Bioway Chemistry Reagent Series

Glycylproline Dipeptidyl Aminopeptidase Test Kit

Detection of Glycylproline Dipeptidyl Aminopeptidase in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R031K11 ***GPDA Test Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

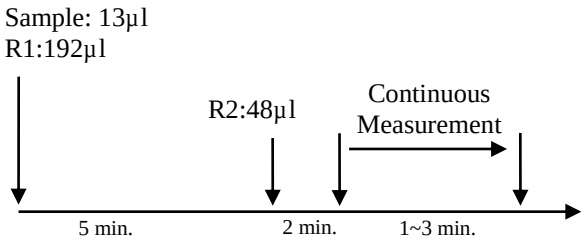

Table 1: Instrument Parameters*

F factor	1955	Slope of reaction	Increase
Testing wavelength	405 nm	Sample volume	13 µl
Test method	Rate Method	R1 volume	192 µl
Reaction temperature	37℃	R2 volume	48 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

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

SUMMARY AND EXPLANATION

Glycylproline Dipeptidyl Aminopeptidase exists in human liver, kidney, connective tissue, salivary gland and serum for catalyzing the hydrolysis of multipeptides from collagen. The level of Glycylproline Dipeptidyl Aminopeptidase in serum is found to be raised in patients with liver cancer, acute hepatitis, cirrhosis or obstructive jaundice. But it is decreased in patients with other diseases such as gastric cancer, rheumatoid arthritis, systemic lupus erythematosus or acute lymphoblastic leukemia. People have used this enzyme for in vitro diagnosis since 1970.

TEST PRINCIPLES

The Kit utilizes enzymatic and kinetic reactions to measure the GPDA activity (U/L) in human serum or plasma. Under alkali condition, GPDA catalyzes the hydrolysis of Gly-Pro-pNA. The process is quantified by measuring the absorabances at 405 nm in a kinetic fashion.

$$\text{Gly-Pro-pNA+ H2O} \xrightarrow{\text{GPDA}} \text{Gly-Pro + p-Nitroaniline}$$

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

MATERIALS PROVIDED

Reagents:

R1	Glycylglycin Tris Sodium azide	8.32g/L 8.5g/L 1g/L
R2	Gly-Pro- pNA	1.62g/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. AFU 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.
5. Reagents contain 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 preventing hemolysis.

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at 2~8℃ for 1 day or frozen at -20℃ for up to 1 month. Be sure to 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 commercially available calibrators 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 13 µl of sample and 192 µl of R1; mix well and incubate at 37℃ for 5 minutes.
2. Add 48µl of R2; mix well and incubate at 37℃ for 2 minutes.
3. Take continuous optical density measurement for 1 to 3 minutes.
4. Calculate average Δ A/min

RESULT

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

$$\text{GPDA (U/L)} = (\Delta A_{test} / \text{min} - \Delta A_{blank} / \text{min}) \times \text{factor (F)}$$

Glycylproline Dipeptidyl Aminopeptidase Test Kit

Detection of Glycylproline Dipeptidyl Aminopeptidase in Human Serum or Plasma on Chemistry Analyzers

The calculation factor for UV spectrophotometer is 1955 when the optical path is 10 mm. Please refer to instrument application if testing under different conditions.

EXPECTED VALUES

46-111 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. The reagent is sensitive to glassware.
4. Samples with GPDA exceeding the maximum measurement range should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0 - 400 U/L (R≥0.990)

Accuracy: Bias proportion 90%~110%

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

REFERENCES

1. Ni RZ *et al.*, World J Gastroenterol. 9(4):710-713 (2003)
2. Junnosuke Kojima *et al.*, Clinica Chimica Acta, 167(3):285–291(1987)

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