,12 U/L à la limite de linéarité de 2000 U/L.

Si la concentration de l'échantillon est supérieure à la limite de linéarité, diluer 1/10 avec du NaCl 9 g/L et multiplier le résultat final par 10.

Précision :

	Intra-essai		Inter-essai	
Moyenne (U/L)	147	494	145	485
SD	1,23	3,60	2,91	8,97
CV (%)	0,84	0,73	2,01	1,85

Sensibilité analytique : 1 U/L = 0,00012 ΔA/min.

Exactitude : Les réactifs SPINREACT (y) ne montrent pas de différences systématiques importantes par rapport à d'autres réactifs commerciaux (x).

Coefficient de corrélation $(r)^2$: 0,9995.

Équation de la droite de régression : y = 1,0846x - 0,3512.

Les résultats des caractéristiques de la méthode dépendent de l'analyseur utilisé.

BIBLIOGRAPHIE

1. Abbot B et al. Creatinine kinase.Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984: 1112-116.
2. Gerhardt W et al. Creatine kinase B-Subunit activity in serum after immunohinhibition of M-Subunit activity. Clin Chem 1979;(25/7): 1274-1280.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
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6. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd edAACC 1995.
7. Mathieu M. et coll. Recommandation pour la mesure de la concentration catalytique de la créatinine kinase dans le sérum humain. Ann. Biol. Clin.,40, (1482), 87.

PRÉSENTATION

Ref: TK41250	Cont.	R1: 10 x 25 mL, R2: 10 x 7 mL
Ref: TK41251		R1: 2 x 25 mL, R2: 2 x 7 mL

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CE

CK-NAC- LQ

CK-NAC-LQ (Creatina quinase)

NAC. Cinético UV. Líquido

Determinação quantitativa de creatina quinase (CK)
IVD
Conservar a 2-8ºC

PRINCÍPIO DO MÉTODO

Determinação cinética da creatina quinase seguindo as recomendações IFCC e DGKC.
A creatina quinase (CK) cataliza a transferência reversível de um grupo fosfato da fosfocreatina ao ADP. Esta reacção acopla-se com outras catalizadas pela hexoquinase (HK) e pela glucose-6-fosfato desidrogenase (G6F-DH):

$$\text{Fosfocreatina + ADP} \xrightarrow{CK} \text{Creatina + ATP}$$

$$\text{ATP + Glucose} \xrightarrow{HK} \text{ADP + Glucose-6-fosfato}$$

$$\text{G6P + NADP}^+ \xrightarrow{G6F-DH} \text{6-Fosfogluconato + NADPH + H}^+$$

A velocidade de formação de NADPH, determinada fotometricamente, é proporcional à concentração catalítica de CK na amostra testada[1,2].

SIGNIFICADO CLÍNICO

A creatina quinase é uma enzima intracelular, distribuída por todo o organismo humano. A sua função fisiológica está associada com a adenosina trifosfato (ATP) produzida quando o músculo se contrai.
O nível de CK no soro está elevado em pacientes com alterações do músculo esquelético e em enfartes do miocardio[1,5,6].
O diagnóstico clínico deve realizar-se tendo em conta todos os dados clínicos e de laboratório.

REAGENTES

R 1	Imidazol pH 6.7	125 mmol/L
	D-Glucose	25 mmol/L
	N-Acetyl-L-Cisteina	25 mmol/L
	Acetato de magnésio	12,5 mmol/L
	NADP	2,52 mmol/L
	EDTA	2,02 mmol/L
	Hexoquinase	≥6 800 U/L
R 2	ADP	15,2 mmol/L
	AMP	25 mmol/L
	di-Adenosina-5- pentafosfato	103 mmol/L
	G6F-DH	≥8 800 U/L
	Fosfato de creatina	250 mmol/L

PREPARAÇÃO

Todos os reagentes estão prontos a ser utilizados.

CONSERVAÇÃO E ESTABILIDADE

Todos os componentes do kit são estáveis até ao final do prazo de validade indicado na etiqueta, quando se mantém os frascos bem fechados a 2-8ºC, protegidos da luz e se evita a sua contaminação.
Não usar reagentes após a data indicada.

Indicadores de deterioração dos reagentes:
- Presença de partículas e turvação.
- Absorvâncias do Branco a 340 nm ≥ 1,60.

MATERIAL ADICIONAL

- Autoanalisador SPINTECH 240.
- Equipamento habitual de laboratório.

AMOSTRAS

Soro livre de hemólise ou plasma heparinizado[1]. Estabilidade: 7 dias a 2-8ºC, protegida da luz. A actividade da creatina quinase diminui cerca de 10% após 1 dia a 2-5ºC ou após 1 hora a 15-25ªC.

VALORES DE REFERÊNCIA[1]

	25ºC	30ºC	37ºC
Homens, até	80 U/L	130 U/L	195 U/L
Mulheres, até	70 U/L	110 U/L	170 U/L

Estes valores são orientativos. É recomendável que cada laboratório estabeleça os seus próprios valores de referência.

CONTROLO DE QUALIDADE

É conveniente analisar junto com as amostras, os soros controlo padronizados: SPINTROL H Normal e Patológico (Ref. 1002120 e 1002210).
Se os valores determinados se encontrarem fora do intervalo de tolerância, rever o instrumento, os reagentes e o calibrador.
Cada laboratório deve dispor do seu próprio Controlo de Qualidade e estabelecer correcções caso os controles não cumpram com as tolerâncias.

APLICAÇÃO AO SPINTECH 240

Item Name CKNAC

DATA INFORMATION
Units U/L
Decimals 0

ANALYSIS
Type RATE
W.Length 1 340
Method Kinetic UV.Liquid

CORR
SLOPE INTER
1.000 x + 0

CALIBRATION
TYPE Linear

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

NORMAL RANGE

		LOW	HIGH
SERUM	MALE	24	195
	FEMALE	24	170

Item Name CKNAC

ASPIRATION
KIND Single ✔ Double

	VOLUME	
SAMPLE	5	µL
REAGENT 1	240	µL
REAGENT 2	60	µL

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

MONITOR
0 LEVEL POINT 1
SPAN 3.000

DATA PROCESS

READ	START	END
MAIN	40	52
SUB		

ABSORBANCE LIMIT
LOW -0.1
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

*Você precisa aplicar o branco neste parâmetro para obter resultados correctos na tela principal de CALIB. Calibração pelo branco de reagente é estável até **7 dias**.*

CARACTERÍSTICAS DO MÉTODO

Intervalo de medida: Desde o limite de detecção 2,12 U/L até ao límite de linearidade de 2000 U/L.
Se a concentração da amostra for superior ao limite de linearidade, diluir 1/10 com ClNa 9 g/L e multiplicar o resultado final por 10.
Precisão:

	Intrasérie		Intersérie	
Média (U/L)	147	494	145	485
SD	1,23	3,60	2,91	8,97
CV (%)	0,84	0,73	2,01	1,85

Sensibilidade analítica: 1 U/L = 0,00012 ΔA/min.
Exactidão: Os reagentes SPINREACT (y) não mostram diferenças sistemáticas significativas quando comparados com outros reagentes comerciais (x).
Coeficiente de correlação(r)[2]: 0,9995
Equação da recta de regressão:y=1,0846x – 0,3512.
As características do método podem variar segundo o analisador utilizado.

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APRESENTAÇÃO

Ref: TK41250	Cont.	R1: 10 x 25 mL, R2: 10 x 7 mL
Ref: TK41251		R1: 2 x 25 mL, R2: 2 x 7 mL

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