

HDL Cholesterol

Direct. Enzymatic colorimetric

Quantitative determination of HDL cholesterol IVD

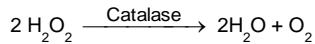
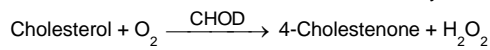
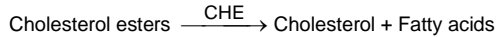
Store at 2-8°C

PRINCIPLE OF THE METHOD

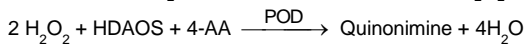
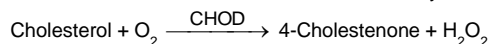
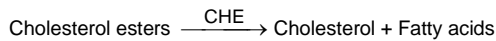
Directly determination of serum HDLc (high-density lipoprotein cholesterol) levels without the need for any pre-treatment or centrifugation of the sample.

The assay takes place in two steps.

- 1° Elimination of lipoprotein no-HDL



- 2° Measurement of HDLc



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

CLINICAL SIGNIFICANCE

HDL particles are high-density lipoproteins that transport cholesterol from the body tissues to the liver. Since HDL can remove cholesterol from the arteries and carry it back to the liver for their excretion, HDL is known as "good cholesterol" because high levels are thought to lower the risk of heart disease and coronary artery disease.

A low HDL cholesterol levels, is considered a greater heart disease risk^{1,5,6}.

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

REAGENTS

| | | |
|-----------------------|--|------------|
| R 1 | N,N-bis(2-hydroxyethyl)-2-aminoethanesulphonic acid pH 6.6 | 100 mM |
| | N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline (HDAOS) | 0.7 mM |
| | Cholesterol Esterase | ≥ 800 U/L |
| | Cholesterol oxidase | ≥ 500 U/L |
| | Catalase | ≥ 300 KU/L |
| R 2 | N,N-bis(2-hydroxyethyl)-2-aminoethanesulphonic acid pH 7.0 | 100 mM |
| | 4 - Aminoantipyrine (4-AP) | 4 mM |
| | Peroxidase | ≥ 3500 U/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. Do not freeze the reagents.

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

- **HDLc/ LDLc CAL:** Once reconstitute 2 weeks at 2-8°C or 3 months at -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 or heparinized plasma, free of hemolysis¹: Anticoagulants containing citrate should not be use.

Removed from the blood clot as soon as possible

Stability of the sample: 7 days at 2-8°C .

APPLICATION SPINLAB 180

| | | | |
|--------------------|-----------------|------------------|-------|
| Name | HDL Cholesterol | Ref. male low | 35.0 |
| Abbr. Name | HDL | Ref. male high | 55.0 |
| Mode | Twopoint | Ref. female low | 45.0 |
| Wavelength | 578 nm | Ref. female high | 65.0 |
| Units | mg/dL | Ref. Ped. Low | * |
| Decimals | 1 | Ref. Ped. High | * |
| Low Conc. | 3.0 mg/dL | Panic value low | * |
| High Conc. | 120.0 mg/dL | Panic value high | * |
| Calibrator name | * | 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 | | |
| Predilución | 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 | | |

QUALITY CONTROL

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

REFERENCE VALUES²

| | Men | Women |
|-------------|---------------|---------------|
| Low risk | > 50 mg/dL | > 60 mg/dL |
| Normal risk | 35 – 50 mg/dL | 45 – 60 mg/dL |
| High risk | < 35 mg/dL | < 45 mg/dL |

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

NOTES

The reagent 2 presents yellowish coloration due to the peroxidase, but it does not affect its functionality.

BIBLIOGRAPHY

1. Naito H K HDL Cholesterol. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1207-1213 and 437.
2. US National Cholesterol Education Program of the National Institutes of Health.
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: SP1001096 | Cont. | R1: 10 x 24 mL, R2: 10 x 8 mL, CAL: 1 x 1 mL |
| Ref: SP1001097 | | R1: 2 x 24 mL, R2: 2 x 8 mL, CAL: 1 x 1 mL |

Determinación cuantitativa de colesterol HDL
IVD.

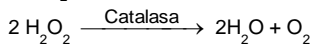
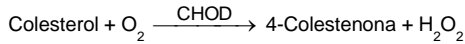
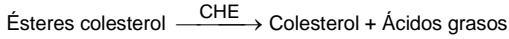
Conservar a 2-8°C

PRINCIPIO DEL MÉTODO

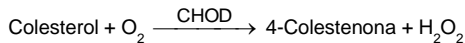
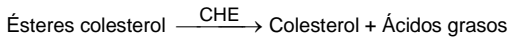
Determinación directa del HDLc (colesterol de lipoproteínas de alta densidad) sin necesidad de pre-tratamiento o centrifugado de la muestra.

La determinación se realiza en dos pasos:

- 1º Eliminación de lipoproteínas no-HDL



- 2º Medición de HDLc



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

SIGNIFICADO CLÍNICO

Las partículas de HDL son lipoproteínas de alta densidad que transportan el colesterol desde los tejidos del cuerpo hasta el hígado. Debido a que las HDL pueden retirar el colesterol de las arterias y transportarlo de vuelta al hígado para su excreción, se les conoce como el colesterol o 'lipoproteína buena', ya que niveles elevados están relacionados con un menor riesgo cardiovascular. Un nivel bajo de colesterol HDL es considerado uno de los principales factores de riesgo cardiovascular y enfermedades de las arterias coronarias^{1,5,6}.

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

REACTIVOS

| | | |
|----------------|---|------------|
| R 1 | N,N-bis (2-hidroxi-etil)-2-aminoetanosulfónico ácido pH 6.6 | 100 mM |
| | N-(2-hidroxi-3-sulfo-propil)-3,5-dimetoxianilina (HDAOS) | 0.7 mM |
| | Colesterol esterasa | ≥800 U/L |
| | Colesterol oxidasa | ≥ 500U/L |
| | Catalasa | ≥300 KU/L |
| R 2 | Ascórbico oxidasa | ≥3000 U/L |
| | N,N-bis (2-hidroxi-etil)-2-aminoetanosulfónico ácido pH 7,0 | 100 mM |
| | 4 - Aminoantipirina | 4 mM |
| HDLc/ LDLc CAL | Peroxidasa | ≥ 3500 U/L |
| | Calibrador. Suero humano liofilizado. | |

PRECAUCIONES
HDLc/ LDLc CAL

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. No congelar los reactivos.

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

 - **HDLc/ LDLc CAL**: Una vez reconstituido es estable 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 con cubeta para lecturas a 600 nm.

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

- Equipamiento habitual de laboratorio.

MUESTRAS

 Suero o plasma:¹ No usar anticoagulantes con citrato.

No utilizar muestras hemolizadas. Separar el suero de los hematíes lo antes posible. Estabilidad de la muestra: 7 días a 2-8°C.

APLICACIÓN AL SPINLAB 180

| | | | |
|----------------------|----------------|-------------------|-------|
| Nombre | HDL Colesterol | Ref. Hombre Inf. | 35.0 |
| Nombre abreviado | HDL | Ref. Hombre Sup. | 55.0 |
| Modo | Twopoint | Ref. Mujer Inf. | 45.0 |
| Long. ondas | 578 nm | Ref. Mujer Sup. | 65.0 |
| Unidades | mg/dL | Ref. Ped. Inf. | * |
| Decimales | 1 | Ref. Ped. Sup. | * |
| Conc. Inferior | 3.0 mg/dL | Valor pánico bajo | * |
| Conc. Superior | 120.0 mg/dL | Valor pánico alto | * |
| Calibrador | * | 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 (0.000) | | |
| 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: SPINROL H Normal y Patológico (Ref. 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.

VALORES DE REFERENCIA²

| | Hombres | Mujeres |
|----------------|---------------|---------------|
| Riesgo menor | > 50 mg/dL | > 60 mg/dL |
| Riesgo normal | 35 – 50 mg/dL | 45 – 60 mg/dL |
| Riesgo elevado | < 35 mg/dL | < 45 mg/dL |

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

NOTAS

El reactivo 2 presenta coloración amarillenta debido a la peroxidasa que contiene, lo cual no afecta en absoluto la funcionalidad del reactivo.

BIBLIOGRAFÍA

- Naito H K HDL Cholesterol. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1207-1213 and 437.
- US National Cholesterol Education Program of the National Institutes of Health.
- 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.

PRESENTACIÓN

 Ref: SP1001096 Cont. R1: 10 x 24 mL, R2:10 x 8 mL, CAL: 1 x 1 mL

Ref: SP1001097 R1: 2 x 24 mL, R2: 2 x 8 mL, CAL: 1 x 1 mL