EN

REF F-DDI-01

STANDARD F

D-dimer FIA

STANDARD™ F D-dimer FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

OBSAH

Test device
(individually in a foil pouch with desiccant)

STANDARD™ Ezi tube+ (10µl)

Disposable dropper (100µl)

Extraction buff er

Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- STANDARD F Analyzer

SPECIMEN COLLECTION AND PREPARATION

■ Whole blood

[Venous whole blood]

1. Collect the venous whole blood into the commercially available sodium citrate tube by venipuncture. It is recommended that collected venous whole blood specimens are used immediately. If venous whole
2. blood in an anticoagulant tube is stored at room temperature (20-25°C/68-77°F), the specimen can be used for testing within 3 hours after collection.
3. If venous whole blood in an anticoagulat tube is stored at refrigerator condition (2-4°C/36-39°F), the specimen can be used for testing within 8 hours after collection.
4. Do not use hemolyzed blood specimens.

[Capillary whole blood]

1. Capillary whole blood should be collected aseptically by fi ngertip.
2. Clean the area to be lanced with an alcohol swab.
3. Squeeze the end of the fi ngertip and pierce with a sterile lancet.
4. Collect the capillary whole blood to the black line of the capillary tube for the testing.
5. The capillary whole blood must be tested immediately after collection.

■ Plasma

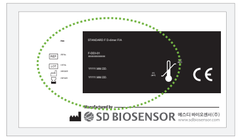
1. Collect the venous whole blood into the commercially available sodium citrate tube by venipuncture and centrifuge blood to get plasma specimen. Plasma in an anti-coagulant tube may be stored at room
2. temperature (20-25°C/68-77°F) for up to 3 hours and in a refrigerator at 2-4°C/36-39°F for up to 7 hours prior to testing.
3. For over 7 hours storage, specimens may need to be frozen under -20ºC / -4ºF for up to 24 hours.
4. It should be brought to room temperature prior to use.

- As known relevant interference, haemolytic specimen, rheumatoid factors-contained specimen and lipaemic/icteric specimen can lead to impair the test results.
- Use of pregnant and neonatal specimens may cause false-positive result.

TEST PROCEDURE

■ Preparation

1. Allow test device and collected specimen to room temperature (15-30°C/59-86°F) prior to testing.
2. Carefully read instructions for use before using the STANDARD F D-dimer FIA.
   * Check the valid expiry date at the back of the foil pouch. Do not use if the expiry date has passed.
3. Check the condition of the test device and desiccant before use.



Obal

Testovací kazetka

Žlutá: platný
Zelená: neplatný

Výsledek

Kontrolní linie se objeví na kazetce po použití.

Před použitím **Po použití**

Nepište a neponičte kód na testovací kazetě.

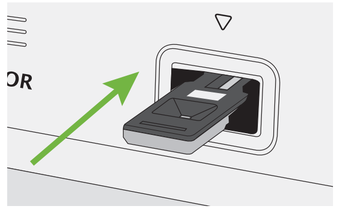
■ Analysis of specimen

STANDARDNÍ TEST **STANDARD F200 and F2400 Analyzer**

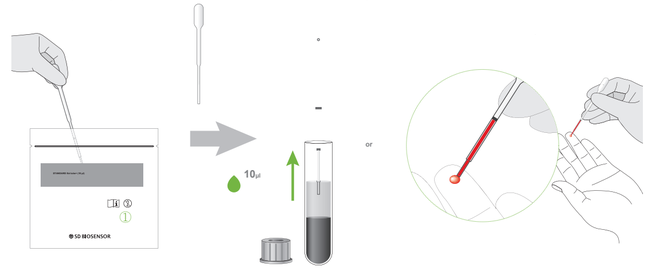
1. Prepare a STANDARD F Analyzer. Take the test device out of the foil pouch and place it on a fl at and dry surface. Write patient information on the label of test device. Select the 'Standard Test' mode according to the analyzer's manual as below.

STANDARD F2400 Analyzátor	'Workplace' → 'Run Test' → Scan or type patient ID and/or operator ID
STANDARD F200 Analyzátor	'Standard Test' mode → Insert patient ID and / or operator ID on the analyzer

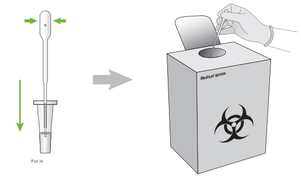
2. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer read the barcode data, and check the test device is valid.



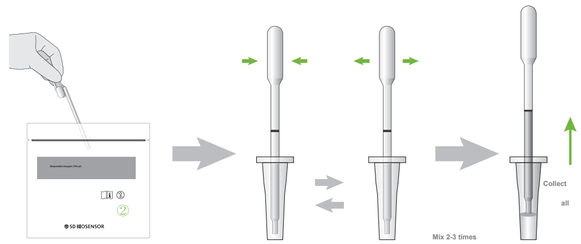
3. Collect 10µl of specimen with a STANDARD Ezi tube+(10µl) - [① labeled].



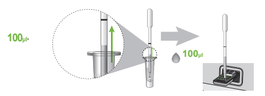
4. Dispense collected specimen into the extraction buff er tube. Then, discard the used STANDARD Ezi tube+ (10µl).



5. Mix specimen and buffer 2-3 times with the disposable dropper (100µl) - [- labeled]. Then, collect all the specimen mixture to the black line of the disposable dropper.



6. Apply 100µl of specimen mixture to the specimen well of the test device .



7. After applying the specimen, immediately press the **'TEST START'** button.

F200 F2400

8. The analyzer will automatically display the test result after 7 minutes.

PERFORMANCE CHARACTERISTICS

■ Analytical Performance

1) Accuracy (Method Comparision)

Results from two studies comparing the STANDARD™ F D-dimer FIA with an automated immunoturbidimetric method are presented at the below;

Regression Analysis		
	Whole Blood	Plasma
Slope	0.9927	0.9905
Y-intercept	8.5607	10.4267
R	0.9991	0.9988
R^2	0.9983	0.9976
n	120	120

System Accuracy		
	Whole Blood	Plasma
Below -1.96SD	0 / 120 (0%)	0 / 120 (0%)
Within ±1.96SD	119 / 120 (99.2%)	118 / 120 (98.3%)
Over +1.96SD	1 / 120 (0.8%)	2 / 120 (1.7%)

2) Analytical Sensitivity – LoB, LoD and LoQ

The analytical sensitivity [Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ)] of STANDARD™ F D-dimer FIA are shown below;

STANDARD F D-dimer FIA		
LoB	LoD	LoQ
8 ng/mL	17.5 ng/mL	25 ng/mL

3) Precision

The following precision results (within-run and day-to-day) meet the acceptance criteria of within-run CV ≤12.5%, total CV ≤12.5%(Plasma) or within-run CV ≤17.5%, total CV ≤17.5%(Whole blood);

		Within Run								
		Level 1			Level 2			Level 3		
		Site 1	Site 2	Site 3	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
Plasma	N	100	100	100	100	100	100	100	100	100
	Ref.	253	251	247	1781	1792	1806	3624	3712	3709
	AVG.	264	263	258	1841	1879	1893	3762	3936	3896
	CV (%)	7.83	7.88	7.84	8.19	7.82	8.05	8.36	7.60	8.67
	DIF (%)	4.25	4.53	4.15	3.35	4.81	4.80	3.80	6.04	5.02
Whole blood	N	100	100	100	100	100	100	100	100	100
	Ref.	261	256	254	1565	1567	1600	3829	3792	3831
	AVG.	276	269	266	1650	1627	1636	4023	4023	4026
	CV (%)	11.68	9.98	10.48	10.32	10.25	10.36	7.92	7.63	8.22
	DIF (%)	5.64	5.09	4.52	5.41	3.85	2.26	5.06	6.08	5.11

Day-to-Day									
	Level 1			Level 2			Level 3		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
N	200	200	200	200	200	200	200	200	200
Ref.	276	277	276	1861	1863	1863	3829	3792	3831
AVG.	288.3	288.5	289.8	1950	1968	1957	4023	4023	4026
CV (%)	7.94	8.39	8.05	8.50	7.96	7.85	7.92	7.63	8.22
DIF (%)	4.56	4.31	4.99	4.80	5.61	5.04	5.06	6.08	5.11

4) Cross Reactivity

STANDARD™ F D-dimer FIA does not be affected by those potential cross-reactive substances below;

Substance	Concentration
Troponin I	5.0 ng/mL
CK-MB	30 ng/mL
C-reactive protein	66 mg/L

5) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations;

Interfering Substances	Concentration
Bilirubin	< 150 µmol/L
Biotin	< 20 ng/mL
Rheumatoid factor	< 80 IU/mL
Hemolysis	< 100 mg/dL
Triglyceride	< 3.5 mmol/L

INTERPRETATION OF TEST RESULTS

Measuring Range	25 - 5,000 ng/ml FEU
Out of measuring range	- If below 25 ng/ml FEU, '25 ↓' message will be - displayed. If above 5,000 ng/ml FEU, '5,000 ↑' message will be displayed.
D-dimer Reference range	≤ 500 ng/ml FEU
Other reference value	D-dimer values < or =500 ng/ml FEU may be used in conjunction with clinical pretest probability to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE).

The D-dimer reference ranges are provided for orientational purpose only.
Clinicians should use the test results in conjunction with the patient's other diagnostic fi ndings and clinical signs and interpret the concrete values in the context of the patient's clinical situation.

EXPLANATION AND SUMMARY

■ Introduction

D-dimer is a reliable and sensitive index of fi brin deposition and stabilization. As such, its presence in specimen should be indicative of thrombus formation. There are many conditions unrelated to thrombosis in which D-dimer concentrations are high, however, making its positive predictive value rather poor. Elevated levels of D-dimer are found in patients with confi rmed deep venous thrombosis (DVT), pulmonary embolism (PE), DIC and trauma. D-dimer levels rise during pregnancy and high levels are associated with complications.

■ Intended use

STANDARD F D-dimer FIA is an *in vitro* diagnostic use to measure the D-dimer in plasma and whole blood specimen. The quantitative measurement of the D-dimer is useful in the diagnosis of evaluation of circulating derivatives of crosslinked fi brin degradation products.

■ Test principle

STANDARD F D-dimer FIA is based on the immunofl uorescence technology with STANDARD F Analyzer manufactured by SD BIOSENSOR to measure the D-dimer concentration in human specimen. The specimen from human should be processed for the preparation using the components of the STANDARD F D-dimer FIA. After applying the specimen mixture to the test device, the complex will be formed on the membrane as the result of the antigen-antibody reaction. The intensity of fl uorescence light produced on the membrane. STANDARD F Analyzers can analyze the D-dimer concentration of the clinical specimen based on a pre-programmed algorithms and display the test result on the screen.

KIT STORAGE AND STABILITY

Store the kit at 2-30°C / 36-86°F out of direct sunlight. Kit materials are stable until expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

1. STANDARD F D-dimer FIA is for *in vitro* diagnostics use only.
2. Carefully follow the instructions and procedures described in this Instructions for use before testing.
3. STANDARD F D-dimer FIA should be used with STANDARD F Analyzer.
4. STANDARD F D-dimer FIA should remain in its original sealed pouch until ready to use. Do not use the test device if pouch is damaged or the seal is broken.
5. STANDARD F D-dimer FIA is single use only. Do not re-use it.
6. Do not use hemolyzed specimens or frozen specimens.
7. Do not use any artifcial materials.
8. Place the analyzer on a flat surface when in use.
9. Wash your hands in warm and soapy water. Rinse well and dry completely before testing.
10. Discard the used test kit according to the proper method.
11. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.
12. Use a STANDARD Ezi tube+ (10µl) - [① labeled on the pouch] for specimen extraction purpose only. Do not use it as a specimen dispenser.
13. Use a Disposable dropper (100µl) - [② labeled on the pouch] for mixing the specimen and for dispensing the specimen mixture into the test device.
14. Check the expiration date printed at the pouch or package.
15. Check the volume (100µl) of extraction buffer.
16. Use the STANDARD F D-dimer FIA at room temperature (15-30°C/59-86°F).
17. All kit components are must be at room temperature (15-30°C/59-86°F) 30 minutes before running the assay.
18. Do not write on the barcode or damage the barcode of the test device.

LIMITATION OF TEST

1. The test should be used for the detection of D-dimer levels in human whole blood and plasma specimens.
2. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
3. Invalid results may occur if a poor-quality specimen is obtained.
4. The test result must always be evaluated with other clinical data available to the physician.

QUALITY CONTROL

■ Calibration

The calibration set test of STANDARD F Analyzer should be conducted according to the analyzer's manual.

[When to use calibration set]

1. Before using the analyzer for the fi rst time.
2. When you drop the analyzer.
3. Whenever you do not agree with the fi nal result.
4. When you want to check the performance of the analyzer and test device.

[How to use calibration set]
Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.
Insert the CAL-1 for white calibration, CAL-2 for UV LED calibaration, and CAL-3 for RGB LED calibration in sequence.
1. vyberte kalibrační set
2. stiskněte start
3. kalibrace je hotová.

STANDARD F analyzer automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEE' message displays on the screen, it means that the analyzer has a problem, so check with test device. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

■ Internal quality control

1. The internal procedural control zone is on the membrane of the test device. STANDARD F analyzers read the fl uorescence signal of the internal procedural control zone and decide whether the result is valid or invalid.
2. The invalid result denotes that the fluorescence signal is not within the pre-set range. If the screen of STANDARD F Analyzer shows 'Invalid', turn off and turn on the analyzer again and re-test with a new test device.

■ External quality control

Quality control testing should be run to check the performance of STANDARD F D-dimer FIA and STANDARD F Analzyer. STANDARD F D-dimer Controll manufactured by SD BIOSENSOR can be used for the external quality control. Control test should be conducted in accordance with the Instructions for use of STANDARD F D-dimer Control. External quality control test should be run:

- once for each new lot.
- once for each untrained operator.
- as required by test procedures in the Instructions for use of STANDARD F D-dimer Control and in accordance with local, state and federal regulations or accreditation requirements.

IDatum vydání: 2023.04 L28DDI1ML4R1

CE IVD

LITERATURA

1. Brill-Edward P, Lee A: D-dimer testing in the diagnosis of acute venous thromboembolism. Thromb Haemost 1999 August;82(2):688-694
2. Heit JA, Minor TA, Andrews JC, et al: Determinants of plasma fibrin D-dimer sensitivity for acute pulmonary embolism as defined by pulmonary angiography. Arch Pathol Lab Med 1999 March;123(3):235-240
3. Heit JA, Meyers BJ, Plumhoff EA, et al: Operating characteristics of automated latex immunoassay tests in the diagnosis of angiographically-defined acute pulmonary embolism. Thromb Haemost 2000 June;83(6):970
4. Bates SM, Grand'Maison A, Johnston M, et al: A latex D-dimer reliably excludes venous thromboembolism. Arch Intern Med 2001 February;161(3):447-453
5. Levi M, ten Cate H: Disseminated intravascular coagulation. N Engl J Med 1999 August;341(8):586-592
6. Feinstein DI, Marder VJ, Colman RW: Consumptive thrombohemorrhagic disorders. In Hemostasis and Thrombosis: Basic Principles and Clinical Practice. Third edition. Edited by RW Colman, J Hirsh, VJ Marder, et al. Philadelphia, PA, JB Lippincott Co., 2001, pp 1197-1234
7. Righini M, Van Es J, Den Exter PL, et al: Age-Adjusted D-Dimer Cutoff Levels to Rule Out Pulmonary Embolism: The ADJUST-PE Study. JAMA 2014;311(11):1117-1124. doi:10.1001/jama.2014.2135
8. Schouten HJ, Geersing GJ, Koek HL, et al: Diagnostic accuracy of conventional or age adjusted D-dimer cutoff values in older patients with suspected venous thromboembolism: systematic review and meta-analysis.BMJ 2013;346:f2492

SYMBOLY

REF	Reference number		Caution		Use by	LOT	Batch code		Consult Instructions for Use		Do not re-use
IVD	*In vitro* Diagnostics		Note		Manufacturer		Date of manufacture		Contains Sufficient for <n> Tests		Keep away from sunlight
	Indicate that you should keep the product dry		To indicate the temperature limitations in which the transport package has to be kept and handled.			CE	This product fulfills the requirements of the European Directive 98/79/EC.		Do not use if packaging is damaged		

EC REP **Authorized Representative**
MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7 66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021

Manufactured by SD Biosensor, Inc.
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

Please contact us for any complaints/inquiries/suggestions via email (sales@sdbiosensor.com), phone (+82-31-300-0400) or website (www.sdbiosensor.com).