AGD

CliniPak

HDL-CHOLESTEROL

(Selective Detergent Method)

Code	Pack Size
AGDSP - HDL40	R1 : 2 X 15 mL R2 : 2 X 5 mL
AGDSP -HDL200	R1-10X15mL R2-10X5mL

INTENDED USE

The reagent kit is intended for In-vitro quantitative determination of High-Density Lipoprotein Cholesterol (HDL-C) in serum & plasma.

CLINICAL SIGNIFICANCE

HDL Stands for High Density Lipoprotein.
HDL is known as 'Good Cholesterol' because high levels are known to lower the risk of heart disease and coronary artery disease. Clinical diagnosis should not be made on single test result; it should integrate clinical, and other laboratory data.

Increased levels : indicates the lower risk of heart disease.

Decreased levels: are considered a greater heart disease risk.

PRINCIPLE

Direct determination of serum HDL high-density lipoprotein cholesterol) levels without the need for any pre- treatment or centrifugation of the sample.The method depends on the properties of a detergent which solubilizes only the HDL so that HDL-C is released to react with the cholesterol esterase, cholesterol oxidase and chromogens to give colour. The non HDL lipoprotein LDL,VLDL and chylomicrons are inhibited from reacting with the enzymes due to absorption of the detergents on their surfaces. The intensity of the colour formed is proportional to the HDL concentration in the sample.

Reaction Phase - I

$$\text{LDL, VDL, Chylomicrons} \xrightarrow[\text{DSBmT+Peroxidase}]{\text{Accelerator+CO}} \text{colourless End Product}$$

Reaction Phase - II

$$\text{HDL-Cholesterol} \xrightarrow{\text{HDL Specific detergent}} \text{HDL Disrupted}$$

$$\text{HDL-Cholesterol} + H_2O + O_2 \xrightarrow{\text{CHE \& CHO}} \text{Cholest-4-en-3-one} + H_2O_2$$

$$H_2O_2 + \text{DSBmT} + \text{4-AAP} \xrightarrow{\text{Peroxidase}} \text{Blue Colour Complex}$$

PROCEDURE

Reagent1 + Sample + Incubation
(220µL) (3µL) (300Sec)
Reagent 2 ⟶ Measurement
(80µL) (600 Sec) (546nm)

REAGENT COMPOSITION

REAGENT 1

Goods Buffer pH 7	≈ 50 mmol/L
Cholesterol Oxidase	≈ 1000 IU/L
Peroxidase	≈ 1300 IU/L
TOOS	≈ 1 mmol/L

REAGENT 2

Goods Buffer pH 7	≈ 50 mmol/L
Cholesterol Esterase	≈ 1500 IU/L
4-Aminoantipyrine	≈ 1 mmol/L
Detergent	≈ 2%
Ascorbate Oxidase	≈ 3000 IU/L

HDL-C Calibrator	Concentration printed on the vial

WORKING REAGENT

Reagent 1 and Reagent 2 are ready to use and are stable up to expiry date on the label.

HDL-C Calibrator: Dissolve with distilled water. Cap and mix gently to dissolve contents.Reconstituted calibrator is stable for 7 days at 2-8°C.

STORAGE AND STABILITY

When stored tightly closed at 2-8°C, protected from light and contamination prevented during use

SAMPLES

Serum or hepairinized plasma,free of hemolysis, removed from blood clot as soon as possible.
Anticoagulants containing citrate should not be used

BASIC PARAMETERS

SHORT NAME	HDL
NAME	HDL CHOLESTEROL
METHOD	SELECTIVE DETERGENT
ASSAY	End point (two point reagent blank)
MAIN WAVE	546nm
SUB WAVE	0
DECIMAL	2
UNIT	mg/dL
R1 VOLUME	220µL
INCUBATION	36 secs
R2 VOLUME	80µL
SAMPLE VOLUME	3µL
INCUBATION	300 secs
MIXING SPEED	1
REACTION TIME (Delay)	560secs
CHECK TIME (Read)	40 secs
LINEAR RANGE	0 - 200 mg/dL
ABSORBANCE RANGE	2.5
CALIBRATION TYPE	SINGLE SPOT LINEARITY
DILUTION RATIO	6
SAMPLE VOLUME	50

LINEARITY

Reagent is linear up to 200 mg/dL.
Dilute the sample appropriately and re-assay if HDL-C concentration exceeds 200 mg/dL.Multiply results with dilution factor.

REFERENCE NORMAL VALUE

Male:35-79.5 mg/dL Female: 42-88 mg/dL
It is recommended that each laboratory should assign its own normal range.

QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes, immediately rinse with plenty of water and seek medical advice.

REFERENCES

- Burtis, C.A.,Ashwood, E.R.editors, Tietz book of Clinical Chemistry. 2nd ed.Philadelphia, W.B. Saunders Company,1994,p.1024-1030.

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