**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 cholesterol 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:

<table>
<thead>
<tr>
<th>R1</th>
<th>Glycine buffer solution, Sodium azide &lt; 0.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>R2</td>
<td>anti-APO B antibodies, glycine buffer, sodium azide &lt; 0.1%</td>
</tr>
</tbody>
</table>

**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°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.

**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.

**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.

**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.


**RESULT**

The APO B value can be obtained by using the calculated ∆OD 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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**Figure 1: Procedure Diagram**

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<table>
<thead>
<tr>
<th>Sample: 3µl</th>
<th>R1:240 µl</th>
<th>O.D. Measurement 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>R2:80 µl</td>
<td></td>
<td>O.D. Measurement 2</td>
</tr>
<tr>
<td>0</td>
<td>300 sec.</td>
<td>600 sec.</td>
</tr>
</tbody>
</table>
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*Refer to Figure 1 and the package insert for detail.*

<table>
<thead>
<tr>
<th>Table 1: Instrument Parameters*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration method</td>
</tr>
<tr>
<td>Wavelength</td>
</tr>
<tr>
<td>Test method</td>
</tr>
<tr>
<td>Test method</td>
</tr>
<tr>
<td>Reaction temperature</td>
</tr>
</tbody>
</table>

**Expected values may vary with age, sex, diet and geographical location.**
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

Not Intended for Sale in the United States.