

**Quantitative determination of LDL cholesterol**
**IVD**

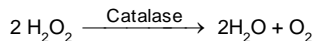
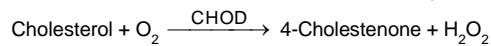
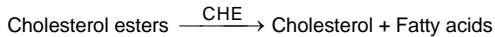
Store at 2-8°C

**PRINCIPLE OF THE METHOD**

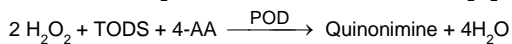
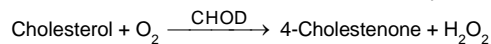
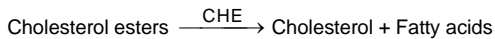
Direct determination of serum LDLc (low-density lipoprotein cholesterol) levels without the need for any pre-treatment or centrifugation steps.

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<sup>1,2,9</sup>.

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

**REAGENTS**

<b>R 1</b> Enzymes	PIPES Buffer	50 mmol/L
	Cholesterol esterase (CHE)	≥600 U/L
	Cholesterol oxidase (CHOD)	≥500 U/L
	Catalase	≥600 KU/L
	TOOS	2 mmol/L
<b>R 2</b> Enzymes	PIPER Buffer	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**

 - Autoanalyzer Spintech 240.  
 - General laboratory equipment.

**SAMPLES**

 Serum, heparinized plasma or EDTA plasma. If any sample show precipitates, centrifuge before using<sup>5</sup>.

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

**REFERENCE VALUES<sup>6,7,8</sup>**

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.

**Conversion factor:** mg/dL x 0,02586 = mmol/L

**QUALITY CONTROL**

Control sera and calibrators are recommended to monitor the performance of assay procedures: SPINTROL H Calibrator, SPINTROL 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.

**APPLICATION SPINTECH 240**

Item Name LDL		CALIBRATION	
<b>DATA INFORMATION</b>		TYPE Linear	
Units	mg/dL		
Decimals	1		
<b>ANALYSIS</b>		STANDARD	
Type	END	#1	* #4
W.Length 1	570	#2	#5
		#3	#6
Method Direct		<b>NORMAL RANGE</b>	
CORR SLOPE INTER 0		SERUM MALE FEMALE	LOW HIGH
Item Name LDL		DATA PROCESS	
<b>ASPIRATION</b>		<b>ABSORBANCE LIMIT</b>	
KIND	Single <input checked="" type="checkbox"/> Double	READ	LOW -3.000
VOLUME		START END	HIGH 3.000
SAMPLE	4 µL	MAIN 50 51	
REAGENT 1	225 µL	SUB 28 29	
REAGENT 2	75 µL	ENDPOINT LIMIT 3 LINEAR CHECK (%)	
Third Mix <input checked="" type="checkbox"/> OFF <input type="checkbox"/> ON		<b>FACTOR</b>	
R1 Blank	Water <input checked="" type="checkbox"/> R1-B	Blank Correction 1.000	
<b>MONITOR</b>		<b>PROZONE CHECK</b>	
0 LEVEL POINT	1	START END	LIMIT (%)
SPAN	3.000	FIRST	<input checked="" type="checkbox"/> Low <input checked="" type="checkbox"/> High
		SECOND	<input checked="" type="checkbox"/> Low <input checked="" type="checkbox"/> High
		THIRD	

*Blank parameter must be performed in order to get good results in CALIB screen from main menu. This parameter calibration is stable for more than 40 days.*

**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<sup>10,11</sup>:** 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)<sup>2</sup>: 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: TK41023

Cont.

R 1: 10 x 24 mL

R 2: 10 x 8 mL

# LDL Colesterol D

Enzimático colorimétrico. Líquido

## Determinación cuantitativa de colesterol LDL

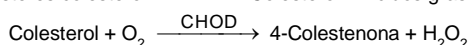
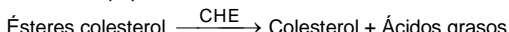
### IVD

Conservar a 2-8°C

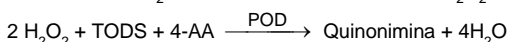
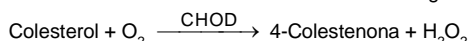
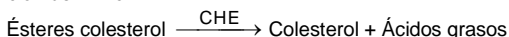
### PRINCIPIO DEL MÉTODO

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<sup>1,2,9</sup>.

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

### 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 Spintech 240.  
- Equipamiento habitual de laboratorio.

### MUESTRAS

Suero, plasma heparinizado o plasma EDTA.

Si alguna muestra presenta precipitados, centrifugarla antes de usarla<sup>5</sup>.

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

### VALORES DE REFERENCIA<sup>6,7,8</sup>

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.

**Factor de conversión:** mg/dL x 0,02586 = mmol/L

### 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.

## APLICACIÓN AL SPINTECH 240

Item Name LDL		CALIBRATION	
<u>DATA INFORMATION</u>		TYPE Linear	
Units	mg/dL		
Decimals	1		
<u>ANALYSIS</u>		STANDARD	
Type	END	#1 *	#4
		#2	#5
		#3	#6
W.Length 1	570		
		<u>NORMAL RANGE</u>	
Method	Direct	SERUM	LOW HIGH
		MALE	
		FEMALE	
<u>CORR</u>			
SLOPE	INTER		
1.000 x +	0		
Item Name LDL		DATA PROCESS	
<u>ASPIRATION</u>		<u>ABSORBANCE LIMIT</u>	
KIND	Single <input checked="" type="checkbox"/> Double	READ	LOW -3.000
		START END	HIGH 3.000
SAMPLE	VOLUME	MAIN 50 51	
REAGENT 1	4 µL	SUB 28 29	
REAGENT 2	225 µL		ENDPOINT LIMIT 3
	75 µL		LINEAR CHECK (%)
		<u>FACTOR</u>	
Third Mix	<input checked="" type="checkbox"/> OFF <input type="checkbox"/> ON	Blank Correction 1.000	
R1 Blank	Water <input checked="" type="checkbox"/> R1-B		
<u>MONITOR</u>		<u>PROZONE CHECK</u>	
0 LEVEL POINT	1	START END	LIMIT (%)
SPAN	3.000	FIRST	<input checked="" type="checkbox"/> Low High
		SECOND	<input checked="" type="checkbox"/> Low High
		THIRD	

Es necesario solicitar el blanco en este parámetro para obtener resultados correctos en la pantalla principal de CALIB. La Calibración de este parámetro es estable más de 40 días.

### 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
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<sup>10,11</sup>:** 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)<sup>2</sup>: 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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- 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.
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- 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: TK41023 Cont. R 1: 10 x 24 mL  
R 2: 10 x 8 mL

# LDL Cholestérol D

Enzymatique colorimétrique. Liquide

## Détermination quantitative de cholestérol LDL IVD

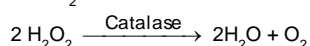
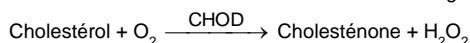
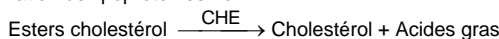
Conserver à 2-8°C

### PRINCIPE DE LA METHODE

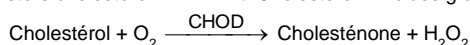
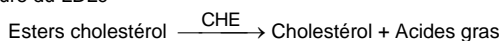
Détermination directe du LDLc (cholestérol de lipoprotéines de faible densité) sans besoin de prétraiter ou centrifuger l'échantillon<sup>3,4</sup>.

La détermination est réalisée en deux étapes :

- 1<sup>o</sup> Élimination de lipoprotéines non-LDL



- 2<sup>o</sup> 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<sup>1,2,9</sup>.

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

### 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 SPINTECH 240.
- Equipement classique de laboratoire

### ÉCHANTILLONS

Sérum, plasma hépariné ou plasma EDTA.

Si un échantillon a précipité centrifugeuse avant d'utiliser<sup>5</sup>.

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

### VALEURS DE REFERENCE<sup>6,7,8</sup>

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.

### 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 SPINTECH 240

Item Name LDL		CALIBRATION	
<b>DATA INFORMATION</b>		TYPE Linear	
Units	mg/dL		
Decimals	1		
<b>ANALYSIS</b>		STANDARD	
Type	END	#1	* #4
W.Length 1	570	#2	#5
		#3	#6
Method Direct		<b>NORMAL RANGE</b>	
<b>CORR</b>		LOW HIGH	
SLOPE	INTER	SERUM	MALE
1.000 x +	0		FEMALE
Item Name LDL		<b>DATA PROCESS</b>	
<b>ASPIRATION</b>		<b>ABSORBANCE LIMIT</b>	
KIND	Single <input checked="" type="checkbox"/> Double	<b>READ</b>	LOW -3.000
		START END	HIGH 3.000
SAMPLE	VOLUME	MAIN 50 51	
4	µL	SUB 28 29	
REAGENT 1	225 µL		ENDPOINT LIMIT 3
REAGENT 2	75 µL		LINEAR CHECK (%)
Third Mix <input checked="" type="checkbox"/> OFF <input type="checkbox"/> ON		<b>FACTOR</b>	
R1 Blank	Water <input checked="" type="checkbox"/> R1-B	Blank Correction 1.000	
<b>MONITOR</b>		<b>PROZONE CHECK</b>	
0 LEVEL POINT	1	START END	LIMIT (%)
SPAN	3.000	FIRST	<input checked="" type="checkbox"/> Low <input checked="" type="checkbox"/> High
		SECOND	<input checked="" type="checkbox"/> Low <input checked="" type="checkbox"/> High
		THIRD	

Dans ce paramètre, le blanc est nécessaire pour obtenir des résultats corrects à l'écran principal de CALIB. L'étalonnage avec le blanc réactif est stable jusqu'à 40 jours.

### 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)	
	SD	CV (%)	SD	CV (%)
31,4	0,42	1,35	32,1	2,87
67,8	1,11	1,64	68,1	2,97

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

**Exactitude<sup>10,11</sup>:** 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)<sup>2</sup>: 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

- 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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### PRÉSENTATION

Ref: TK41023

Cont.

R 1: 10 x 24 mL

R 2: 10 x 8 mL

**Determinação quantitativa de colesterol LDL**
**IVD**

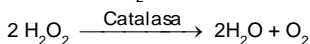
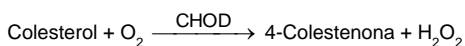
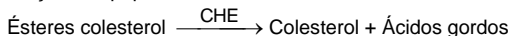
Conservar a 2-8°C

**PRINCÍPIO DO METODO**

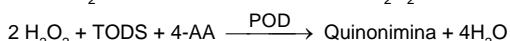
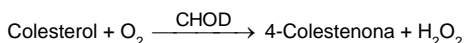
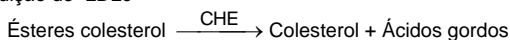
Determinação directa do LDLc (colesterol de lipoproteínas de baixa densidade) sem necessidade de pre-tratamento ou centrifugação da amostra.

A determinação realiza-se em dois passos:

- 1º Eliminação de lipoproteínas no-LDL



- 2º Medição de LDLc



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

**SIGNIFICADO CLINICO**

 As partículas de LDLc são lipoproteínas que transportam o colesterol para as células. Níveis altos de colesterol LDL são um factor de risco de aparecimento de doenças cardiovasculares, o tão conhecido por "mau colesterol". Níveis altos de colesterol LDL estão relacionados com obesidade, diabetes e nefrose<sup>1,2,9</sup>.

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

**PREPARAÇÃO**

R 1 e R 2: Prontos para utilização.

**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 utilizar reagentes fora de prazo.

R1 e R2: Uma vez abertos, são estáveis por 4 semanas a 2-8°C

**Indicadores de deterioração dos reagentes:**

- Presença de partículas e turvação.

**MATERIAL ADICIONAL**

- Autoanalisador SPINTECH 240.

- Equipamento habitual de laboratório.

**AMOSTRAS**

Soro, plasma heparinizado ou plasma com EDTA.

 Se uma amostra precipitou centrifuga antes usá-la<sup>5</sup>.

Soro é estável durante 6 dias a 2-8 ° C. Não congelar as amostras.

**VALORES DE REFERENCIA<sup>6,7,8</sup>**

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 referencia.

**CONTROLO DE QUALIDADE**

É conveniente calibrar e 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.

**APLICAÇÃO AO SPINTECH 240**

Item Name LDL <b>DATA INFORMATION</b> Units mg/dL Decimals 1 <b>ANALYSIS</b> Type END W.Length 1 570 Method Direct <b>CORR</b> SLOPE INTER 1.000 x + 0		<b>CALIBRATION</b> TYPE Linear STANDARD #1 * #4 #2 #5 #3 #6 <b>NORMAL RANGE</b> LOW HIGH SERUM MALE FEMALE	
Item Name LDL <b>ASPIRATION</b> KIND Single <input checked="" type="checkbox"/> Double VOLUME SAMPLE 4 µL REAGENT 1 225 µL REAGENT 2 75 µL Third Mix <input checked="" type="checkbox"/> OFF <input type="checkbox"/> ON R1 Blank Water <input checked="" type="checkbox"/> R1-B		<b>DATA PROCESS</b> <b>ABSORBANCE LIMIT</b> <b>READ</b> START END MAIN 50 51 SUB 28 29 ENDPOINT LIMIT 3 LINEAR CHECK (%)	
<b>MONITOR</b> 0 LEVEL POINT 1 SPAN 3.000		<b>FACTOR</b> Blank Correction 1.000 <b>PROZONE CHECK</b> START END LIMIT (%) FIRST <input checked="" type="checkbox"/> Low High SECOND <input checked="" type="checkbox"/> Low High THIRD	

 Você precisa aplicar o branco neste parâmetro para obter resultados correctos na tela principal de CALIB. Calibração pelo branco de reagente é estável até **40 dias**.

**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<sup>10,11</sup>:** 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)<sup>2</sup>: 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: TK41023

Cont.

R 1: 10 x 24 mL

R 2: 10 x 8 mL