WELDONBIOTECH

Inspiration for life science

Wel-Chem D-Dimer Assay Kit

Configuration

The Wel-Chem D-Dimer Assay reagent is provided in below packaging configuration:

Catalog No.	Kit size(80ml)
DED-150WB	R1: 2 x 30 mL R2: 2 x 10 mL

Calibrators and controls sold separately

INTENDED USE

In vitro test for the quantitative determination of D-Dimer in human plasma. When D-Dimer values below the cutoff are obtained, deep venous thrombosis (DVT) of the lower limb and pulmonary embolism (PE) can be excluded with high sensitivity In disseminated intravasal coagulation (DIC)/consumptive coagulopathy, fibrin degradation products are a sensitive marker. Monitoring the fibrin-specific degradation products can be used to confirm or refute a tentative diagnosis, estimate the potential risk for patients with existing DIC and monitor an initiated therapy.

TEST PRINCIPLE

Latex particles of uniform size are coated with monoclonal antibodies to the D-Dimer epitope. The antigen/antibody complexes produced by the addition of samples containing D-Dimer lead to an increase in the turbidity of the test reactants. The change of absorbance with time is dependent on the concentration of D-Dimer epitopes in the sample. The precipitate is determined turbidimetrically.

REAGENT COMPOSITION

R1	TRIS buffer: preservatives	100 mmol/L 0.95g/L
R2	preservatives Latex particles coated with monoclonal anti-human D-Dimer antibodies.	0.95 g/L Appropriate amount
D-Dimer calibrator	D-Dimer (Protein matrix)	Refer to label of vial for concentration(Calibrator can be traced to standard material).
D-Dimer diluent	TRIS buffer	50 mmol/L

Note:Different batches of reagent components cannot be interchangeable.

STORAGE AND STABILITY

Unopened kit components:18 months capped at 2-8 ° C.
Reagent 1: 28 days opened and refrigerated at 2-8 °C.
Reagent 2: 28 days opened and refrigerated at 2-8 °C.
Calibrator: 18 months capped at 2-8°C. Immediately use after open. Discard after use.
For details, please refer to the kit for packaging.

SPECIMEN PREPARATION

Only the specimens of citrated plasma were tested and found acceptable. Centrifuge samples containing precipitates before performing the assay. Stability: 4 days at 2-8℃.
After the income of whole blood, mix immediately. Avoid bubbles. The plasma was separated by a centrifuge（3000rpm, 10minutes）
Icterus: No significant interference up to approximate conjugated and unconjugated bilirubin concentration: 30 mg/dL.
Lipemia (Intralipid): No significant interference up to 1000 mg/dL.
Hemolysis: No significant interference up to approximate hemoglobin concentration: 500 mg/dL.

TESTING METHOD

1. a）Liquid, ready for use.
b）Redissolving of calibrator: Carefully open the bottle avoiding the loss of lyophilizate, and pipette in the appropriate amount of deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.

2. Assay parameter:

Reaction	2-point rate	Temperature	37℃
Wavelength	700 nm	Cuvette light path	1 cm
Sample	4 μl	R1	180 μl
R2	60 μl		

3. Operation procedure

4. Calibration

a). Use PREB calibrator or other appropriate calibrator for daily calibration. b). Calibration frequency: 1) after regent lot change, 2) as required following quality control procedures.

5. Calculate

a). Calibration curve

Plot the calibration curve according to the absorbency variation (A calibration-A blank) of calibration and corresponding concentration. Calculate the amount of D-Dimer by comparing with calibration curve.

6. Quality control

For quality control, use certified control materials.
Each laboratory should establish corrective measures to be taken if values fall outside the limits.

EXPECTED VALUES

≤1.0 mg FEU/L
Reference source:Mitsubishi Chemical Corporation《LPIA-ACE D-Dimer》, Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

EXPLANATION OF RESULTS

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

LIMITATIONS

1. Linear range can up to 20mg FEU/L according to this product specification.
2. Dilute the high concentration sample 1/3 with saline and reassay the sample.
2. Linear range depend on ratio of sample and reagent, and analyzer used.
3. Reduce the sample volume can improve the linear range, but also reduce the sensitivity.
4. The repeatability test of samples having concentration<0.5mg FEU/L are not very well

PERFORMANCE DATA

1. Appearance and traits: R1: Colorless transparent liquid, R2: White latex liquid; D-dimer calibrator dilution: Colorless or light yellow liquid; D-dimer calibrator: After lyophilisation, the visual observation should be colorless or pale yellow liquid.
2. Linear range: 0.5-20.0mg FEU/L. R(coefficient of determination) ≥0.990. When concentration≥10mg FEU /L, relative deviationB%≤20%; when concentration＜10mg FEU /L, absolute deviationB≤2.0mg FEU /L.
3. Precision: within-reagent lot CV≤8 %, between-reagent lot CV≤10.0%.
4. Blank absorbance A (700nm, 1cm) ≤1.60.
5. Analytical sensitivity: The calculated absorbency difference (ΔA) under 1 mg FEU/L should be≥0.25 mAbs.
6. Accuracy: Comparison method: Correlation coefficient(r)≥ 0.975, Relative deviation≤20.0%.
7. Calibrator Accuracy: Comparison method: correlation coefficient r≥0.975, concentration ≥10 mg FEU/L, relative deviation B% ≤ 20%; concentration <10 mg FEU/L, absolute deviation B ≤ 2.0 mg FEU/L.
8. Calibrator homogeneity: between-reagent CV ≤10.0%.

PRECAUTIONS AND WARNINGS

1. For IVD use only.
2. Avoid contamination during the assay procedure.
3. Don't use expired reagent.
4. Stop using the reagent in which particle and/or turbid occurred.
5. Don't freeze the reagent. The frozen reagent will result in false result.
6. All samples and reactive waste should be treated in accordance with the relevant regulations

REFERENCES

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Weldon Biotech (India) Private Limited

Plot No.: 31, Sector- 2, I.I.E., SIDCUL, Haridwar

Pin- 249403, Uttarakhand, Tel.: 01334-239441-42

Email: info@weldonbiotech.com

mfg@weldonbiotech.com

Ph. No. 08006553470

Website: www.weldonbiotech.com

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