

LDL Cholesterol D

Enzymatic colorimetric. Liquid

Quantitative determination of LDL cholesterol IVD

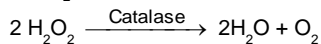
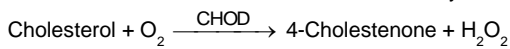
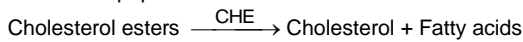
Store at 2-8°C

PRINCIPLE OF THE METHOD

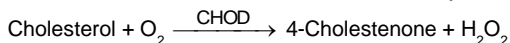
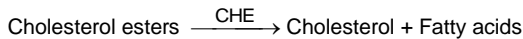
Direct determination of serum LDLc (low-density lipoprotein cholesterol) levels without the need for any pre-treatment or centrifugation steps.

The assay takes place in two steps.

– 1° Elimination of lipoprotein no-LDL



– 2° Measurement of LDLc



The intensity of the color formed is proportional to the LDLc concentration in the sample.

CLINICAL SIGNIFICANCE

The LDLc particle is lipoproteins that transport cholesterol to the cells. Often called “bad cholesterol” because high levels are risk factor for coronary heart disease and are associated with obesity, diabetes and nephrosis^{1,2,9}.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENTS

R 1 Enzymes	PIPES Buffer pH 7,0	50 mmol/L
	Cholesterol esterase (CHE)	≥600 U/L
	Cholesterol oxidase (CHOD)	≥500 U/L
	Catalase	≥600 U/mL
	TOOS	2 mmol/L
R 2 Enzymes	PIPES Buffer pH 7,0	50 mmol/L
	4 – Aminoantipyrine (4-AA)	4 mmol/L
	Peroxidase (POD)	≥4 KU/L

PREPARATION

R 1 and R 2: 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 and contaminations are prevented during their use.

R 1 and R 2: Once opened is stable 4 weeks at 2-8°C.

Signs of reagent deterioration:

- Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- SPIN640 / SPIN640Plus Autoanalyzer.

- General laboratory equipment.

SAMPLES

Serum, heparinized plasma or EDTA plasma. If any sample show precipitates, centrifuge before using⁵.

Serum stable 6 days at 2-8°C. Do not freeze the samples.

QUALITY CONTROL

Control sera and calibrators are recommended to monitor the performance of assay procedures: SPINROL H Calibrator, SPINROL H Normal and Pathologic (Ref. 1002011, 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.

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	210
Test	LDL	Vol. R2	70
Full Name	LDL Cholesterol	Vol. R3	
Standard nº	1	Vol. R4	
SAMPLE VOLUME		RESULT SETUP	
Vol. Sample Stand.	3	Decimal	0.1 Slope 1
Vol. Sample Increas.		Unit	mg/dL Inter. 0
Vol. Sample Dec			
REACTION PARAMETERS			
Reac. Type	Fixed Time	Direction	Increase
Pri. Wave.	570	Reagent Blank	0-0
Sec. Wave.		React. Time	43-76

SPIN640Plus APPLICATION

EDIT PARAMETERS			
Test	LDL	No.	**
Full name	LDL Cholesterol	Print name	LDL
Reac. Type	Fixed Time	Direction	Increase
Pri. Wave.	605	Sec. Wave.	
Unit	mg/dL	Decimal	0.1
Reagent Blank	0 - 0	React. Time	51 - 82
Vol. Sample	3 ul	R1	210 ul
Increased		R2	70 ul
Decreased		R3	
Sample blank		R4	

The Calibration is stable until **36 days**. After this period the Calibration must be performed again in order to obtain good results.

REFERENCE VALUES^{6,7,8}

Optimal	< 100 mg/dL
Near or above optimal	100-129 mg/dL
Borderline high	130-160 mg/dL
High	> 160 mg/dL

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

PERFORMANCE CHARACTERISTICS

Measuring range: From *detection limit* of 10 mg/dL to *linearity limit* of 976 mg/dL.

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

Precision:

Media (mg/dL)	Intraserie (n= 20)		Interserie (n= 20)	
	31,4	67,8	32,1	68,1
SD	0,42	1,11	0,92	2,02
CV (%)	1,35	1,64	2,87	2,97

Sensibility: 1 mg/dL = 0,001784 (A).

Accuracy^{10,11}: 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: 0,99123.

Regression equation: y = 0,914x + 1,58283.

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

BIBLIOGRAPHY

- Naito H. K., et al, Clin Chem, 41: 132-133, 1995.
- Seidel d., et al, Internist, 28: 606-314, 1987.
- Weiland H. and Seidel D., J Lip Res, 24: 904-909, 1983.
- Friedewald w.F., et al, Clin Chem, 18:499-502, 1972.
- Clinical Laboratory Diagnostics: use and Assesment of Clinical Laboratory Results: First Edition T-H Books Germany; p 172.
- Rifai N., et al, Clin Chem, 38 : 150-160, 1992.
- National Cholesterol Education Program. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA, Vol.285, No. 19; p.2846-2897 Publication 2001.
- Armstrong V., et al, Arztl Lab, 31: 325-330, 1985.
- Bachorik P.S. and Ross J.W., Clin Chem, 41: 1414-1420, 1995.
- Passing H. and Bablok W., J Clin Chem Clin Biochem, 21: 709-720, 1983.
- Bablok W., et al, J Clin Chem Clin Biochem, 26: 783-790, 1988.

PACKAGING

Ref: MD41023	Cont.	R 1: 4 x 30 mL
		R 2: 2 x 20 mL

LDL Colesterol D

Enzimático colorimétrico. Líquido

Determinación cuantitativa de colesterol LDL IVD

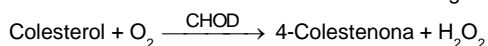
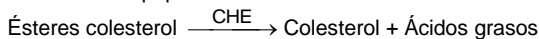
Conservar a 2-8°C

PRINCIPIO DEL MÉTODO

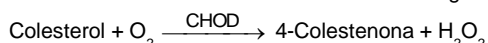
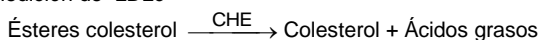
Determinación directa del LDLc (colesterol de lipoproteínas de baja densidad) sin necesidad de pre-tratamiento o centrifugado de la muestra.

La determinación se realiza en dos pasos:

– 1º Eliminación de lipoproteínas no-LDL



– 2º Medición de LDLc



La intensidad del color formado es proporcional a la concentración de LDLc presente en la muestra ensayada.

SIGNIFICADO CLÍNICO

Las partículas de LDLc son lipoproteínas que transportan el colesterol a las células. Niveles elevados de colesterol LDL son un factor de riesgo de desarrollo de enfermedades cardiovasculares, a menudo se le denomina "colesterol malo". Niveles altos de colesterol LDL están relacionados con obesidad, diabetes y nefrosis^{1,2,9}.

El diagnóstico clínico debe realizarse teniendo en cuenta todos los datos clínicos y de laboratorio.

REACTIVOS

R 1 Enzimas	TAMPÓN PIPES PH 7,0	50 mmol/L
	Colesterol esterasa (CHE)	≥600 U/L
	Colesterol oxidasa (CHOD)	≥500 U/L
	Catalasa	≥600 KU/L
	TOOS	2 mmol/L
R 2 Enzimas	TAMPÓN PIPES PH 7,0 4 –	50 mmol/L
	Aminoantipirina (4-AA)	4 mmol/L
	Peroxidasa (POD)	≥4 KU/L

PREPARACIÓN

R 1 y R 2: Listos para su uso.

CONSERVACIÓN Y ESTABILIDAD

Todos los componentes del kit son estables hasta la fecha de caducidad indicada en la etiqueta del vial, cuando se mantienen los viales bien cerrados a 2-8°C, protegidos de la luz y se evita la contaminación.

R 1 y R 2: Una vez abiertos son estables 4 semanas a 2-8°C.

Indicadores de deterioro de los reactivos:

- Presencia de partículas y turbidez.

MATERIAL ADICIONAL

- Autoanalizador SPIN640 / SPIN640Plus.
- Equipamiento habitual de laboratorio.

MUESTRAS

Suero, plasma heparinizado o plasma EDTA.

Si alguna muestra presenta precipitados, centrifugarla antes de usarla⁵.

El suero es estable 6 días a 2-8°C. No congelar las muestras.

CONTROL DE CALIDAD

Es conveniente calibrar y analizar junto con las muestras sueros control y calibradores valorados: SPINTROL H Calibrador, SPINTROL H Normal y Patológico (Ref. 1002011, 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.

PARA LA CARGA DE REACTIVOS MEDIANTE EL CÓDIGO DE BARRAS SE DEBE PRECARGAR LA "BASE DE DATOS" DISPONIBLE BAJO SOLICITUD A SPINREACT.

APLICACIÓN AL SPIN640

TEST INFORMATION		REAGENT VOLUME		
Nº	**	Vol. R1	210	
Test	LDL	Vol. R2	70	
Full Name	LDL Cholesterol	Vol. R3		
Standard nº	1	Vol. R4		
SAMPLE VOLUME		RESULT SETUP		
Vol. Sample Stand.	3	Decimal	0.1	Slope 1
Vol. Sample Increas.		Unit	mg/dL Inter. 0	
Vol. Sample Dec				
REACTION PARAMETERS				
Reac. Type	Fixed Time	Direction	Increase	
Pri. Wave.	570	Reagent Blank	0-0	
Sec. Wave.		React. Time	43-76	

APLICACIÓN AL SPIN640Plus

EDIT PARAMETERS			
Test	LDL	No.	**
Full name	LDL Cholesterol	Print name	LDL
Reac. Type	Fixed Time	Direction	Increase
Pri. Wave.	605	Sec. Wave.	
Unit	mg/dL	Decimal	0.1
Reagent Blank	0 - 0	React. Time	51 - 82
Vol. Sample	3 ul	R1	210 ul
Increased		R2	70 ul
Decreased		R3	
Sample blank		R4	

La Calibración es estable hasta **36 días**. Pasado este período es necesario solicitar de nuevo la Calibración para la obtención de buenos resultados.

VALORES DE REFERENCIA^{6,7,8}

Óptimo	< 100 mg/dL
Bueno	100-129 mg/dL
Moderadamente alto	130-160 mg/dL
Alto	> 160 mg/dL

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

CARACTERÍSTICAS DEL MÉTODO

Rango de medida: Desde el *límite de detección* 10 mg/dL hasta el *límite de linealidad* 976 mg/dL. Si la concentración de la muestra es superior al límite de linealidad, diluir 1/2 con NaCl 9 g/L y multiplicar el resultado final por 2.

Precisión:

Media (mg/dL)	Intraserie (n= 20)		Interserie (n= 20)	
	31,4	67,8	32,1	68,1
SD	0,42	1,11	0,92	2,02
CV (%)	1,35	1,64	2,87	2,97

Sensibilidad analítica: 1mg/dL = 0,001784 (A).

Exactitud^{10,11}: Los reactivos de SPINREACT (y) no muestran diferencias sistemáticas significativas cuando se comparan con otros reactivos comerciales (x).

Los resultados obtenidos con 50 muestras fueron los siguientes:

Coefficiente de regresión (r)²: 0,99123.

Ecuación de la recta de regresión: y= 0,914x + 1,58283

Las características del método pueden variar según el analizador utilizado.

BIBLIOGRAFÍA

- Naito H. K., et al, Clin Chem, 41: 132-133, 1995.
- Seidel d., et al, Internist, 28: 606-314, 1987.
- Weiland H. and Seidel D., J Lip Res, 24: 904-909, 1983.
- Friedewald w.F., et al, Clin Chem, 18:499-502, 1972.
- Clinical Laboratory Diagnostics: use and Assesment of Clinical Laboratory Results: First Edition T-H Books Germany; p 172.
- Rifai N., et al, Clin Chem, 38 : 150-160, 1992.
- National Cholesterol Education Program. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA, Vol.285, No. 19; p.2846-2897 Publication 2001.
- Armstrong V., et al, Arztl Lab, 31: 325-330, 1985.
- Bachorik P.S. and Ross J.W., Clin Chem, 41: 1414-1420, 1995.
- Passing H. and Bablok W., J Clin Chem Clin Biochem, 21: 709-720, 1983.
- Bablok W., et al, J Clin Chem Clin Biochem, 26: 783-790, 1988.

PRESENTACIÓN

Ref: MD41023	Cont.	R 1: 4 x 30 mL
		R 2: 2 x 20 mL

LDL Cholestérol D

Enzymatique colorimétrique. Liquide

Détermination quantitative de cholestérol LDL IVD

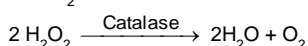
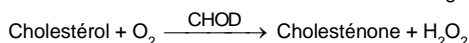
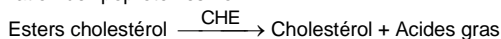
Conserver à 2-8°C

PRINCIPE DE LA METHODE

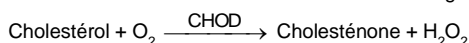
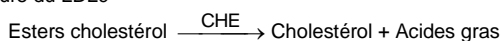
Détermination directe du LDLc (cholestérol de lipoprotéines de faible densité) sans besoin de prétraiter ou centrifuger l'échantillon^{3,4}.

La détermination est réalisée en deux étapes :

- 1^o Élimination de lipoprotéines non-LDL



- 2^o Mesure du LDLc



L'intensité de la couleur formée est proportionnelle à la concentration de LDLc présent dans l'échantillon testé.

SIGNIFICATION CLINIQUE

Les particules de LDLc sont des lipoprotéines qui transportent le cholestérol dans les cellules. Des niveaux élevés de cholestérol LDL constituent un facteur de risque de développement de maladies cardiovasculaires, c'est pourquoi on l'appelle souvent « mauvais cholestérol ». Des niveaux élevés de cholestérol LDL sont rattachés à l'obésité, aux diabètes et à la néphrose^{1,2,9}.

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

RÉACTIFS

R 1	Tampon PIPES pH 7,0	50 mmol/L
	Cholestérol-estérase (CHE)	≥600 U/L
	Cholestérol-oxydase (CHOD)	≥500 U/L
	Catalase	≥600 KU/L
	TOOS	2 mmol/L
R 2	Tampon PIPES pH 7,0	50 mmol/L
	4-Aminoantipyrine (4-AA)	4 mmol/L
	Peroxydase (POD)	≥4 KU/L

PRÉPARATION

R 1 et R 2 : Prêts à l'emploi.

CONSERVATION ET STABILITE

Tous les composants du kit sont stables jusqu'à la date de péremption indiquée sur l'étiquette, et si les flacons sont maintenus hermétiquement fermés à 2-8°C, à l'abri de la lumière et des sources de contamination.

R 1 et R 2 : Une fois ouverts, ils sont stables 4 semaines à 2-8°C.

Indices de détérioration des réactifs:

- Présence de particules et turbidité.

MATERIEL SUPPLEMENTAIRE

- Auto-analyseur SPIN640 / SPIN640Plus.
- Equipement classique de laboratoire.

ÉCHANTILLONS

Sérum, plasma hépariné ou plasma EDTA.

Si un échantillon a précipité centrifugeuse avant d'utiliser⁵.

Le sérum est stable pendant 6 jours à 2-8 °C Ne pas congeler les échantillons.

CONTROLE DE QUALITE

Il est conseillé d'analyser conjointement les échantillons de sérum dont les valeurs ont été contrôlées: SPINROL H Normal et pathologique (Réf. 1002120 et 1002210).

Si les valeurs se trouvent en dehors des valeurs tolérées, analyser l'instrument, les réactifs et le calibre.

Chaque laboratoire doit disposer de son propre contrôle de qualité et déterminer les mesures correctives à mettre en place dans le cas où les vérifications ne correspondraient pas aux attentes.

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

APPLICATION AU SPIN640

TEST INFORMATION		REAGENT VOLUME	
N°	**	Vol. R1	210
Test	LDL	Vol. R2	70
Full Name	LDL Cholesterol	Vol. R3	
Standard n°	1	Vol. R4	
SAMPLE VOLUME		RESULT SETUP	
Vol. Sample Stand.	3	Decimal	0.1 Slope 1
Vol. Sample Incons.		Unit	mg/dL Inter. 0
Vol. Sample Dec			
REACTION PARAMETERS			
Reac. Type	Fixed Time	Direction	Increase
Pri. Wave.	570	Reagent Blank	0-0
Sec. Wave.		React. Time	43-76

APPLICATION AU SPIN640Plus

EDIT PARAMETERS			
Test	LDL	No.	**
Full name	LDL Cholesterol	Print name	LDL
Reac. Type	Fixed Time	Direction	Increase
Pri. Wave.	605	Sec. Wave.	
Unit	mg/dL	Decimal	0.1
Reagent Blank	0 - 0	React. Time	51 - 82
Vol. Sample	3 ul	R1	210 ul
Increased		R2	70 ul
Decreased		R3	
Sample blank		R4	

L'étalonnage est stable jusqu'à **36 jours**. Passé ce délai, doit étalonner de nouveau pour obtenir de bons résultats.

VALEURS DE REFERENCE^{6,7,8}

Optimal	< 100 mg/dL
Bon	100-129 mg/dL
Modérément élevé	130-160 mg/dL
Élevé	> 160 mg/dL

Ces valeurs sont données à titre d'information. Il est conseillé à chaque laboratoire de définir ses propres valeurs de référence.

CARACTERISTIQUES DE LA METHODE

Plage de mesure: Depuis la limite de détection de 10 mg/dL, jusqu'à la limite de linéarité de 976 mg/dL

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

Précision:

Moyenne mg/dL)	Intra-série (n= 20)		Inter-série (n= 20)	
	31,4	67,8	32,1	68,1
SD	0,42	1,11	0,92	2,02
CV (%)	1,35	1,64	2,87	2,97

Sensibilité analytique: 1mg/dL = 0,001784 (A).

Exactitude^{10,11}: Les réactifs de SPINREACT (y) ne présentent pas de différences systématiques significatives quand ils sont comparés à d'autres réactifs commerciaux (x).

Les résultats obtenus avec 50 échantillons ont été les suivants:

Coefficient de corrélation (r)²: 0,99123

Equation de la Coubre de régression: y= 0,914x + 1,58283

Les caractéristiques de la méthode peuvent varier suivant l'analyseur employé

BIBLIOGRAPHIE

- Naito H. K., et al, Clin Chem, 41: 132-133, 1995.
- Seidel d., et al, Internist, 28: 606-314, 1987.
- Weiland H. and Seidel D., J Lip Res, 24: 904-909, 1983.
- Friedewald w.F., et al, Clin Chem, 18:499-502, 1972.
- Clinical Laboratory Diagnostics: use and Assesment of Clinical Laboratory Results: First Edition T-H Books Germany; p 172.
- Rifai N., et al, Clin Chem, 38 : 150-160, 1992.
- National Cholesterol Education Program. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA, Vol.285, No. 19; p.2846-2897 Publication 2001.
- Armstrong V., et al, Arztl Lab, 31: 325-330, 1985.
- Bachorik P.S. and Ross J.W., Clin Chem, 41: 1414-1420, 1995.
- Passing H. and Bablok W., J Clin Chem Clin Biochem, 21: 709-720, 1983.
- Bablok W., et al, J Clin Chem Clin Biochem, 26: 783-790, 1988.

PRÉSENTATION

Ref: MD41023	Cont.	R 1: 4 x 30 mL
		R 2: 2 x 20 mL



LDLc -D

LDL Colesterol D

Enzimático colorimétrico. Líquido

Determinação quantitativa de colesterol LDL IVD

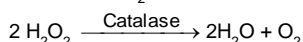
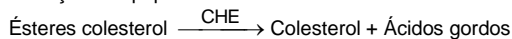
Conservar a 2-8°C

PRINCÍPIO DO METODO

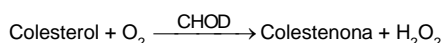
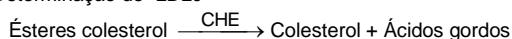
Determinação directa do LDLc (colesterol de lipoproteínas de baixa densidade) sem necessidade de pré-tratamento ou centrifugação da amostra^{3,4}.

A determinação é feita em dois passos:

- 1º Eliminação de lipoproteínas não-LDL



- 2º Determinação de LDLc



A intensidade da coloração formada é proporcional à concentração de LDLc presente na amostra testada.

SIGNIFICADO CLINICO

As partículas de LDLc são lipoproteínas que transportam o colesterol para as células. Níveis elevados de colesterol LDL são um factor de risco de desenvolvimento de patologias cardiovasculares, pelo que frequentemente é denominado de " mau colesterol". Níveis elevados de colesterol LDL estão relacionados com obesidade, diabetes e nefrose^{1,2,9}.

O diagnóstico clínico deve realizar-se tendo em conta todos os dados clínicos e de laboratório.

REAGENTES

R 1	Tampão PIPES pH 7,0	50 mmol/L
	Colesterol esterase (CHE)	≥600 U/L
	Colesterol oxidase (CHOD)	≥500 U/L
	Catalase	600KU /L
	TOOS	2 mmol/L
R 2	Tampão PIPER pH 7,0	50 mmol/L
	4 - Aminoantipirina (4-AA)	4 mmol/L
	Peroxidase (POD)	≥4k U/L

PREPARAÇÃO

R 1 e R 2: 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.

- R 1 e R 2: Uma vez abertos são estáveis 4 semanas a 2-8°C.

Indicadores de deterioração dos reagentes:

- Presença de partículas e turvação.

MATERIAL ADICIONAL

- Auto-analisador SPIN640 / SPIN640Plus.
- Equipamento habitual de laboratório.

AMOSTRAS

Soro, plasma heparinado ou plasma com EDTA.
Se uma amostra precipitou centrífuga antes usá-la⁵.
Soro é estável durante 6 dias a 2-8 ° C. Não congelar as amostras.

CONTROLO DE QUALIDADE

É conveniente analisar juntamente com as amostras, os soros controlo valorizados: 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 correções caso os controlos não cumpram com as tolerâncias.

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

APLICAÇÃO AO SPIN640

TEST INFORMATION		REAGENT VOLUME	
Nº	**	Vol. R1	210
Test	LDL	Vol. R2	70
Full Name	LDL Cholesterol	Vol. R3	
Standard nº	1	Vol. R4	
SAMPLE VOLUME		RESULT SETUP	
Vol. Sample Stand.	3	Decimal	0.1 Slope 1
Vol. Sample Increas.		Unit	mg/dL Inter. 0
Vol. Sample Dec			
REACTION PARAMETERS			
Reac. Type	Fixed Time	Direction	Increase
Pri. Wave.	570	Reagent Blank	0-0
Sec. Wave.		React. Time	43-76

APLICAÇÃO AO SPIN640Plus

EDIT PARAMETERS			
Test	LDL	No.	**
Full name	LDL Cholesterol	Print name	LDL
Reac. Type	Fixed Time	Direction	Increase
Pri. Wave.	605	Sec. Wave.	
Unit	mg/dL	Decimal	0.1
Reagent Blank	0 - 0	React. Time	51 - 82
Vol. Sample	3 ul	R1	210 ul
Increased		R2	70 ul
Decreased		R3	
Sample blank		R4	

Calibração pelo branco de reagente é estável até **36 dias**. Após este período, é necessário voltar a aplicar o reagente em branco para validar a calibração

VALORES DE REFERENCIA^{6,7,8}

Ótimo	< 100 mg/dL
Bom	100-129 mg/dL
Moderadamente Alto	130-160 mg/dL
Alto	> 160 mg/dL

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

CARACTERÍSTICAS DO MÉTODO

Intervalo de medida: Desde o limite de detecção de 10 mg/dL até ao limite de linearidade de 976 mg/dL. Se a concentração da amostra for superior ao limite de linearidade, diluir 1/2 com NaCl 9 g/L e multiplicar o resultado final por 2.

Precisão:

Média (mg/dL)	Intraserie (n= 20)		Interserie (n= 20)	
	31,4	67,8	32,1	68,1
SD	0,42	1,11	0,92	2,02
CV (%)	1,35	1,64	2,87	2,97

Sensibilidade: 1mg/dL = 0,001784 (A).

Exactidão^{10,11}: Os reagentes SPINREACT (y) não amostram diferenças sistemáticas significativas quando se comparam com outros reagentes comerciais (x).

Os resultados obtidos com 50 amostras foram os seguintes

Coeficiente de correlação (r)²: 0,99123.

Equação da recta de regressão: y= 0,914x + 1,58283.

As características do método podem variar segundo o analisador utilizado.

BIBLIOGRAFIA

- Naïto H. K., et al, Clin Chem, 41: 132-133, 1995.
- Seidel d., et al, Internist, 28: 606-314, 1987.
- Weiland H. and Seidel D., J Lip Res, 24: 904-909, 1983.
- Friedewald w.F., et al, Clin Chem, 18:499-502, 1972.
- Clinical Laboratory Diagnostics: use and Assesment of Clinical Laboratory Results: First Edition T-H Books Germany; p 172.
- Rifai N., et al, Clin Chem, 38 : 150-160, 1992.
- National Cholesterol Education Program. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA, Vol.285, No. 19; p.2846-2897 Publication 2001.
- Armstrong V., et al, Arztl Lab, 31: 325-330, 1985.
- Bachorik P.S. and Ross J.W., Clin Chem, 41: 1414-1420, 1995.
- Passing H. and Bablok W., J Clin Chem Clin Biochem, 21: 709-720, 1983.
- Bablok W., et al, J Clin Chem Clin Biochem, 26: 783-790, 1988

APRESENTAÇÃO

Ref: MD41023

Cont.

R 1: 4 x 30 mL
R 2: 2 x 20 mL

