

Intended use

The Apolipoprotein A1-HA is an *in vitro* turbidimetric immunoassay for the quantitative determination of apolipoprotein A1 in serum or plasma.

Summary and explanation of the test

Apolipoproteins are components of lipoproteins in plasma and are important units which determine structure, functions and metabolism of lipoproteins. Apolipoprotein determinations are valuable for diagnosis of lipid metabolism disorders. Apolipoprotein A1 is contained in high-density lipoproteins (HDL), enhances the solubilization of HDL cholesterol, activates lecithin cholesterol acyltransferase (LCAT), and decreases upon atherosclerotic disorders. Therefore, apolipoprotein A1 carries out considerable functions in lipid metabolism. Laser nephelometry and turbidimetric immunoassay methods are currently used instead of single radial immunodiffusion (SRID). The Apolipoprotein A1-HA is based on the turbidimetric immunoassay methodology.

Principle of the method

When a sample is mixed with the R1 and the R2, apolipoprotein A1 in the sample combines specifically with anti-human apolipoprotein A1 antibodies in the reagent to yield an insoluble aggregate that causes increased turbidity. The degree of turbidity can be measured optically and is proportional to the amount of apolipoprotein A1 in the sample.

Reagents

Contents and storage conditions

R1: Buffer	3 bottles x 45 mL	Store at 2 - 10°C.
R2: Antibody	1 bottle x 19 mL	Store at 2 - 10°C. (Do not freeze)

Components

R1: Buffer, (pH 7.5)	Phosphate buffer	100 mmol/L
	Sodium Azide	0.1 %
R2: Antibody	Anti-human apolipoprotein A1, goat	1.15 mg Ag/mL
	Sodium Azide	0.1 %

Reagent preparation

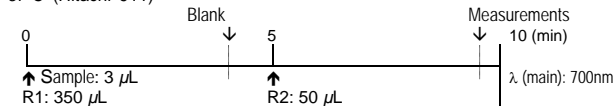
- R1: Use Buffer as supplied. This solution is stable until expiration date.
After opening the bottle, store at 2 to 10 degree C and use within 14 days.
- R2: Use Antibody as supplied. This solution is stable until expiration date.
After opening the bottle, store at 2 to 10 degree C and use within 14 days.

Specimen collection and preservation

Samples: Use serum as specimen.
Assay samples immediately after collection.

Standard procedure

37°C (Hitachi®911)



The above standard procedure is an example. Instrument applications are available upon request.

Results

The final results are automatically calculated and printed in concentration. The results are given in mg/dL.

Performance

Sensitivity

- When distilled water is assayed, the absorbance is not more than 0.05.
- When a control serum (apolipoprotein A1 150 mg/dL) is assayed, the absorbance is from 0.12 to 1.00.

Specificity

When a control serum of known concentration is assayed, the assay value falls within the range of ± 15 % of the known concentration.

Precision

When a sample is assayed 5 times in a run, CV is within 10 %.

Measurement range

Up to 250 mg/dL apolipoprotein A1 (In the case of using standard procedure).
When apolipoprotein A1 value exceeds 250 mg/dL, dilute sample 1 +2 with saline, repeat assay and multiply result by 3.
Antigen excess is not observed up to apolipoprotein A1 concentration of 600 mg/dL.

Correlation

Sample	Serum	Plasma
Correlation coefficient	r = 0.971 (n=58)	r = 0.989 (n= 55)
Regression equation	y = 0.945 x +14.7	y = 1.02 x - 1.39
x	TIA, a product from company A (mg/dL)	
y	Wako Apolipoprotein A1-HA (mg/dL)	

Interfering substances

Ascorbic acid, bilirubin and hemolysis do not have a significant effect on the assay.
Heparin, citrate, oxalate, EDTA and sodium fluoride do not affect the measurements when they are used in their respective usual quantities.

Expected value³

Serum	Male:	128 ± 24 mg/dL
	Female:	141 ± 23 mg/dL

Physical or chemical indications of instability

The presence of precipitates in the reagents or values of control sera outside the manufacturer's acceptable range may be an indication of reagent instability.

Instruments

The reagent is designed to be used on commercially available automated analyzers. Refer to the operating manual for a description of instrument operation and specifications.
A validation by the user in practice at the customer's site in the form of measurements of adequate control or patient sera in sufficient number is indispensable.

Warnings and precautions

- For *in vitro* diagnostic use only.
- The usage and application of this test is reserved for professional use only. Please refer to respective national and local regulations and legislation.
- Not to be used internally in humans and animals.
- Do not use the reagents described above in any procedures other than those described herein. Performance cannot be guaranteed if the reagents are used in other procedures or for other purposes.
- Operate the instruments according to operator's manuals under appropriate conditions. Store the reagents under the specified conditions. Do not use reagents past the expiration date stated on each reagent container label
- Do not use reagents that were frozen in error. Such reagents may give false results.
- After opening the reagents, it is recommended to use them immediately. When the opened reagents are stored, cap the bottles and keep them under the specified conditions.
- Do not use the containers and other materials in the kit for any purpose other than those described herein.
- In some instances, falsely high or low results occur due to non-specific turbidity. If a result is questionable, inspect the reaction course or dilute the sample and repeat analysis.
- Use Wako Apo A1, A2 & B High Level Calibrator for preparation of a calibration curve. Read the instruction sheet in the package of the calibrator thoroughly before use.
- When discarding the reagents, dispose of them according to local or national regulations.
- R1 and R2 contain 0.1% of sodium azide as a stabiliser. Sodium azide may react with lead or copper plumbing to form explosive compounds. Even though the reagents contain minute quantities of sodium azide, drains should be flushed well with a large amount of water, when discarding the reagents.
- If the reagents come in contact with mouth, eye or skin, wash off immediately with a large amount of water. Consult a physician if necessary.
- When substances that may cause non-specific reactions (such as heterophilic antibodies) exist in samples, they may give falsely elevated or lowered results. This assay should not be used as the sole determinant for clinical diagnosis.
- This kit contains components classified as follows according to the European Directive 1999/ 45/ EC.

Code letter and hazard designation



Xn Harmful (Sodium Azide)

Risk phrases:

R 22 Harmful if swallowed.

Safety phrases:

- S 14 Keep away from acids.
- S 28 After contact with skin, wash immediately with plenty of water.
- S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- S 60 This material and its container must be disposed of as hazardous waste.
- S 61 Avoid release to the environment. Refer to special instructions/safety data sheets.

Quality control

A quality control program is recommended for all clinical laboratories.

References

- Kosner, G. M. : Adv. Lipid Res., 20: 1 - 43 (1983).
- Koga, T. : Jpn. J. Clin. Chem., 19: 19 - 27 (1990) (in Japanese).
- Koga, T. : Nihon Rinsho, 598 (suppl.): 504 - 506 (1989) (in Japanese).

Ordering information

Code No.	Product	Package
410-27201	Apolipoprotein A1-HA	R1: 3 x 45 mL R2: 1 x 19 mL
415-77202	Apo A1, A2 & B High Level Calibrator	Set CAL: 1 x for 1 mL DIL: 1 x 3 mL