# Bioway Chemistry Reagent Series
# Apolipoprotein E Test Kit

***Detection of Apolipoprotein E in Human Serum or Plasma on Chemistry Analyzers***

***Cat. No. R010K11*** ***Apolipoprotein E Test Kit***

## *SUMMARY OF TEST PROCEDURE*

**Figure 1: Procedure Diagram**

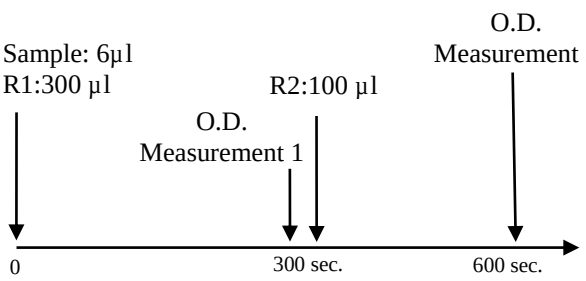


**Table 1: Instrument Parameters***

| | | | |
|---|---|---|---|
| Calibration method | 6 point non-linear | Slope of reaction | increase |
| Wavelength | Pr:340 nm<br>Se: 700 nm | Sample volume | 6 µl |
| Test method | 2 point end | R1 volume | 300 µl |
| Reaction temperature | 37℃ | R2 volume | 100 µl |

*Refer to Figure 1 and the package insert for detail

## *INTENDED USE*

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

## *SUMMARY AND EXPLANATION*

Apolipoprotein E (APO E) is a class of apolipoprotein found in the chylomicron and VLDLs that binds to a specific receptor on liver cells and peripheral cells. APO E is needed for the normal catabolism of triglyceride-rich lipoprotein constituents. APO E deficiency gives rise to high cholesterol and triglyceride levels, promoting atherosclerosis. APO E levels are also associated with cardiovascular disease, Alzheimer's disease, immunoregulation, and cognition.

## *TEST PRINCIPLES*

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

## *MATERIALS PROVIDED*

**Reagents:**

| | |
|---|---|
| **R1** | Tris buffer solution, polyethylene glycol, Sodium azide < 0.1% |
| **R2** | anti-APO E antibodies, buffer, sodium azide < 0.1% |

## *MATERIALS NEEDED BUT NOT PROVIDED*

1. Automated chemistry analyzer.
2. APO E 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. 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 or plasma (EDTA or heparin) 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 5 days.

## *TEST PROCEDURE (see Figure 1)*

No pretreatment required for reagents and samples.

**Calibration:** 6 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 6 µl of sample and 300 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 100 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 E value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

## *EXPECTED VALUES*

2.9 – 5.3 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.

## *QUALITY CONTROL*

Using 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.

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## *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**: 0.1– 10.0 mg/dL (R≥0.995)

**Precision**: Within Run: CV≤6%;
Run-to-Run: CV≤10%

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

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

## *REFERENCES*


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2. Neighborhood psychosocial environment, apolipoprotein E genotype, and cognitive function in older adults. Lee BK, *et al*. Arch Gen Psychiatry, 2011 Mar.
3. Singh PP, Singh M, Mastana SS (2006). "APOE distribution in world populations with new data from India and the UK.". *Ann.Hum. Biol.* 33 (3): 279–308.
4. Strittmatter WJ, Roses AD (1995). "Apolipoprotein E and Alzheimer disease.". *Proc. Natl. Acad. Sci. U.S.A.* 92 (11): 4725-7.
5. Zhang HL, Wu J, Zhu J (2010). "The role of apolipoprotein e in guillain-barré syndrome and experimental autoimmune neuritis". *J. Biomed. Biotechnol.* 2010: 357412.


Not Intended for Sale in the United States.


Pointe Biotech (Nanjing) Co., Ltd.

No.85,Xingmin South Road, Jiang Ning District, Nanjing,P.R.China 211100
Tel:86-25-52425019,
Fax:86-25-52424836
info@biowaydx.com