Bioway Chemistry Reagent Series
D Dimer Test Kit

Detection of D-Dimer in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R027K11 ***D Dimer test Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

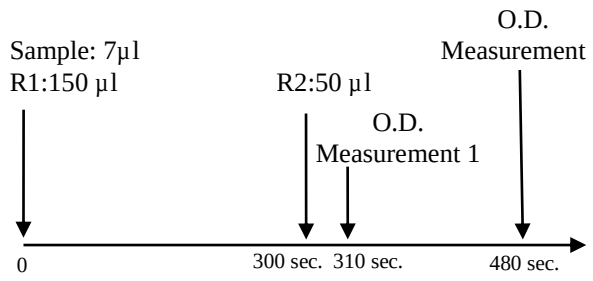

Table 1: Instrument Parameters*

Calibration method	5 point non-linear	Slope of reaction	increase
Wavelength	570 nm	Sample volume	7 µl
Test method	2 point end	R1 volume	150 µl
Reaction temperature	37℃	R2 volume	50 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **D-dimer Reagent Kit** (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of d-dimer protein in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

D-dimer is a fibrin degradation product, a small protein fragment present in blood after fibrinolysis degrades a blood clot. D-dimer is normally undetectable in the blood and is synthesized only after a clot has formed and is in the process of being broken down. D-dimer levels rise when a significant formation and breakdown of blood clots occurs. D-dimer is useful in diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE), and disseminated intravascular coagulation (DIC).

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the d-dimer level in human serum or plasma. During the test, d-dimer in the sample binds with the specific anti-d-dimer antibody that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of d-dimer in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Tris buffer solution. Sodium azide < 0.1%
R2	Latex suspension, anti-d-dimer antibodies, buffer solution, sodium azide < 0.1%

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. D-dimer 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 heparin plasma samples.
It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 8° C for up to 1 day or at -80° C for up to 6 months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 5 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 7 µl of sample and 150 µl of R1; mix well and incubate at 37℃ for 300 seconds.
2. Add 50 µl of R2, mix well and incubate at 37℃ for 10 seconds.
3. Take optical density measurement OD 1 after 10 seconds incubation.
4. Take optical density measurement OD 2 at 480 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

The d-dimer value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

0-1.35 mg/L.
It is recommended for each laboratory to establish its own expected values.

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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. 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 – 20 mg/L (R≥0.990)

Precision: Within Run: CV≤8%;
Run-to-Run: CV≤10%

Interference: no interference detected for: saturated bilirubin (19.6 mg/dL), free bilirubin (18.4 mg/dL), Rheumatoid factor (500 IU/mL), and hemoglobin (460 mg/dL).

Reagent Blank Absorbance: at 570nm wavelength and 10 mm optical diameter, O.D. ≤ 1.70

REFERENCES

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3. Rylatt, D.B., et al. An Immunoassay for Human D-DImer using Monoclonal Antibodies. Thromb. Res. 31(6): 767-778; 1986.
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Not Intended for Sale in the United States.

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