Bioway Chemistry Reagent Series

Alpha-L-Fucosidase Reagent Kit

Detection of Alpha-L-Fucosidase in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R003K11 ***AFU Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

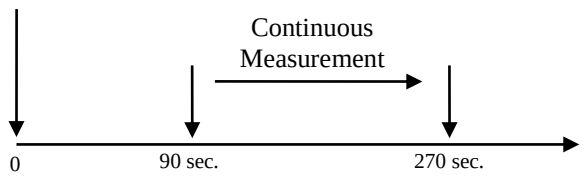

Table 1: Instrument Parameters*

F factor	1250	Reaction temperature	37℃
Primary wavelength	405 nm	Slope of reaction	increase
Secondary wavelength	480 nm	Sample volume	30 µl
Test method	rate	R1 volume	270 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **AFU Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of Alpha-L-Fucosidase in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Alpha-L-Fucosidase (AFU) is a lysosomal enzyme involved in the degradation of fucoglycoconjugates. Serum AFU activity is useful in the diagnosis of hepatocellular carcinoma (HCC) in addition to testing Alpha-fetoprotein (AFP). Although AFP is a more commonly accepted method for early detection of HCC, not all HCC secrete AFP. The AFP levels occurs normal in 40% of patients with early HCC and in 15-20% of patients with advanced HCC. Measurement of both AFP and AFU significantly increases the detection specificity and sensitivity for HCC. Increases AFU levels in serum are early indication of HCC.

TEST PRINCIPLES

The Kit utilizes enzymatic and kinetic reactions to measure the AFU activity (U/L) in human serum or plasma. During the test, the synthetic substrate 2-chloro-4-nitrophenyl-α-L-fucopyranoside is cleaved enzymatically by AFU. The process is quantified by measuring the absorabances at 405 nm in a kinetic fashion.

2-chloro-4-nitrophenyla-α-L-fucopyranoside + H2O $\xrightarrow{\text{AFU}}$ α-L-fucoside + 2-chloro-4-nitrophenol

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

MATERIALS PROVIDED

Reagents:

R1	Phosphate buffer, substrate CNP-AFU

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. AFU 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. 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 or EDTA plasma samples. **Do not use heparin plasma samples.**
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 up to 3 days or frozen at -20℃ for up to 1 month. 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 Bioway calibrator set 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 30 µl of sample and 270 µl of R1; mix well and incubate at 37℃ for 90 seconds.
2. Take continuous optical density measurement for 180 seconds.
3. Calculate average Δ A/min

RESULT

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

AFU (U/L） = ΔA/min × factor (F)
The calculation factor for UV spectrophotometer is 1250 when the optical path is 10 mm. Please refer to instrument application if testing under different conditions.

EXPECTED VALUES

12 - 40 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 AFU exceeding the maximum measurement range should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0 - 150 U/L (R≥0.995)

Precision: Within Run: CV≤5%;
Run-to-Run: CV≤6%

Interference: no interference detected for: Bilirubin (60 mg/dL), triglycerides (750 mg/dL), and hemoglobin (200 mg/dL)

REFERENCES

1. Ayde D. et al. Value of the serum α-L-fucosidase activity in the diagnosis of colorectal cancer. Oncology, 59: 310 (2000).
2. Giardina MG. et al. Serum α-L-fucosidase. A useful marker in the diagnosis of hepatocellular carcinoma. Cancer, 70: 1044 (1992)
3. Zielke K. et al. Fucosidsis: diagnosis by serum assay of α-L-fucosidase. J. Lab. Clin. Med. 79: 164 (1972).

Not Intended for Sale in the United States.

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