Bioway Chemistry Reagent Series

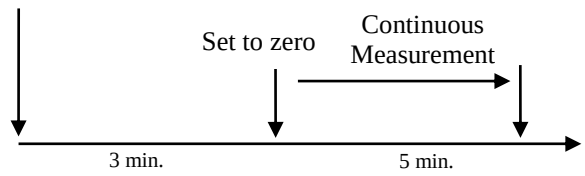
Angiotensin Converting Enzyme Test Kit

Detection of Angiotensin Converting Enzyme in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R001K11 ***ACE Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram



*Refer to Figure 1 and the package insert for detail

Table 1: Instrument Parameters*

F factor	1700	Slope of reaction	increase
Testing wavelength	Dλ : 405 nm Sλ : 505 nm	Sample volume	10 µl
Test method	Rate Method	R1 volume	200 µl
Reaction temperature	37℃	R2 volume	100 µl

INTENDED USE

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

SUMMARY AND EXPLANATION

Leucine aminipeptidase is normal found in liver and small intestine cells. A raised leucine aminopeptidase level in serum represents possible pancreatic or hepatobiliary diseases and play a role diagnosing benign jaundice, .

TEST PRINCIPLES

The Kit utilizes enzymatic and kinetic reactions to measure the LAP activity (U/L) in human serum or plasma. In pH7.5 phosphate buffer,

process is quantified by measuring the absorabances at 405 nm in a kinetic fashion.

L-Leucine p-Nitroanilide + H2O $\xrightarrow{\text{LAP}}$ L-Leucine + p-Nitroaniline

The rate of increase in absorbance at 405 nm is directly proportional to the LAP activity in the sample.

MATERIALS PROVIDED

Reagents:

R1	Phosphate buffer, pH7.5	0.1mmol/L
R2	L-Leucine p-Nitroanilide	4.0mmol/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. LAP control and calibrator 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. The reagent is 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.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum preventing hemolysis. **Do not use EDTA-treated plasma samples.**
It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be frozen at -20℃ and avoid repeated freeze-thaw cycle.

TEST PROCEDURE (see Figure 1)

Reagent 1 and 2 are liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using Randox calibrator set (Level 1/2/3) for optimal results.

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

1. Add 10 µl of sample and 200 µl of R1; mix well and incubate at 37℃ for 3 to 5 minutes.
2. Add 100µl of R2; mix well and incubate at 37℃ for 1 minute.
3. Take continuous optical density measurement for 1 to 3 minutes.
4. Calculate average Δ A/min

RESULT

The LAP activity in U/L can be obtained by the following calculation:

LAP (U/L） = (ΔA_{test} / min - ΔA_{blank} / min)× factor (F)
The calculation factor for UV spectrophotometer is 1700 when the optical path is 10 mm. Please refer to instrument application if testing under different conditions.

EXPECTED VALUES

35-68 U/L

It is recommended for each laboratory to establish its own expected values

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.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.

2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with LAP exceeding the maximum measurement range should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0 - 400 U/L (R≥0.990)

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

Interference: no interference detected for: Bilirubin (1026 μmol/L), triglycerides (11.3mmol/L), and hemoglobin (4 g/L)

REFERENCES

1. G. Mericas *et al.*, J. Clin. Path., 17: 52-55 (1968).
2. A. Marcilla *et al.*, Clinical and Vaccine Immunology, 15(1):95-100 (2008)

Not Intended for Sale in the United States.

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