

LDL Cholesterol D

Enzymatic colorimetric. Liquid

Quantitative determination of LDL cholesterol IVD

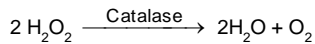
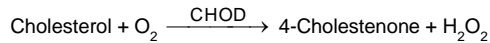
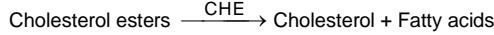
Store at 2-8°C

PRINCIPLE OF THE METHOD

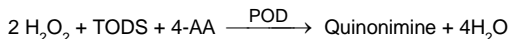
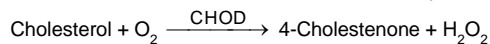
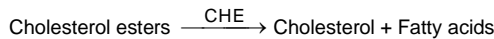
Direct determination of serum LDLc (low-density lipoprotein cholesterol) levels without the need for any pre-treatment or centrifugation steps.

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	50 mmol/L
	Cholesterol esterase (CHE)	≥600 U/L
	Cholesterol oxidase (CHOD)	≥500 U/L
	Catalase	≥600 KU/L
R 2 Enzymes	TOOS	2 mmol/L
	PIPES Buffer	50 mmol/L
	4 - Aminoantipyrine (4-AA)	4 mmol/L
	Peroxidase (POD)	≥ 4 KU/L
HDLc/LDLc CAL	Calibrator. Lyophilized human serum	

PRECAUTIONS

HDLc/LDLc CAL: Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as potentially infectious.

PREPARATION

DUAL MODE: Ready to use.

- **HDLc/LDLc CAL:** Dissolve the contents with 1 mL of distilled water. Cap vial and mix gently to dissolve contents.

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.

- **HDLc/LDLc CAL:** Once reconstitute 30 hours at 20-25°C, 2 weeks at 2-8°C or 3 months -20°C.

- Do not use reagents over the expiration date.

Signs of reagent deterioration:

- Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 600 nm.

- Matched cuvettes 1,0 cm light path.

- 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.

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.

APPLICATION SPINLAB 180

Name	LDL Colesterol	Ref. male low	49.0
Abbr. Name	LDL	Ref. male high	172.0
Mode	Twopoint	Ref. female low	63.0
Wavelength	578 nm	Ref. female high	167.0
Units	mg/dL	Ref. Ped. Low	*
Decimals	1	Ref. Ped. High	*
Low Conc.	0.0 mg/dL	Panic value low	*
High Conc.	250.0 mg/dL	Panic value high	*
Calibrator name	CAL	Control 1	*
Prozone check	No	Control 2	*
		Control 3	*
		Correlat. factor	1.000
		Correlat. offset	0.000
DUAL MODE			
Sample blank	No		
R1 bottle (mL)	25 mL		
normal volume	225 µL		
rerun volume	225 µL		
Sample			
normal volume	3.0 µL		
rerun volume	2.0 µL		
R2 bottle (mL)	5 mL		
normal volume	75.0 µL		
rerun volume	75.0 µL		
Predilution	No		
Slope blank	No		
Point one, two	24, 236 sec.		
Factor			
Reagent blank	Yes (0.000)		
Low Absorbance	-0.100 Abs		
High Absorbance	3.000 Abs		
R. Abs. L. Limit	-0.100 Abs		
R. Abs. H. Limit	3.000 Abs		
Substrate depletion	3.000 Abs		

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures: SPINCONTROL H Normal and Pathologic (Ref. 1002120 and 1002210).

If control values are found outside the defined range, check the instrument, reagents and calibrator 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 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
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: SP41023 Cont. R1:10 x 24 mL, R 2: 10 x 8 mL, CAL: 1 x 1 mL
 Ref: SP41024 Cont. R1: 2 x 24 mL, R 2: 2 x 8 mL, CAL: 1 x 1 mL

LDL Colesterol D

Enzimático colorimétrico. Líquido

Determinación cuantitativa de colesterol LDL

IVD

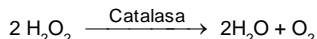
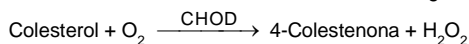
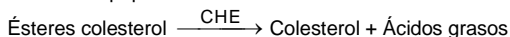
Conservar a 2-8°C

PRINCIPIO DEL MÉTODO

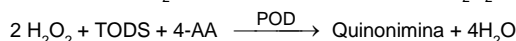
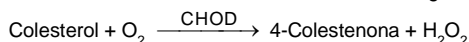
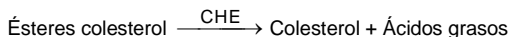
Determinación directa del LDLc (colesterol de lipoproteínas de baja densidad) sin necesidad de pre-tratamiento o centrifugado de la muestra.

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	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	50 mmol/L
	4 - Aminoantipirina (4-AA)	4 mmol/L
	Peroxidasa (POD)	≥4 KU/L
HDLc/LDLc CAL	Calibrador. Suero humano liofilizado	

PRECAUCIONES

HDLc/LDLc CAL: Todos los componentes de origen humano han resultado ser negativos para el antígeno HBs, HCV y para el anti-HIV (1/2). Sin embargo, deben tratarse con precaución como potencialmente infecciosos.

PREPARACIÓN

MODO DUAL: Reactivos listos para su uso.

HDLc/LDLc CAL: Reconstituir el contenido de un vial con 1 mL de agua destilada. Tapar el vial y mezclar suavemente hasta disolver su contenido.

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.

HDLc/LDLc CAL: Una vez reconstituido es estable 30 horas a 20-25°C, 2 semanas a 2-8°C o 3 meses a -20°C. No usar reactivos fuera de la fecha indicada.

Indicadores de deterioro de los reactivos:

- Presencia de partículas y turbidez.

MATERIAL ADICIONAL

- Espectrofotómetro o analizador para lecturas a 600 nm.

- Cubetas de 1,0 cm de paso de luz.

- 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.

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.

APLICACIÓN AL SPINLAB 180

Nombre	LDL Colesterol	Ref. Hombre Inf.	49.0
Nombre abreviado	LDL	Ref. Hombre Sup.	172.0
Modo	Twopoint	Ref. Mujer Inf.	63.0
Long. ondas	578 nm	Ref. Mujer Sup.	167.0
Unidades	mg/dL	Ref. Ped. Inf.	*
Decimales	1	Ref. Ped. Sup.	*
Conc. Inferior	0.0 mg/dL	Valor pánico bajo	*
Conc. Superior	250.0 mg/dL	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			
Blanco muestra	No		
Frasco R1 (mL)	25 mL		
Vol. normal	225 µL		
Vol. repet.	225 µL		
Muestra			
Vol. normal	3.0 µL		
Vol. repet.	2.0 µL		
Frasco R2 (mL)	5 mL		
Vol. normal	75.0 µL		
Vol. repet.	75.0 µL		
Predilución	No		
Pendiente Blco.	No		
1º, 2º punto	24, 236 seg.		
Factor			
Blanco reactivo	Si		
Absorbancia inf.	-0.100 Abs		
Absorbancia sup.	3.000 Abs		
Lim. Inf. Abs. React.	-0.100 Abs		
Lim. Sup. Abs. React.	3.000 Abs		
Agotamiento sustrato	3.000 Abs		

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, se debe revisar los instrumentos, los reactivos y la calibración.

Cada laboratorio debe disponer de 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* 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:

 Coeficiente 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.
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- Parsing 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: SP41023 R1:10 x 24 mL, R 2: 10 x 8 mL, CAL: 1 x 1 mL
 Ref: SP41024 Cont R1: 2 x 24 mL, R 2: 2 x 8 mL, CAL: 1 x 1 mL

LDL Cholestérol D

Enzymatique colorimétrique. Liquide

Détermination quantitative de cholestérol LDL IVD

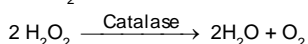
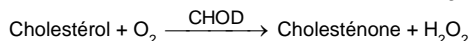
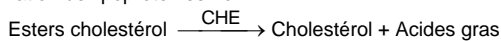
Conserver à 2-8°C

PRINCIPE DE LA METHODE

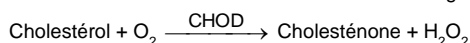
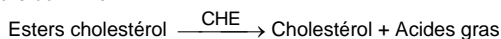
Détermination directe du LDLc (cholestérol de lipoprotéines de faible densité) sans besoin de prétraiter ou centrifuger l'échantillon^{3,4}.

La détermination est réalisée en deux étapes :

- 1° Élimination de lipoprotéines non-LDL



- 2° 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	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	50 mmol/L
	4-Aminoantipyrine (4-AA)	4 mmol/L
	Peroxydase (POD)	≥4 KU/L
	HDLc/LDLc CAL	Calibrateur. Sérum humain lyophilisé

PRÉCAUTIONS

HDLc/LDLc CAL: Tous les composants d'origine humaine sont apparus comme négatifs pour l'antigène HBs, HCV et pour l'anti-HIV (1/2). Toutefois, ils doivent être traités avec précaution car ils sont potentiellement infectieux.

PRÉPARATION

R 1 et R 2 : Prêts à l'emploi.

HDLc/LDLc CAL: Reconstituer le contenu d'un flacon avec 1 mL d'eau distillée. Boucher le flacon et mélanger doucement jusqu'à dissoudre son contenu.

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 SPINLAB 180.
- 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.

APPLICATION AU SPINLAB 180

Name	LDL Colesterol	Ref. male low	49.0
Abbr. Name	LDL	Ref. male high	172.0
Mode	Twopoint	Ref. female low	63.0
Wavelength	578 nm	Ref. female high	167.0
Units	mg/dL	Ref. Ped. Low	*
Decimals	1	Ref. Ped. High	*
Low Conc.	0.0 mg/dL	Panic value low	*
High Conc.	250.0 mg/dL	Panic value high	*
Calibrator name	CAL	Control 1	*
Prozone check	No	Control 2	*
		Control 3	*
		Correlat. factor	1.000
		Correlat. offset	0.000
DUAL MODE			
Sample blank	No		
R1 bottle (mL)	25 mL		
normal volume	225 µL		
rerun volume	225 µL		
Sample			
normal volume	3.0 µL		
rerun volume	2.0 µL		
R2 bottle (mL)	5 mL		
normal volume	75.0 µL		
rerun volume	75.0 µL		
Predilution	No		
Slope blank	No		
Point one, two	24, 236 sec.		
Factor			
Reagent blank	Yes (0.000)		
Low Absorbance	-0.100 Abs		
High Absorbance	3.000 Abs		
R. Abs. L. Limit	-0.100 Abs		
R. Abs. H. Limit	3.000 Abs		
Sustrate depletion	3.000 Abs		

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 Courbe de régression: y= 0,914x + 1,58283

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

BIBLIOGRAPHIE

1. Naito H. K., et al, Clin Chem, 41: 132-133, 1995.
2. Seidel d., et al, Internist, 28: 606-314, 1987.
3. Weiland H. and Seidel D., J Lip Res, 24: 904-909, 1983.
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7. 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.
8. Armstrong V., et al, Arztl Lab, 31: 325-330, 1985.
9. Bachorik P.S. and Ross J.W., Clin Chem, 41: 1414-1420, 1995.
10. Passing H. and Bablok W., J Clin Chem Clin Biochem, 21: 709-720, 1983.
11. Bablok W., et al, J Clin Chem Clin Biochem, 26: 783-790, 1988.

PRÉSENTATION

Ref: SP41023	Cont.	R1:10 x 24 mL, R 2: 10 x 8 mL, CAL: 1 x 1 mL
Ref: SP41024		R1: 2 x 24 mL, R 2: 2 x 8 mL, CAL: 1 x 1 mL

LDL Colesterol D

Enzimático colorimétrico. Líquido

Determinação quantitativa de colesterol LDL

IVD

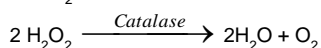
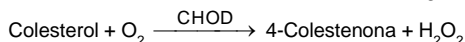
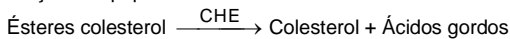
Conservar a 2-8°C

PRINCÍPIO DO METODO

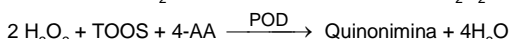
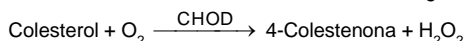
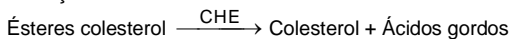
Determinação directa do LDLc (colesterol de lipoproteínas de baixa densidade) sem necessidade de pré-tratamento ou centrifugação da amostra.

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 Enzimas	Tampão PIPES	50 mmol/L
	Colesterol esterase (CHE)	≥600 U/L
	Colesterol oxidase (CHOD)	≥500 U/L
	Catalase	600KU /L
	TOOS	2 mmol/L
R 2 Enzimas	Tampão PIPER	50 mmol/L
	4 - Aminoantipirina (4-AA)	4 mmol/L
	Peroxidase (POD)	≥4k U/L
HDLc/LDLc CAL	Padrão. Soro humano liofilizado	

PRECAUÇÕES

HDLc/LDLc CAL: Todos os componentes de origem humana deram resultado negativo para o antígeno HBs, HCV e para o anti-HIV (1/2). No entanto, devem ser tratados com precaução como potencialmente infecciosos.

PREPARAÇÃO

MODO DUAL: Prontos a utilizar.

HDLc/LDLc CAL: Reconstituir o conteúdo de um frasco com 1 mL de água destilada. Tapar o frasco e agitar suavemente até dissolução do seu conteúdo.

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.

- **HDLc/LDLc CAL:** Uma vez reconstituído, 30 horas a 20-25°C, 2 semanas a 2-8°C ou 3 meses a -20°C.

Não usar reagentes fora de prazo.

Indicadores de deterioração dos reagentes:

- Presença de partículas e turvação.

MATERIAL ADICIONAL

- Espectrofotómetro ou analisador para leituras a 600 nm.

- Cuvetes de 1,0 cm de passo de luz.

- Equipamento habitual de laboratório.

AMOSTRAS

Soro, plasma heparinizado ou plasma com EDTA.

Se uma amostra precipitou centrifuga antes usarlá⁵.

Soro é estável durante 6 dias a 2-8 ° C.

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.

APLICAÇÃO AO SPINLAB 180

Nome	LDL Colesterol	Ref. Homem Inf.	49.0
Nome abreviado	LDL	Ref. Homem Sup.	172.0
Modo	Twopoint	Ref. Mulher Inf.	63.0
Long. ondas	578 nm	Ref. Mulher Sup.	167.0
Unidades	mg/dL	Ref. Ped. Inf.	*
Decimais	1	Ref. Ped. Sup.	*
Conc. Inferior	0.0 mg/dL	Valor pânico baixo	*
Conc. Superior	250.0 mg/dL	Valor pânico alto	*
Calibrador	CAL	Control 1	*
Chequeo prozona	Não	Control 2	*
		Control 3	*
		Factor correl.	1.000
		Offset de correl.	0.000
MODO DUAL			
Branco amostra	Não		
Frasco R1 (mL)	25 mL		
Vol. normal	225 µL		
Vol. repet.	225 µL		
Amostra			
Vol. normal	3.0 µL		
Vol. repet.	2.0 µL		
Frasco R2 (mL)	5 mL		
Vol. normal	75.0 µL		
Vol. repet.	75.0 µL		
Prediluição	Não		
Pendente Blco.	Não		
1º, 2º punto	24, 236 seg.		
Factor			
Branco reactivo	Si		
Absorvância inf.	-0.100 Abs		
Absorvância sup.	3.000 Abs		
Lim.Inf. Abs. React.	-0.100 Abs		
Lim.Sup. Abs. React.	3.000 Abs		
Agotamento sustrato	3.000 Abs		

CONTROLO DE QUALIDADE

É conveniente analisar juntamente com as amostras, os soros controlo valorizados: SPINROL 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.

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

Coefficiente 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.

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APRESENTAÇÃO

Ref: SP41023	Cont.	R1:10 x 24 mL, R 2: 10 x 8 mL, CAL: 1 x 1 mL
Ref: SP41024		R1: 2 x 24 mL, R 2: 2 x 8 mL, CAL: 1 x 1 mL