Diagnostic Kit for D-Dimer

(fluorescence immunochromatographic assay)

Instructions for Use

INTENDED USE

This kit is applicable to in vitro quantitative determination of D-Dimer in human plasma/whole blood/fresh finger terminal blood samples and is mainly used for implementing auxiliary diagnosis of venous thrombus and disseminated intravascular coagulation as well as monitor thrombolytic therapy. This kit only provides test result of D-Dimer. The obtained result should be analyzed in combination with other clinical information. It must only be used by healthcare professionals.

SUMMARY

Causes of D-Dimer increase include: 1. Secondary excessive fibrinolysis, such as hypercoagulable state, disseminated intravascular coagulation, nephropathy, organ transplantation rejection, thrombolytic therapy, etc. 2. Intravascular activated thrombogenesis and fibrinolysis activity. 3. Myocardial infarction, cerebral infarction, pulmonary embolism, venous thrombus, surgery, tumor, disseminated intravascular coagulation, infection, tissue necrosis etc. D-Dimer reflects fibrinolysis function and can be used for auxiliary diagnosis of venous thrombus and disseminated intravascular coagulation as well as monitoring of thrombolytic therapy.

PRINCIPLE OF DETECTION

This kit uses the double-antibody sandwich reaction principle with high specificity and fluorescence immunochromatography to quantitatively test the D-Dimer in the plasma/whole blood/fresh finger terminal blood samples. Test strip contains anti-D-Dimer antibody pre-immobilized on the test area (T) of the membrane and goat anti-chicken IgY antibody in the control area (C). The labeling pad contains pre-coated fluorescently labeled anti-D-Dimer antibody and chicken IgY antibody. In the detection of samples, D-Dimer antigen in the samples firstly binds to fluorescently labeled anti-D-Dimer antibody to form an immune complex. Under the immunochromatographic effect, the complex and the sample flow in the inside nitrocellulose membrane towards the absorbent paper. The complex binds with the coated anti D-Dimer antibody while it passes through test area (T), to form “anti D-Dimer antibody-D-Dimer antigen-fluorescence-labeled anti D-Dimer antibody” complex and thus aggregate. When passing through the control area (C), the fluorescently labeled chicken IgY antibody binds to the coated goat anti-chicken IgY antibody to form a "goat anti-chicken IgY antibody-fluorescently labeled chicken IgY antibody" complex and agglutinates. The D-Dimer concentration in the sample is positively correlated with the fluorescence intensity, and the concentration of D-Dimer in the sample can be detected by the fluorescence immune analyzer.

MAIN KIT COMPONENTS

Catalogue number	53350501	53350505	53350520	53350525
specification	1 Test/Kit	5 Tests/Kit	20 Tests/Kit	25 Tests/Kit

Components				
Test device	1	5	20	25
Sample diluents	1	5	20	25
Instructions for Use	1	1	1	1

MAIN ACTIVE INGREDIENTS

1. Test line (T line): T line area of nitrocellulose membrane is coated with anti-D-Dimer antibody.
2. Control line (C line): C line area of nitrocellulose membrane is coated with Goat anti-chicken IgY antibody.
3. Labeling pad: It is coated with fluorescent-microsphere-labeled anti D-Dimer antibody and chicken IgY antibody.
4. Main component of sample diluent is 20mM, pH7.4 PBS solution.

STORAGE CONDITION

1. The kit should be stored at 2℃~30℃. The shell life of the kit is 24 months.
2. The sample diluent should be capped immediately after opening and kept in a cool place.
3. Do not use the kit after the expiration date.

APPLICABLE INSTRUMENT

The test must be quantified with Igloo Reader Pro, available from goodscare GmbH, Germany.

SAMPLE COLLECTION AND STORAGE

1. This kit is indicated for testing of venous whole blood, plasma, and fresh finger terminal blood. For whole blood and plasma samples, can use anticoagulant such as EDTA-K2, heparin, and sodium citrate.
2. Any sample taken from human may be infectious and shall be disposed using standard bio-safety procedures.
3. To avoid interference with the test result, do not use hyperlipidemic, hemolytic or turbid sample.
4. Whole blood collection: Following standard blood collection procedures, whole blood samples were collected by venipuncture using a blood collection tube containing an appropriate anticoagulant. Blood should be tested as soon as possible after blood collection. If the test cannot be carried out in time, the sample should be stored at 2℃~8℃ for 2 days.
5. Plasma collection: According to standard blood drawing procedures, venipuncture whole blood samples should be collected with blood collection tubes containing appropriate anticoagulants, and plasma should be separated as soon as possible after blood collection to avoid hemolysis. The separated plasma should be tested as soon as possible. If it cannot be detected in time, the separated samples can be stored at 2°C~8°C for 7 days. If frozen below -15℃, samples can be stores for 6 months.
6. Fresh terminal blood of fingertips should be used immediately after collection.
7. Avoid repeated freezing-thawing of sample. Turbid sample or sample with sediment shall be tested after centrifugation or filtered to clarity.
8. Before test, sample should be in room temperature and mixed thoroughly.

REAGENT PREPARATION

1. Use immediately after open the aluminum foil bag.
2. Before test, restore the reagent to room temperature.

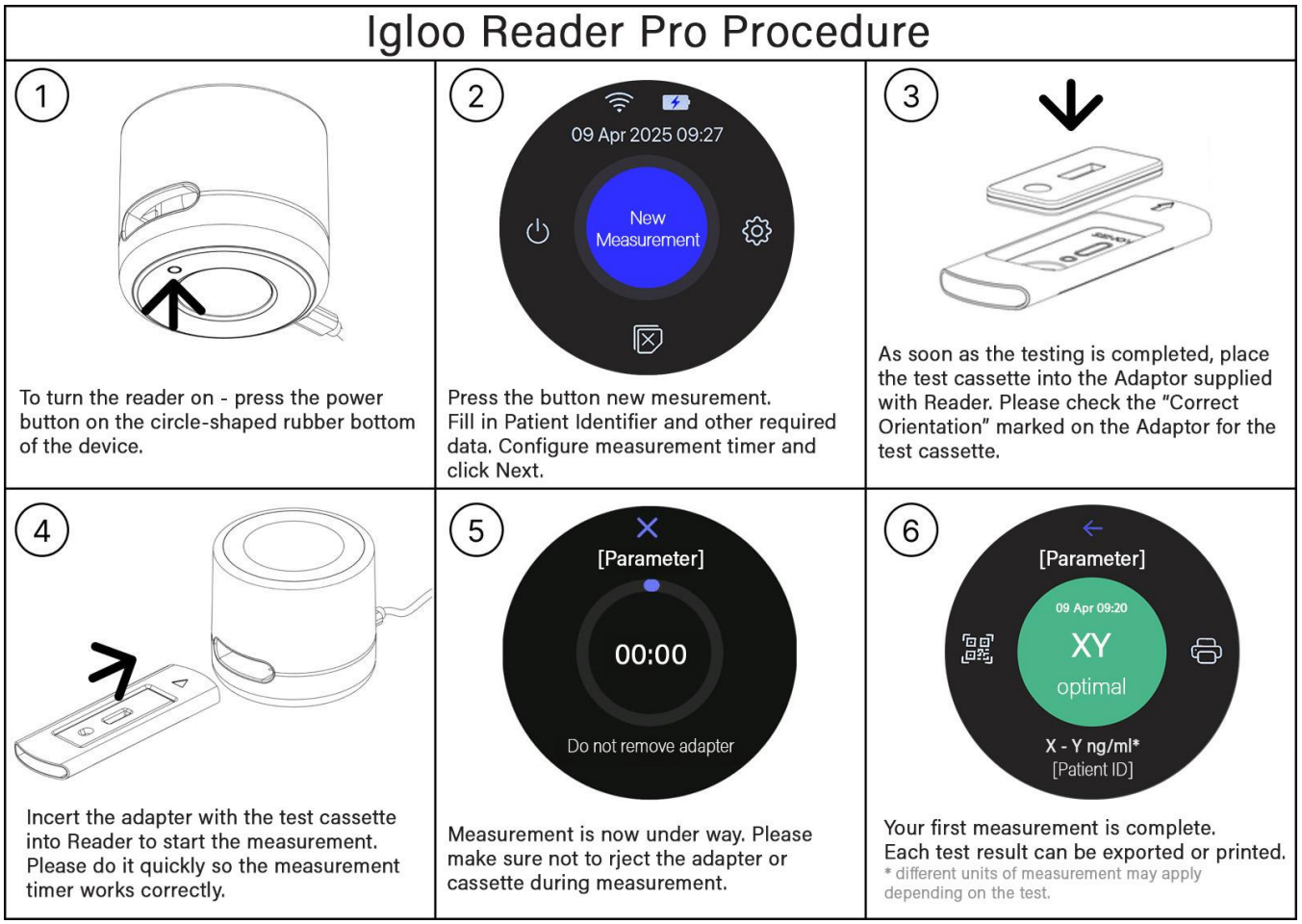
TEST METHOD

Read the instruction for use and test operation manual completely before the test and restore the reagent to room

temperature before the test. Do not perform the test without restoring the reagent to room temperature to avoid affecting the accuracy of the test results.

Drip the sample into the test device

(1) Open the aluminum foil bag package, take out the test device, and horizontally place it on examination table;
(2) Take out sample buffer, add 10μL of plasma/whole blood/fresh finger terminal blood sample, and mix well;
(3) Add 80μL of above mixed solution into the sample hole of test device;
(4) Reaction time is 10 minutes.



REFERENCE INTERVAL

1. Study of D-Dimer reference interval is conducted through referring to C28-A2 document published by US Clinical and Laboratory Standards Institute (CLSI)- How to Define and Determine Reference Intervals in the Clinical Laboratory - Second Edition and WST 402-2012 Define and Determine the Reference Intervals in Clinical Laboratory. Conduct a study of the D-Dimer reference area, the obtained reference interval of D-Dimer is: 0.5mg FEU/L.
2. Due to difference in geography, race, age etc., each laboratory is suggested to establish reference interval of D-Dimer that is suitable for local populations and has clinical significance.

INTERPRETATION OF THE RESULT

1. If the measured D-Dimer concentration of the sample is higher than the range of reference value, state such as physiological change or stress reaction should be excluded. It is indeed abnormal and should be diagnosed in combination with clinical symptoms. Above result is only for reference.
2. Test result of this method is only applicable to evaluation using the reference value established in this method

and cannot be directly compared with result of other method.

3. Other factors that may cause wrong test result include technical reason, operation error and other sample factors.

PRECAUTIONS

1. This kit can only be used for in vitro diagnosis.
2. This kit is for healthcare professionals only.
3. Before test, restore reagent and sample to room temperature.
4. This kit is disposable.
5. Do not use expired reagent.
6. Sample collection and storage must be performed in strict accordance with this instruction.
7. The reagent should be stored in strict accordance with the conditions specified in this instruction for use. Do not store the reagent under freezing condition.
8. Do not open the aluminum foil bags before test and protect the products from moisture; do not use if the aluminum foil bags are damaged or if the test reagents are wet.
9. For all components of the kit, it is recommended not to mix or interchange different batches.
10. Excessive or insufficient sample may lead to deviation of result.
11. Do not confuse sample hole with result observation window. Adding sample to result observation window will make test result invalid.
12. Test method should strictly follow the instruction for use.
13. For specific explanation of test result, analysis shall be performed in combination with clinical information.
14. The used reagent and sample shall be properly disposed as medical waste with risk of biological infection and handled safely.
15. Desiccant in aluminum foil bag is inedible.
16. Sample diluent is only used for test. Do not drink it. Wrong use may lead to biological hazard.
17. During test, test procedure, precautions and result explanation of the reagent must be followed to avoid wrong result.

PRODUCT PERFORMANCE INDEX

Evaluation performed using internal enterprise reference, that all performance indexes of this kit conform to standard. Specific performance indexes are as below:

1. Reportable range of the reagent (kit) is 0.2mg FEU/L~80mg FEU/L.
2. Linear range: Linearity of the reagent (kit) is within 0.2mg FEU/L~10mg FEU/L. Analysis performance meets the following requirement:

a) The correlation coefficient (r) of linearity should be≥0.9900

3. Accuracy: The recovery rate should be within the range of [85% ~ 115%].
4. Limit of detection: ≤0.1mg FEU/L.
5. Repeatability: CV≤15%.
6. HOOK effect: When D-Dimer concentration is ≤100 mg FEU/L, there is no HOOK effect.
7. Specificity: No cross-reaction phenomenon occurs when the following substances are tested under the shown concentration condition.

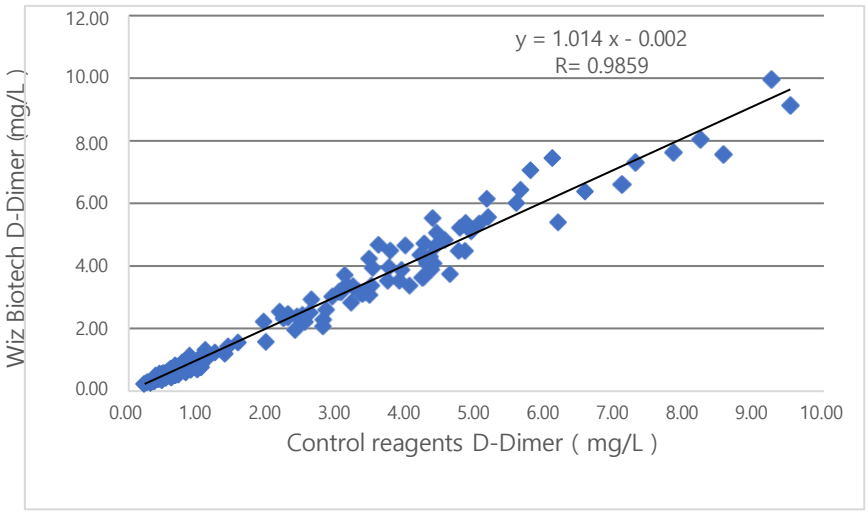
Material	Concentration	Material	Concentration
FDP	120mg/L	VC	2000mg/L
Barbituric acid	100mg/L	-	-

8. Interfering substance: Following substances are found to cause no interference when they are tested at the given concentration.

Interfering substance	Concentration	Interfering substance	Concentration
Bilirubin	2.0 mg/mL	Triglyceride	40.0 mg/mL
Hemoglobin	10.0 mg/mL	Rheumatoid factor	1500.0IU/mL

9. Clinical performance

Clinical evaluation performance of the product is assessed through collecting 148 clinical samples. Use a corresponding marketed immunoturbidimetry kit as the control reagent, and compare the test results Their comparability is studied by linear regression. The correlation coefficients of the two tests are Y=1.014X-0.002 and R=0.9859, respectively.



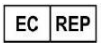
LIMITATION

1. This reagent is only used for testing of human whole blood, plasma, and fresh finger terminal blood.
2. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.
3. Test shall be carried out at normal room temperature (18℃~25℃).
4. Linearity range of the kit is 0.2mg FEU/L~10mg FEU/L. To measure accurate concentration of high-concentration sample that exceeds measurement linearity range of the kit, measurement and calculation should be performed after dilution to within the linearity range of the kit. Maximum dilution multiple of this kit under saline or sample diluent condition is 8. Reportable range is 0.2mg FEU/L~80mg FEU/L.
5. Due to low concentration of the analyte, this method cannot detect analyte, this will lead to result deviation.
6. Since some non-specific reactions or other cross reactions cannot be fully studied, false positive results may occur in this test.
7. This test has a low probability of false positive results. Therefore, all positive results must be verified by other method.
8. If the obtained result is questionable, immediately re-test or use other method to test the sample.
9. Test result of this reagent can only be used as an auxiliary means for doctor or other diagnosis. Test result should be combined with other clinical and laboratory data. If test result is not consistent with clinical evaluation, further examination will be required.

LITERATURE REFERENCES

[1] Han D, ó Hartaigh B, Lee JH, etc. Impact of D-Dimer for Prediction of Incident Occult Cancer in Patients with Unprovoked Venous Thromboembolism. PLoS One. 2016;11(4): e0153514. Published 2016 Apr 13.
[2] Lucassen WA, Erkens PM, Geersing GJ, etc. Qualitative point-of-care D-dimer testing compared with quantitative D-dimer testing in excluding pulmonary embolism in primary care. J Thromb Haemost. 2015;13(6):1004-1009.
[3] Giannitsis E, Mair J, Christersson C, etc. How to use D-dimer in acute cardiovascular care. Eur Heart J Acute Cardiovasc Care. 2017;6(1):69-80.

SYMBOLS

Symbol	interpretation	Symbol	interpretation	Symbol	interpretation
	Consult instructions for use		Tests per kit		Manufacturer
	In Vitro Diagnostic Medical Device		Use-by date		Do not re-use
	Store at 2℃～30℃		Catalogue number		Batch code
	Authorized Representative in the European Community		Caution		Biological risks
	Don't use the product when the package is damaged		Keep dry		


Xiamen Wiz Biotech Co., Ltd.
Address: 3-4 Floor, NO.16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road, Haicang District, Xiamen City, Fujian Province, 361026, P.R. China
Tel: +86-592-6808278 Fax: +86-592-6808279

EC REP Qarad EC-REP BV
Pas 257, 2440 Geel, Belgium

CE

CE-02.01-2022.04.14 EN
F1F0174
α .01 250403