

Apolipoprotein A1 (APOA1) Diagnostic Reagent Kit (Immunoturbidimetry Assay) Product Instruction

Product name

Generic Name: Apolipoprotein A1 (APOA1)
Diagnostic Reagent Kit (Immunoturbidimetry Assay)
Abbreviation: APOA1

Package Specifications

R1	R2
40ml×1	10ml×1
60ml×1	15ml×1
60ml×2	15ml×2

Calibrator (lyophilized):
Specification 1 (1mL×1; 1 level);
Quality Control (lyophilized):
Specification 1 (1mL×1; 1 level);

Intended use

Apolipoprotein A1 (APOA1) diagnostic reagent is used for quantitative in vitro determination of Apolipoprotein A1 in human serum on photometric systems.

Clinical significance

Lipids are synthesized in the intestine or liver and are transported to tissues and organs after hydrophilic adaptation by a series of an outer monolayer of protein (an apolipoprotein) and polar lipids (phospholipids and unesterified cholesterol) plus an inner core of neutral lipids (triglycerides and cholesterol esters).

The apolipoproteins interact with a series of enzymes and tissue receptors and are therefore responsible for further metabolism and catabolism of the micelle.

The A apolipoproteins are the main form of protein found in high density lipoproteins (HDL), although chylomicrons are also present. The main role of APOA1 is in the activation of LCAT and removal of free cholesterol from extra-hepatic tissues.

APOA1 may therefore be described as non-atherogenic, showing an inverse relationship to cardiovascular risk.

Principle

This method is based on the reaction of a sample containing human Apo A1 and specific antiserum to form an insoluble complex which can be measured turbidimetrically at 340 nm. By constructing a calibrator curve from the absorbances of calibrators the concentration of Apo A1 can be determined.

Main ingredient

Name	Ingredients	Concentration
R1	Buffer solution	100 mmol/L
	Polyethylene glycol	4%
	NaCl	3%
R2	Buffer solution	100 mmol/L
	Goat anti-human APOA1 antibody	30%
	Tween-20	1g/L

Storage and stability

This kit stays stable for 18 months when stored in a dark condition at 2-8° C (do not freeze). After being opened for the first time, the kit can be stored at 2-8° C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation

Fresh serum.
-20°C, stable for 7 days.

Assay procedure

Main wavelength	340 nm	Sample(S)	2 μl
Subwavelength	700 nm	Reagent 1	260 μl
Reaction temperature	37°C	Reagent 2	65 μl
Cuvette light path	1cm	Reaction type	Two Point End

1. Reagent preparation

This reagent is liquid and can be used directly.

2. Operation steps

Add to the cuvette:	
Sample (S)	2 μl
R1	260 μl
Mix well, incubate at 37° C for 5 minutes, then add	
R2	65 μl
Mix well, incubate at 37 °C for 1 minute, absorbance A1; incubate at 37°C for 5 minutes, absorbance A2 $\Delta A = A2 - A1$	

Calculations

Calculate and plot $\Delta A = (A2 - A1)$ of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and read values in g/L on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

Reference interval

1.06g/L - 1.6g/L

It is recommended that each laboratory should establish its own reference interval.

Quality control

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics

Measuring range

0.1g/L - 2.4g/L

Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

Sensitivity

When a control serum (0.15g/L) is used as a sample, the range of absorbance change is >0.06.

Interference

The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Bilirubin	30mg/dl
Haemoglobin	5 g/L
Intralipid	0.3 %
VC	0.5 g/L
Heparin Sodium	100U/ml

Automation

Special adaptations for automatic analyzers can be made on request.

General precautions

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution. Reagents with different lot numbers should not be interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Parameters

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	16-34
Wave Length Sec	700
Wave Length Prim	340
ABS. Limit	32000
Sample Volume (uL)	2
R1 Volume (uL)	260
R2 Volume (uL)	0
R3 Volume (uL)	65
Calibration Type	SPLINE
Calibration Point	5
Span Point	3
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume (uL)	2
Sample DIL. VOL.	/
R1 Volume (uL)	260
R2 Volume (uL)	65
Reagent DIL. VOL.	/
Measure Wave 1	340
Measure Wave 2	700
METHOD	End
SLOPE	-
Method Point	9-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5

Dynamic Range L	-9999999
Dynamic Range H	9999999
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	5AB
Formula	SPLINE
STD(1) Conc.#	*
Unit	g/L

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