

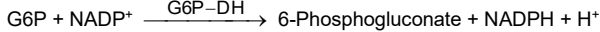
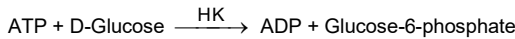
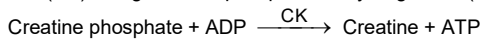
Quantitative determination of creatine kinase liquid (CK) IVD

Store at 2-8°C

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):


 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
R 2	ADP	15.2 mmol/L
	AMP	15.2 mmol/L
	di-Adenosine-5- pentaphosphate	25 mmol/L
		103 mmol/L
	Glucose-6-phosphate dehydrogenase	≥8 800 U/L
	Creatine phosphate	250 mmol/L

Optional

CK-Nac / CK-MB CONTROL	Lyophilized human serum	Ref: 1002260
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PRECAUTIONS

R1: H360-May damage fertility or the unborn child. Contains: Imidazole (C3H4N2)

Follow the precautionary statements given in MSDS and label of the product.

PREPARATION

R1 and R2 ready to be used.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, 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

- SPINLAB 180 autoanalyzer
- Laboratory equipment.

SAMPLES

Serum free of hemolysis or heparin plasma.

Stability 7 days at 2-8°C, protected from light.

The creatin kinase activity decreases 10% after 1 day at 2-5°C or after 1 hour at 15-25°C.

REFERENCE VALUES¹

	25°C	30°C	37°C
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.

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures: SPINROL 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.

APPLICATION SPINLAB 180

Name	CK-NAC	Ref. male low	24
Abbr. Name	CK	Ref. male high	195
Mode	Kinetic	Ref. female low	24
Wavelength	340 nm	Ref. female high	170
Units	U/L	Ref. Ped. Low	*
Decimals	0	Ref. Ped. High	*
Low Conc.	10 U/L	Control 1	*
High Conc.	2000 U/L	Control 2	*
Calibrator name	CAL	Control 3	*
Prozone check	No	Correlat. factor	1.000
		Correlat. offset	0.000
DUAL MODE			
Sample blank	No	Sample blank	No
R1 bottle (mL)	25 mL	R1 bottle (mL)	25 mL
normal volume	240 µL	normal volume	300 µL
rerun volume	240 µL	rerun volume	300 µL
Sample		Sample	
normal volume	5 µL	normal volume	6 µL
rerun volume	5 µL	rerun volume	6 µL
R2 bottle (mL)	5 mL		
normal volume	60 µL		
rerun volume	60		
Predilution	No		
Slope blank	No		
Delay, min. time	103.133 sec.	Delay, min. time	183, 177 sec.
Linearity limit	10.0 %	Linearity limit	10.0 %
Factor	-	Factor	-
Vol. repet.			30.0 µL
Reagent blank	No	Reagent blank	No
Low Absorbance	-0.100 Abs	Low Absorbance	-0.100 Abs
High Absorbance	3.000 Abs	High Absorbance	3.000 Abs
R. Abs. L. Limit	-0.100 Abs	R. Abs. L. Limit	-0.100 Abs
R. Abs. H. Limit	3.000 Abs	R. Abs. H. Limit	3.000 Abs
R. Abs. Deviation	3.000 Abs	R. Abs. Deviation	3.000 Abs

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)	SD	CV (%)	
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.

INTERFERENCES

 No interferences were observed with glucose until 7 g/L, hemoglobin until 5 g/L and triglycerides 7 mmol/L. A list of drugs and other interfering substances with CK determination has been reported by Young et. al^{3,4}.

BIBLIOGRAPHY

1. Abbot B et al. Creatinine kinase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984: 1112-1116.
2. Gerhardt W et al. Creatine kinase B-Subunit activity in serum after immunoinhibition 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. Recommendation pour la mesure de la concentration catalytique de la créatinine kinase dans la sérum humain. Ann. Biol. Clin.,40, (1482), 87.

PACKAGING

Ref: SP41250	Cont.	R1: 10 x 20 mL
		R2: 10 x 5 mL

CK-NAC-LQ (Creatina quinasa)

NAC. Cinético UV. Líquido

Determinación cuantitativa de creatina quinasa (CK)

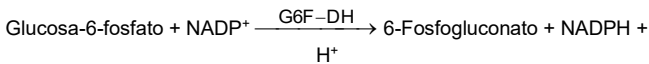
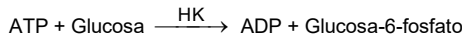
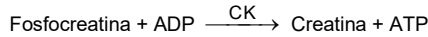
IVD

Conservar a 2-8°C

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):



La velocidad de formación de NADPH, determinado fotométricamente, 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 está 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
R 2	Hexokinase	≥6 800 U/L
	ADP	15.2 mmol/L
	AMP	25 mmol/L
	di-Adenosina-5- pentafosfato	103 mmol/L
	Glucosa-6-fosfato deshidrogenasa (G6F-DH)	≥8 800 U/L
	Fosfato de creatina	250 mmol/L

Opcional

CK-Nac / CK-MB CONTROL	Suero humano liofilizado	Ref: 1002260
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PRECAUCIONES

R1: H360-Puede perjudicar a la fertilidad o al feto. Contiene: Imidazol (C3H4N2)

Seguir los consejos de prudencia indicados en la FDS y etiqueta del producto.

PREPARACIÓN

R1 y R2 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 2-8°C, 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 SPINLAB 180
- Equipamiento habitual de laboratorio.

MUESTRAS

Suero libre de hemólisis o plasma heparinizado¹. Estabilidad: 7 días a 2-8°C, protegida de la luz.

La actividad de la creatina quinasa disminuye un 10% tras 1 día a 2-5°C ó tras 1 hora a 15-25°C.

VALORES DE REFERENCIA

	25°C	30°C	37°C
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.

CONTROL DE CALIDAD

Es conveniente analizar junto con las muestras sueros control valorados: SPINROL H Normal y Patológico (Ref. 1002120 y 1002210).

Si los valores hallados se encuentran fuera del rango de tolerancia, se debe revisar el instrumento, los reactivos y la técnica.

Cada laboratorio debe disponer su propio Control de Calidad y establecer correcciones en el caso de que los controles no cumplan con las tolerancias.

APLICACIÓN AL SPINLAB 180

Nombre	CK-NAC	Ref. Hombre Inf.	24
Nombre abreviado	CK	Ref. Hombre Sup.	195
Modo	Cinética	Ref. Mujer Inf.	24
Long. ondas	340 nm	Ref. Mujer Sup.	170
Unidades	U/L	Ref. Ped. Inf.	*
Decimales	0	Ref. Ped. Sup.	*
Conc. Inferior	10 U/L	Valor pánico bajo	*
Conc. Superior	2000 U/L	Valor pánico alto	*
Calibrador	CAL	Control 1	*
Chequeo prozona	No	Control 2	*
		Control 3	*
		Factor correl.	1.000
		Offset de correl.	0.000
MODO DUAL		MODO MONO	
Blanco muestra	No	Blanco muestra	No
Frasco R1 (mL)	25 mL	Frasco R1 (mL)	25 mL
Vol. normal	240 µL	Vol. normal	300 µL
Vol. repet.	240 µL	Vol. repet.	300 µL
Muestra		Muestra	
Vol. normal	5 µL	Vol. normal	6 µL
Vol. repet.	5 µL	Vol. repet.	6 µL
Frasco R2 (mL)	5 mL		
Vol. normal	60 µL		
Vol. repet.	60 µL		
Predilución	No		
Pendiente Blco.	No		
Retr., tiempo min.	103.133 seg.	Retr., tiempo min.	183,177seg.
Lim. Linealidad	10%	Lím. Linealidad	10 %
Factor	-	Factor	-
Blanco reactivo	No	Blanco reactivo	No
Absorbancia inf.	-0.100 Abs	Absorbancia inf.	-0.100 Abs
Absorbancia sup.	3.000 Abs	Absorbancia sup.	3.000 Abs
Lim.Inf. Abs. React.	-0.100 Abs	LimInf. Abs. React.	-0.100 Abs
Lim.Sup. Abs. React.	3.000 Abs	LimSup. Abs. React.	3.000 Abs
Desv. Abs. React.	3.000 Abs	Desv. Abs. React.	3.000 Abs

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:

Media (U/L)	Intraserie		Interserie	
	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).

Coefficiente 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.

INTERFERENCIAS

No se ha observado interferencia de la glucosa hasta 7 g/L, hemoglobina hasta 5 g/L y triglicéridos hasta 7 mmol/L. Se han descrito varias drogas y otras sustancias que interfieren en la determinación de la Creatina quinasa.

BIBLIOGRAFÍA

1. Abbot B et al. Creatinine kinase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984: 1112-1116.
2. Gerhardt W et al. Creatine kinase B-Subunit activity in serum after immunoinhibition 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. Recommendation pour la mesure de la concentration catalytique de la créatinine kinase dans le sérum humain. Ann. Biol. Clin.,40, (1482), 87.

PRESENTACIÓN

Ref: SP41250

Cont.

R1: 10 x 20 mL

R2: 10 x 5 mL



CK-NAC-LQ (Créatine kinase)

CK-NAC. Cinétique UV. Liquide

Détermination quantitative de créatine kinase (CK)

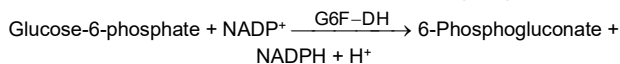
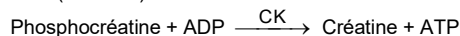
IVD

A conserver entre 2-8°C

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) :


 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^{1,5,6,7}.

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-Acétyle-L-Cystéine	25 mmol/L
	Acétate de magnésium	12,5mmol/L
	NADP	2,52 mmol/L
	EDTA	2,02 mmol/L
R 2	Hexokinase	≥6 800 U/L
	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

Facultatif

CK-NAC / CK-MB CONTROL	Sérum humain lyophilisé	Réf : 1002260
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PRÉCAUTIONS

R1: H360-Peut nuire à la fertilité ou au fœtus. Contient: imidazole (C3H4N2).

Suivez les conseils de prudence donnés en SDS et étiquette.

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 2-8°C 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 ≥ 1,00.

ÉQUIPEMENTS SUPPLÉMENTAIRES

- Auto-analyseur SPINLAB 180
- Equipement classique de laboratoire

ÉCHANTILLONS

 Sérum sans hémolyse ou plasma hépariné¹. Stabilité : 7 jours à 2-8°C, protégé de la lumière.

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

VALEURS DE RÉFÉRENCE¹

	25°C	30°C	37°C
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 : SPINCONTROL 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 SPINLAB 180

Name	CK-NAC	Ref. male low	24
Abbr. Name	CK	Ref. male high	195
Mode	Kinetic	Ref. female low	24
Wavelength	340 nm	Ref. female high	170
Units	U/L	Ref. Ped. Low	*
Decimals	0	Ref. Ped. High	*
Low Conc.	10 U/L	Control 1	*
High Conc.	2000 U/L	Control 2	*
Calibrator name	CAL	Control 3	*
Prozone check	No	Correlat. factor	1.000
		Correlat. offset	0.000
DUAL MODE		MONO MODE	
Sample blank	No	Sample blank	No
R1 bottle (mL)	25 mL	R1 bottle (mL)	25 mL
normal volume	240 µL	normal volume	300 µL
rerun volume	240 µL	rerun volume	300 µL
Sample		Sample	
normal volume	5 µL	normal volume	6µL
rerun volume	5 µL	rerun volume	6µL
R2 bottle (mL)	5 mL		
normal volume	60 µL		
rerun volume	60 µL		
Predilution	No		
Slope blank	No		
Delay, min. time	103.133 sec.	Delay, min. time	183, 177 sec.
Linearity limit	10.0 %	Linearity limit	10.0 %
Factor	-	Factor	-
Reagent blank	No	Reagent blank	No
Low Absorbance	-0.100 Abs	Low Absorbance	-0.100 Abs
High Absorbance	3.000 Abs	High Absorbance	3.000 Abs
R. Abs. L. Limit	-0.100 Abs	R. Abs. L. Limit	-0.100 Abs
R. Abs. H. Limit	3.000 Abs	R. Abs. H. Limit	3.000 Abs
R. Abs. Deviation	3.000 Abs	R. Abs. Deviation	3.000 Abs

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	
	147	494	145	485
Moyenne (U/L)				
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.

INTERFERENCES

Aucune interférence du glucose jusqu'à 7 g/L, de l'hémoglobine jusqu'à 5 g/L et de triglycérides jusqu'à 7 mmol/L n'a été observée.

 Plusieurs drogues et autres substances, interférant dans la détermination de la créatine kinase^{3,4} ont été décrites.

BIBLIOGRAPHIE

1. Abbot B et al. Creatinine kinase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984: 1112-1116.
2. Gerhardt W et al. Creatine kinase B-Subunit activity in serum after immunoinhibition 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 le sérum humain. Ann. Biol. Clin.,40, (1482), 87.

PRÉSENTATION

Réf: SP41250

Cont.

R1: 10 x 20 mL

R2: 10 x 5 mL

CK-NAC-LQ (Creatina quinase)

NAC. Cinético UV. Líquido

Determinação quantitativa de creatina quinase (CK)

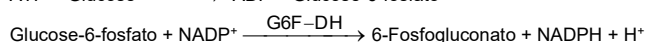
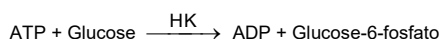
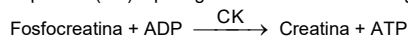
IVD

Conservar a 2-8°C

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 a ADP. Esta reacção insere-se com outras catalizadas pela hexoquinase (HK) e pela glucose-6-fosfato desidrogenase (G6F-DH):


 A velocidade de formação de NADPH, determinado fotometricamente, é proporcional à concentração catalítica de CK-B 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 contraí. O nível de CK no soro fica elevado em pacientes com alterações do músculo esquelético e em enfartes do miocárdio.^{1,5,6} O diagnóstico clínico deve realizar-se tendo em conta todos os dados clínicos e laboratoriais.

REAGENTES

R 1	Imidazol pH 6,7	125 mmol/L
	D-Glucose	25 mmol/L
	N-acetyl-L-cisteína	25 mmol/L
	Acetato de magnésio	12,5 mol/L
	NADP	2,52 mmol/L
R 2	EDTA	2,02 mmol/L
	Hexoquinase	≥ 6 800 U/L
	ADP	15,2 mmol/L
	AMP	25 mmol/L
	di-Adenosina-5- pentafofato	103 mmol/L
Anti CK-M	Glucosa-6-fosfato desidrogenase (G6F-DH)	≥ 8 800 U/L
	Fosfato de creatina	250 mmol/L

Opcional

CK-Nac / CK-MB CONTROL	Soro humano liofilizado	Ref: 1002260
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PRECAUÇÕES

R1: H360-Pode prejudicar a fertilidade ou o feto. Contém: Imidazole (C3H4N2).

Seguir os conselhos de prudência dados em SDS e etiqueta.

PREPARAÇÃO

R1 e R2 estão prontos a utilizar.

CONSERVAÇÃO E ESTABILIDADE

Todos os componentes do kit são estáveis, até ao final do prazo de validade indicado no rótulo, quando mantidos nos frascos bem fechados, a 2-8°C, protegidos da luz e evitando a sua contaminação.

Não usar reagentes após a data indicada.

Indicadores de deterioração dos reagentes:

- Presença de partículas e turvação.
- Absorvâncias (A) do Branco a 340 nm ≥ 1,60.

EQUIPAMENTO ADICIONAL.

- Autoanalisador SPINLAB 180
- Equipamento habitual de laboratório.

AMOSTRAS

 Soro livre de hemólise ou plasma heparinizado¹. Estabilidade: 7 dias a 2-8°C, protegida da luz.

A actividade da CK-MB no soro diminui cerca de 10% após 1 dia a 2-5°C ou após 1 hora a 15-25°C.

VALORES DE REFERENCIA¹

	25°C	30°C	37°C
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 juntamente com as amostras soros controlo standardizados: SPINTROL H Normal e Patológico (Ref. 1002120 e 1002210).

Se os valores determinados estiverem fora do intervalo de tolerância, verificar o equipamento, os reagentes e o calibrador.

Cada laboratório deve dispor do seu próprio Controlo de Qualidade e estabelecer correcções caso os controlos não cumpram com as tolerâncias.

APLICAÇÃO AO SPINLAB 180

Nome	CK-NAC	Ref. Homem Inf.	24
Nome abreviado	CK	Ref. Homem Sup.	195
Modo	Cinética	Ref. Mulher Inf.	24
Long. ondas	340 nm	Ref. Mulher Sup.	170
Unidades	U/L	Ref. Ped. Inf.	*
Decimais	0	Ref. Ped. Sup.	*
Conc. inferior	10 U/L	Valor pânico baixo	*
Conc. Superior	2000 U/L	Valor pânico alto	*
Calibrador	CAL	Controlo 1	*
Chequeo prozona	Não	Controlo 2	*
		Controlo 3	*
		Factor correl.	1.000
		Offset de correl.	0.000
MODO DUAL		MODO MONO	
Branco amostra	Não	Branco amostra	Não
Frasco R1 (mL)	25 mL	Frasco R1 (mL)	25 mL
Vol. normal	240 µL	Vol. normal	300 µL
Vol. repet.	240 µL	Vol. repet.	300 µL
Amostra		Amostra	
Vol. normal	5 µL	Vol. Normal	6 µL
Vol. repet.	5 µL	Vol. repet.	6 µL
Frasco R2 (mL)	5 mL		
Vol. normal	60 µL		
Vol. repet.	60 µL		
Prediluição	No		
Pendente B/c.	No		
Retr., tempo min.	103.133 seg.	Retr., tempo min.	183, 177 seg.
Lim. Linearidade	10%	Lim. Linearidade	10 %
Factor	-	Factor	-
Branco reagente	Não	Branco reagente	No
Absorvância inf.	-0.100 Abs	Absorvância inf.	-0.100 Abs
Absorvância sup.	3.000 Abs	Absorvância sup.	3.000 Abs
Lim. Inf. Abs. React.	-0.100 Abs	Lim. Inf. Abs. React.	-0.100 Abs
Lim. Sup. Abs. React.	3.000 Abs	Lim. Sup. Abs. React.	3.000 Abs
Desv. Abs. React.	3.000 Abs	Desv. Abs. React.	3.000 Abs

CARACTERÍSTICAS DO MÉTODO

Intervalo de medida: Desde o limite de detecção 2,12 U/L até ao limite de linearidade de 2000 U/L.

Se a concentração da amostra for superior ao limite de linearidade, diluir 1/10 com NaCl 9 g/L e multiplicar o resultado final por 10.

Precisão:

Média (U/L)	Intrasérie		Intersérie	
	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.

INTERFERÊNCIAS

 Não foi observada interferência da glucose até 7 g/mL, hemoglobina até 5 g/L e triglicéridos até 7 mmol/L. Foram descritas várias drogas e outras substâncias que interferem na determinação da CK-MB^{3,4}.

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APRESENTAÇÃO

Ref: SP41250

Cont.

R1: 10 x 20 mL

R2: 10 x 5 mL