Bioway Chemistry Reagent Series

The Serum Apolipoprotein B Detection Kit

Detection of Apolipoprotein B in Human Serum on Chemistry Analyzers

Cat. No. R009K11 ***The Apo B Detection Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

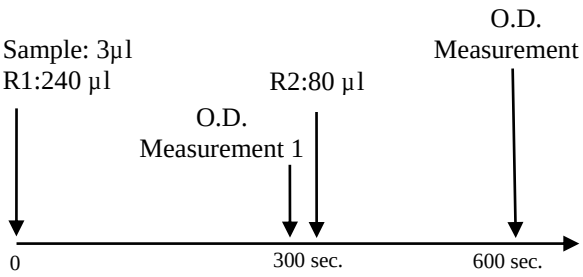

Table 1: Instrument Parameters*

Calibration method	5 point non-linear	Slope of reaction	increase
Wavelength	Pr:340 nm Se: 700 nm	Sample volume	3 µl
Test method	2 point end	R1 volume	240 µl
Reaction temperature	37℃	R2 volume	80 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

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

SUMMARY AND EXPLANATION

Apolipoprotein B (APO B) is the major protein component of low density lipoprotein (LDL). It enables the reaction with LDL receptors in the liver and on cell walls and transports cholesterol from the liver to tissue cells. Studies have shown APO B to have a direct relationship to coronary artery disease and an inverse relationship with APO A1. APO B levels are useful in assessment of cardiovascular risk in addition to LDL cholesterol levels. Elevated levels of APO B can be an indication of increased cardiovascular risk even when total cholesterol and LDL cholesterols are within the normal range.

TEST PRINCIPLES

The Kit utilizes immunoturbidimetry to measure the APO B level in human serum. During the test, APO B in the sample binds with the specific anti-APO B 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 B in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Glycine buffer solution. Sodium azide < 0.1%
R2	anti-APO B antibodies, glycine buffer, sodium azide < 0.1%

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. APO B 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℃. 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℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Samples containing levels of APO B above the assay range should be diluted with saline and retested.
6. 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.

1. Add 3 µl of sample and 240 µl of R1; mix well and incubate at 37℃ for 300 seconds.
2. Take optical density measurement OD 1 just before addition of R2.
3. Add 80 µl of R2, mix well and incubate at 37℃.
4. Take optical density measurement OD 2 at 600 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

The APO B value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

60 – 110 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 – 200 mg/dL (R≥0.990)

Precision: Within Run: CV≤4%;
Run-to-Run: CV≤6%

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

Reagent Blank Absorbance: at 340nm wavelength and 10 mm optical diameter, O.D. ≤ 0.30

REFERENCES

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4. Snidermann AD. Can. J. Cardiol. 1988; 4 Suppl.: 24 A.
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Not Intended for Sale in the United States.

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