

# Bioway Chemistry Reagent Series

## The Apolipoprotein A1 Detection Kit

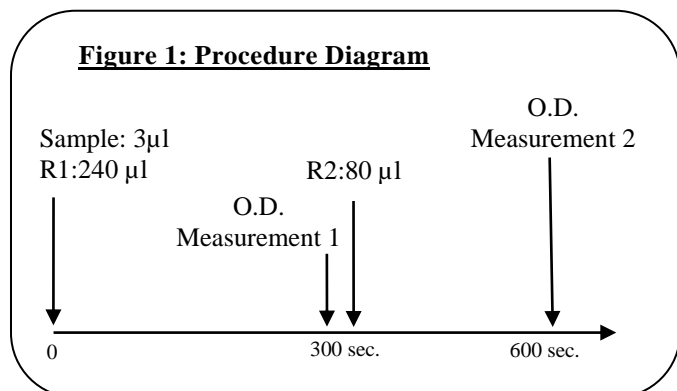
Detection of Apolipoprotein A1 in Human Serum on Chemistry Analyzers



Cat. No. R008K11

The Apo A1 Detection Kit

### SUMMARY OF TEST PROCEDURE



\*Refer to Figure 1 and the package insert for detail

**Table 1: Instrument Parameters\***

Calibration method	5 point non-linear	Slope of reaction	increase
Wavelength	Pr:600 nm Se: 800 nm	Sample volume	3 µl
Test method	2 point end	R1 volume	240 µl
Reaction temperature	37°C	R2 volume	80 µl

### INTENDED USE

**Bioway Chemistry Reagent Series Apolipoprotein A1 Reagent Kit** (the Kit) is an immunoturbidimetric assay intended for *in vitro* quantitative detection of apolipoprotein A1 in human serum on automated clinical chemistry analyzers.

### SUMMARY AND EXPLANATION

Apolipoprotein A1 (APO A1) is the major protein component of high density lipoprotein (HDL). It activates Lecithin cholesterol acyltransferase (LCAT) and removes free cholesterol from extra hepatic tissues. Several studies have shown APO A1 to have an inverse relationship to coronary artery disease and a direct relationship with APO B. APO A1 and APO B levels are useful in assessment of cardiovascular risk in addition to HDL and LDL cholesterol levels.

### TEST PRINCIPLES

The Kit utilizes immunoturbidimetry to measure the APO A1 level in human serum. During the test, APO A1 in the sample binds with the specific anti-APO A1 antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of APO A1 in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

### MATERIALS PROVIDED

#### Reagents:

<b>R1</b>	Glycine buffer solution. Sodium azide < 0.1%
<b>R2</b>	anti-APO A1 antibodies, glycine buffer, sodium azide < 0.1%

### MATERIALS NEEDED BUT NOT PROVIDED

- Automated chemistry analyzer.
- APO A1 calibrator set (available for purchase) and control set (commercially available).

### INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

### STORAGE AND STABILITY

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8°C after opening.

### PRECAUTIONS

- The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
- Samples containing levels of APO A above the assay range should be diluted with saline and retested.
- Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

### SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2-4°C for up to 3 days or at -20°C for up to 6 months. Avoid repeated freezing and thawing.

### TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

**Calibration:** 5 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

**Test procedure:** see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

- Add 3 µl of sample and 240 µl of R1; mix well and incubate at 37°C for 300 seconds.
- Take optical density measurement OD 1 just before addition of R2.
- Add 80 µl of R2, mix well and incubate at 37°C.
- Take optical density measurement OD 2 at 600 seconds.
- Calculate  $\Delta OD = OD 2 - OD 1$

### RESULT

The APO A1 value can be obtained by using the calculated  $\Delta OD$  to find the corresponding value on a calibration curve prepared with known values.

### EXPECTED VALUES

100 – 160 mg/dL.

It is recommended for each laboratory to establish its own expected values. Expected values may vary with age, sex, diet and geographical location.

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### QUALITY CONTROL

Using 2-level commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

### LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

### PERFORMANCE CHARACTERISTICS

**Linearity:** 30 – 240 mg/dL ( $R \geq 0.990$ )

**Precision:** Within Run:  $CV \leq 4\%$ ;  
Run-to-Run:  $CV \leq 6\%$

**Interference:** no interference detected for: Bilirubin (60 mg/dL), triglycerides (1000 mg/dL), and hemoglobin (10 g/L).

**Reagent Blank Absorbance:** at 600nm wavelength and 10 mm optical diameter, O.D.  $\leq 0.20$

### REFERENCES

1. Arvovina SM, Albere JJ, Dati F., et al, International federation of clinical chemistry standardization project for measurements of apolipoprotein AI, Clin Chem, 1991,37:1676.
2. Kottke BA, et al. Mayo Clin. Proc. 1986; 61: 313.
3. Ritchie, RF (ed). Serum Proteins in Clinical Medicine, Volume 1 Laboratory Section. Scarborough, ME: Foundation for Blood Research; 12.01-5; 1996.
4. Snidermann AD. Can. J. Cardiol. 1988; 4 Suppl.: 24 A.
5. Sandkamp M. Diagnose & Labor 1990; 40: 37.

Not Intended for Sale in the United States.

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