

Creatine kinase - MB

Anti CK-M. Immunoinhibition. Kinetic UV. Liquid

Quantitative determination of creatine kinase MB (CK-MB)
IVD

Store at 2-8°C

PRINCIPLE OF THE METHOD

The procedure involves measurement of CK activity in the presence of an antibody to CK-M monomer. This antibody completely inhibits the activity of CK-MM and half of the activity of CK-MB while not affecting the B subunit activity of CK-MB and CK-BB. Then it's used the CK method to quantitatively determine CK-B activity^{1,2}. The CK-MB activity is obtained by multiplying the CK-B activity by two.

CLINICAL SIGNIFICANCE

CK-MB is an enzyme formed by the association of two subunits from muscle (M) and nerve cells (B). CK-MB is usually present in serum at low concentration; it is increased after an acute infarct of myocardium and later descends at normal levels. Also is increased, rarely, in skeletal muscle damage^{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 D-Glucose N-Acetyl-L-Cysteine Magnesium acetate NADP EDTA Hexokinase	125 mmol/L 25 mmol/L 25 mmol/L 12,5 mmol/L 2,52 mmol/L 2,02 mmol/L ≥6 800 U/L
Anti-human polyclonal CK-M antibody (sheep) sufficient to inhibit up to 2 000 U/L of CK-MM		
R 2	ADP AMP di-Adenosine-5'-pentaphosphate Glucose-6-phosphate DH Creatine phosphate	15,2 mmol/L 25 mmol/L 103 mmol/L ≥8 800 U/L 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 2-8°C, protected from light and contaminations prevented.

Do not use reagents over the expiration date.

Signs of reagent deterioration:

- Presence of particles and turbidity.
- Blank absorbance (A) at 340 nm ≥ 1.60.

ADDITIONAL EQUIPMENT

- SPIN640 / SPIN640Plus Autoanalyzer.
- General laboratory equipment.

SAMPLES

Serum free of hemolysis or heparin plasma¹: Stability 7 days at 2-8°C, protected from light.

CK-MB activity decreases a 10% after 24 hours at 4°C or 1 hour at 25°C.

REFERENCE VALUES

CK-MB > 24 U/L

CK-MB Activity × 100: 6-25 % CK-MB Activity in the sample
CK Total Activity

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

QUALITY CONTROL

CK-Nac/CK-MB specific control sera (Ref. 1002260 or Ref. 1002262) are recommended to monitor the performance of assay procedures.

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.

BARCODED REAGENTS LOAD MUST BE PRECEDED OF A SPINREACT "DATABASE" COPY INTO THE ANALYZER SOFTWARE. IT IS AVAILABLE UNDER REQUEST TO SPINREACT.

SPIN640 APPLICATION

TEST INFORMATION		REAGENT VOLUME		
Nº	**	Vol. R1	240	
Test	CKMB	Vol. R2	60	
Full Name	Creatin Kinase-MB	Vol. R3		
Standard nº	1	Vol. R4		
SAMPLE VOLUME		RESULT SETUP		
Vol. Sample Stand.	12	Decimal	1	Slope 1
Vol. Sample Increas.		Unit	U/L	Inter. 0
Vol. Sample Dec				
REACTION PARAMETERS				
Reac. Type	Fixed Time	Direction	Increase	
Pri. Wave.	340	Reagent Blank	0-0	
Sec. Wave.		React. Time	50-80	

SPIN640Plus APPLICATION

EDIT PARAMETERS			
Test	CKMB	No.	**
Full name	CKMB	Print name	CKMB
Reac. Type	Fixed Time	Direction	Increase
Pri. Wave.	340	Sec. Wave.	
Unit	U/L	Decimal	0
Reagent Blank	0-0	React. Time	56-82
Vol. Sample	12 ul	R1	240 ul
Increased		R2	60 ul
Decreased		R3	
Sample blank		R4	

The Calibration is stable until 32 days. After this period the Calibration must be performed again in order to obtain good results.

The Calibration of this parameter should be performed using the CK-Nac / CK-MB CONTROL Ref. 1002260 or Ref. 1002262 (high level).

PERFORMANCE CHARACTERISTICS

Measuring range: From detection limit of 1,9 U/L to linearity limit of 318 U/L.

If the results obtained were greater than linearity limit, dilute the sample 1/1 with NaCl 9 g/L and multiply the result by 2.

Precision:

	Intra-assay		Inter-assay	
Mean (U/L)	33,7	166,5	31,3	161,0
SD	1,00	3,76	1,19	3,47
CV (%)	2,96	2,26	3,81	2,15

Sensitivity: 1 U/L = 0,000134 (A).

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: 0,999.

Regression equation: y = 0,976 x - 0,269.

The results of the performance characteristics depend on the analyzer used.

LIMITATION OF THE PROCEDURE

- 1- The method will also measure any CK-BB isoenzyme present in serum. The activity of the isoenzyme is usually negligible; however, if a significant amount of CK-BB activity is present the CK-MB activity will be overestimated.
- 2- A macro form of BB (immunoglobulin complexed) has been observed which will be measured as B in the assay. If the measured CK-B activity exceeds 20% of the total CK activity, the presence of macro BB should be suspected.

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.

PACKAGING

Ref: MD41254	Cont.	R1: 4 x 40 mL
		R2: 2 x 20 mL



CK-MB-LQ (Créatine kinase – MB)

Anti CK-M. Immuno-inhibition. Cinétique UV. Liquide

**Détermination quantitative de la créatine kinase-MB(CK-MB)
IVD**

Conserver à 2 - 8 °C

PRINCIPE DE LA MÉTHODE

Méthode basée sur la mesure de l'activité de la CK en présence de l'anticorps anti CK-M, qui inhibe complètement l'activité de la CK-MM et la sous-unité (M) de la CK-MB, sans affecter l'activité de la CK-B et de la CK-BB. La méthode de la CK permet de déterminer l'activité de la CK-B dans l'échantillon testé^{1,2}. L'activité de la CK-MB est obtenue en multipliant par deux l'activité de CK-B.

SIGNIFICATION CLINIQUE

La CK-MB est une enzyme composée de deux sous-unités, la sous-unité M exprimée dans le muscle et la sous-unité B, exprimée dans les cellules nerveuses. La CK-MB se trouve dans le sérum en faibles concentrations, elle augmente à la suite d'un infarctus du myocarde, puis diminue à des niveaux normaux. Elle peut augmenter, plus rarement, en cas de traumatismes musculo-squelettiques^{5,6,7,8}. 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-Acetyl-L-Cystéine	25 mmol/L
	Acétate de magnésium	12,5 mmol/L
	NADP	2,52 mmol/L
	EDTA	2,02 mmol/L
	Hexokinase	≥6 800 U/L
Anticorps polyclonal (mouton) anti CK-M humain suffisant pour inhiber jusqu'à 2 000 U/L de CK-MM		
R 2	ADP	15,2 mmol/L
	AMP	25 mmol/L
	di-Adénosine-5'-pentaphosphate	103 mmol/L
	Glucose 6-phosphate	≥8 800 U/L
	déshydrogénase (G6F-DH)	250 mmol/L
	Phosphocréatine	

PRÉPARATION

Tous les réactifs sont prêts à l'emploi.

CONSERVATION ET STABILITÉ

Tous les composants du kit sont stables jusqu'à la date d'expiration indiquée sur l'étiquette du flacon, lorsque les flacons sont maintenus bien fermés à 2-8 °C, protégés de la lumière et en évitant leur contamination.

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

Indicateurs de détérioration des réactifs :

- Présence de particules et turbidité.
- Absorbance (A) du Blanc à 340 ≥ 1,2.

MATÉRIEL SUPPLÉMENTAIRE

- Auto-analyseur SPIN640 / SPIN640Plus.
- Équipement habituel de laboratoire.

ÉCHANTILLONS

Sérum exempt d'hémolyse ou plasma hépariné. Stabilité : 7 jours à 2-8 °C, protégé de la lumière.

L'activité de la CK-MB dans le sérum diminue de 10 % après 24 heures à 4 °C ou après 1 heure à 25 °C.

VALEURS DE RÉFÉRENCE

Les soupçons de lésion myocardique reposent sur les trois conditions suivantes :

	25 °C	30 °C	37 °C
CK-MB	> 10 U/L	> 15 U/L	> 24 U/L
CKTOTAL	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

Actividad de la CK - MB x 100 = 6 - 25 % de actividad de la CK - MB

Actividad de la CK Total

Ces valeurs sont données à titre d'information. Chaque laboratoire devrait établir ses propres valeurs de référence.

CONTRÔLE DE QUALITÉ

Il convient d'utiliser des contrôles de sérum spécifiques CK-NAC/ CK-MB (Réf.1002260).

Si les valeurs obtenues sont en-dehors de la plage de tolérance, l'instrument, les réactifs et la technique devront être vérifiés.

Chaque laboratoire doit disposer de son propre Contrôle de Qualité et établir des corrections en cas de non-conformité en termes de tolérances des contrôles.

**POUR TRAVAILLER AVEC CODES A BARRES, IL FAUT CHARGER
LA BASE DE DONNEES QUE VOUS DEVEZ SOLICITER
PREALABLEMENT A SPINREACT.**

APPLICATION AU SPIN640

TEST INFORMATION		REAGENT VOLUME		
Nº	**	Vol. R1	240	
Test	CKMB	Vol. R2	60	
Full Name	Creatin Kinase-MB	Vol. R3		
Standard nº	1	Vol. R4		
SAMPLE VOLUME		RESULT SETUP		
Vol. Sample Stand.	12	Decimal	1	Slope 1
Vol. Sample Increas.		Unit	U/L	Inter. 0
Vol. Sample Dec				
REACTION PARAMETERS				
Reac. Type	Fixed Time	Direction		Increase

APPLICATION AU SPIN640Plus

EDIT PARAMETERS			
Test	CKMB	No.	**
Full name	CKMB	Print name	CKMB
Reac. Type	Fixed Time	Direction	
Pri. Wave.	340	Sec. Wave.	Increase
Unit	U/L	Decimal	0
Reagent Blank	0 - 0	React. Time	56 - 82
Vol. Sample	12 ul	R1	240 ul
Increased		R2	60 ul
Decreased		R3	
Sample blank		R4	

L'étalonnage est stable jusqu'à **32 jours**. Passé ce délai, doit étalonner de nouveau pour obtenir de bons résultats.

L'étalonnage de ce paramètre doit être fait avec le CK-NAC/CK-MB contrôle.

CARACTÉRISTIQUES DE LA MÉTHODE

Plage de mesure : Depuis la *limite de détection* de 1,9U/L jusqu'à la *limite de linéarité* de 318U / L.

Si la concentration de l'échantillon est supérieure à la limite de linéarité, diluer 1/1 avec du NaCl 9 g/L et multiplier le résultat final par 2.

Précision :

	Intra-série		Inter-série	
Moyenne (U/L)	33,7	166,5	31,3	161,0
SD	1,00	3,76	1,19	3,47
CV (%)	2,96	2,26	3,81	2,15

Sensibilité analytique : 1U/L= 0,000134 (A).

Exactitude : Les réactifs SPINREACT (y) n'ont pas montré de différences systématiques significatives par rapport aux autres réactifs commerciaux (x).

Coefficient de corrélation (r)²: 0,999.

Équation de la droite de régression : y = 0,976x - 0,269.

Les caractéristiques de la méthode peuvent varier selon l'analyseur utilisé.

LIMITATIONS DE LA MÉTHODE

Cette méthode mesure également l'activité de l'isoenzyme CK-BB présente dans le sérum, bien qu'elle soit, en général, insignifiante. Néanmoins, en cas de présence importante de CK-BB, l'activité de la CK-MB présente serait surestimée.

Si l'activité CK-B obtenue est supérieure à 20 % de l'activité de la CK totale, il faut suspecter la présence de macro BB (complexe d'immunoglobuline), mesurée comme B lors de l'essai.

BIBLIOGRAPHIE

- Abbot B et al. Creatinine kinase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984: 1112-116.
- Gerhardt W. et al. Creatine kinase B-Subunit activity in serum after immunohinhibition of M-Subunit activity. Clin Chem 1979;(25/7): 1274-1280.
- Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AAC Press, 1995.
- Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AAC 2001.
- Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AAC 1999.
- Tietz NW et al. Clinical Guide to Laboratory Tests, 3rd ed AAC 1995.

PRÉSENTATION

Ref: MD41254	Cont.	R1: 4 x 40 mL
		R2: 2 x 20 mL



Determinação quantitativa de creatina quinasa-MB (CK-MB)

IVD

Conservar a 2-8°C

PRINCIPIO DO MÉTODO

Método baseado na medição da actividade da CK na presença do anticorpo anti CK-M, que inibe completamente a actividade da CK-MM e a subunidade(M) da CK-MB, não afectando a actividade da CK-B e da CK-BB. Através do método da CK determina-se a actividade da CK-B na amostra ensaiada^{1,2}. A actividade da CK-MB obtém-se multiplicando por dois a actividade da CK-B.

SIGNIFICADO CLÍNICO

A CK-MB é uma enzima composta de duas subunidades, a subunidade M existente no músculo e a subunidade B, existente nas células nervosas. A CK-MB encontra-se no soro em concentrações baixas, aumentando como consequência de um enfarte do miocárdio retomando depois os níveis normais. Pode aumentar, mas raramente, em situações de traumatismos do músculo esquelético^{5,6}. O diagnóstico clínico deve realizar-se tendo em conta todos os dados clínicos e de laboratório.

REACTIVOS

R 1	Imidazol pH 6.7 D-Glucose N-Acetyl-L-Cisteina Acetato de magnesio NADP EDTA Hexokinase	125 mmol/L 25 mmol/L 25 mmol/L 12,5 mmol/L 2,52 mmol/L 2,02 mmol/L ≥6 800 U/L
Anticorpo policlonal (ovelha) anti CK-M humano suficiente para inibir até 2 000 U/L de CK-MM		
R 2	ADP AMP di-Adenosina-5-pentafosfato Glucose-6-fosfato DH (G6F-DH) Fosfato de creatina	15,2 mmol/L 25 mmol/L 103 mmol/L ≥8 800 U/L 250 mmol/L

PREPARAÇÃO

Todos os reagentes estão prontos para utilização.

CONSERVAÇÃO E ESTABILIDADE

Todos os componentes do kit são estavéis até à data de validade indicada na etiqueta desde que os frascos sejam mantidos bem fechados, a 2-8°C, protegidos da luz e se evite a sua contaminação. Não utilizar os reagentes fora do prazo da data indicada.

Indicadores de deterioração dos reagentes :

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

MATERIAL ADICIONAL

- Autoanalizador SPIN640 / SPIN640Plus.
- Equipamento habitual de laboratório.

AMOSTRAS

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

A actividade da CK-MB no soro diminui em 10% após as 24 horas a 4°C ou após 1 hora a 25°C.

VALORES DE REFERENCIA

A suspeita de lesão do miocárdio baseia-se nas três seguintes condições:

	25°C	30°C	37°C
CK-MB	> 10 U/L	> 15 U/L	> 24 U/L
CK TOTAL	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

Actividade da CK-MB x 100: 6-25 % de actividade da CK-MB

Actividade da CK Total

Estes valores são orientativos. Recomenda-se que cada laboratório estabeleça os seus próprios valores de referência.

CONTROLO DE QUALIDADE

É conveniente utilizar controlos de soros específicos CK-Nac/ CK-MB (Ref.1002260).

Caso os valores se encontrem fora do intervalo de tolerância, devem ser revistos o equipamento, os reagentes e a técnica.

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

PARA CARREGAR REAGENTES POR CODIGO DE BARRAS DEVE PRÉ-CARREGAR O "BANCO DE DADOS" DISPONÍVEL MEDIANTE ORDEM A SPINREACT.

APLICAÇÃO AO SPIN640

TEST INFORMATION		REAGENT VOLUME		
Nº	**	Vol. R1	240	
Test	CKMB	Vol. R2	60	
Full Name	Creatin Kinase-MB	Vol. R3		
Standard nº	1	Vol. R4		
SAMPLE VOLUME		RESULT SETUP		
Vol. Sample Stand.	12	Decimal	1	Slope 1
Vol. Sample Increas.		Unit	U/L	Inter. 0
Vol. Sample Dec				
REACTION PARAMETERS				
Reac. Type	Fixed Time	Direction	Increase	
Pri. Wave.	340	Reagent Blank	0-0	
Sec. Wave.		React. Time	50-80	

APLICAÇÃO AO SPIN640Plus

EDIT PARAMETERS			
Test	CKMB	No.	**
Full name	CKMB	Print name	CKMB
Reac. Type	Fixed Time	Direction	Increase
Pri. Wave.	340	Sec. Wave.	
Unit	U/L	Decimal	0
Reagent Blank	0-0	React. Time	56 - 82
Vol. Sample	12 ul	R1	240 ul
Increased		R2	60 ul
Decreased		R3	
Sample blank		R4	

Calibração pelo branco de reagente é estável até 32 dias. Após este período, é necessário voltar a aplicar o reagente em branco para validar a calibração. Calibração deste parâmetro deve ser feito com o CK-Nac / CK-MB CONTROL Ref.1002260 o Ref. 1002262 (alto nível).

CARACTERÍSTICAS DO MÉTODO

Intervalo de medição: Desde o limite de deteção de 1,9 U/L até ao limite de linearidade de 318 U/L.

Se a concentração da amostra for superior ao limite de linearidade, diluir 1/1 com NaCl 9 g/L e multiplicar o resultado final por 2

Precisão:

	Intrasérie		Intersérie	
Média (U/L)	33,7	166,5	31,3	161,0
SD	1,00	3,76	1,19	3,47
CV (%)	2,96	2,26	3,81	2,15

Sensibilidade analítica: 1 U/L = 0,000134 (A).

Exatidão: Os reagentes da SPINREACT (y) não apresentam diferenças sistemáticas significativas quando comparados com outros reagentes comerciais (x).

Coeficiente de regressão (r)²: 0,999.

Equação da reta de regressão: y= 0,976 x -0,269.

As características do método podem variar de acordo com o analisador utilizado.

LIMITAÇÕES DO MÉTODO

- Este método mede também a actividade da isoenzima CK-BB que se encontra presente no soro, apesar de ser insignificante. Contudo, perante uma presença significativa de CK-BB, a actividade da CK-MB presente seria sobreestimada.
- Caso a actividade de CK-B obtida exceda em 20% a actividade da CK total, deve suspeitar-se da presença de macro BB (complexo de imunoglobulina), medida como B no ensaio.

BIBLIOGRAFIA

- Abbot B et al. Creatinine kinase. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984: 1112-116.
- Gerhardt W. et al. Creatine kinase B-Subunit activity in serum after immunohinhibition of M-Subunit activity. Clin Chem 1979;(25/7): 1274-1280.
- Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
- Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
- Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
- Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

APRESENTAÇÃO

Ref: MD41254

Cont.

R1: 4 x 40 mL

R2: 2 x 20 mL

