Quality approved by SD BIOSENSOR / For *In vitro* use only

STANDARD F
U-Albumin FIA

REF F-UALB

STANDARD™ F U-Albumin FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

EXPLANATION AND SUMMARY

[Introduction]

STANDARD F U-Albumin FIA evaluates the quantity of a protein called albumin in human urine specimen. Albumin is normally found in the blood and filtered by the kidneys[2]. When the kidneys are working properly, albumin is not present in the urine. However, small amounts of albumin leak into the urine when the kidneys are damaged. This condition is called microalbuminuria[1-4]. Microalbuminuria is most frequently caused by kidney damage from diabetes. However, many other conditions can lead to kidney damage, such as high blood pressure, heart failure, cirrhosis, or systemic lupus erythmatosus (SLE). If early kidney damage is not treated, larger amounts of albumin and protein may leak into the urine[5,6]. This condition is called macroalbuminuria or proteinuria. When the kidneys spill protein, it can mean serious kidney damage is present. This can lead to chronic kidney disease. A urine albumin (U-Albumin) test can be done on a specimen of urine collected randomly (usually after the first time you urinate in the morning), a specimen collected over a 24-hour period, or a specimen collected over a specific period of time, such as 4 hours or overnight[7].

[Intended use]

The STANDARD F U-Albumin FIA is an *in vitro* diagnostic use to measure the albumin in the urine from the human. This test is for professional use to measure U-Albumin to aid to predict the diabetic nephropathy and cardiovascular diseases (CVD). STANDARD F U-Albumin FIA should be used with the appropriate analyzer, STANDARD F Analyzers, manufactured by SD BIOSENSOR.

[Test principle]

STANDARD F U-Albumin FIA is based on the immunofluorescence technology with STANDARD F Analyzer manufactured by SD BIOSENSOR to measure the albumin concentration in urine specimen. The specimen from human should be processed for the preparation using the components of the STANDARD F U-Albumin FIA. Albumin in urine specimen interacts with europium conjugated monoclonal anti-albumin contained in the fluorescent tablet of Spoit (Yellow) and makes complex. When applying the specimen mixture to the test device, the complex with a reaction mixture and monoclonal anti-albumin in the test device will be formed on the membrane as the result of the antigen-antibody reaction. The intensity of the fluorescence light is scanned and converted into an electric signal which is proportional to the intensity of fluorescence light produced on the membrane. STANDARD F Analyzer can analyze the albumin concentration of the clinical specimen based on a pre-programmed algorithms and display the test result on the screen.

[Kit contents]

① Test device (individually in a foil pouch with desiccant and Spoit™) ② Extraction buffer ③ Instructions for use

[Materials required but not provided]

- STANDARD F Analyzer

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 U-Albumin FIA is only use for *in vitro* diagnostic.
2. Carefully follow instructions and procedures described in this instructions for use before testing.
3. STANDARD F U-Albumin FIA should be used with STANDARD F Analyzer.
4. STANDARD F U-Albumin FIA should remain in its original sealed pouch until ready to use. Do not use the test kit if the pouch is damaged or the seal is broken.
5. STANDARD F U-Albumin FIA is only single use. Do not re-use it.
6. Do not use any artificial materials.
7. Before testing, check the fluorescent tablet of Spoit (Yellow) if it is not contaminated or broken.
8. Place the analyzer on a flat surface when in use.
9. Wash your hands in warm, soapy water. Rinse well and dry completely before testing.
10. Discard the used test kit according to the proper method.
11. Mix the human urine specimen and extraction buffer well. And then, collect all of the mixed solution.
12. Check the expiration date printed at the pouch or package.
13. Human urine specimen, fluorescent tablet and extraction buffer should be well mixed by using the rubber at the top of the Spoit. And then, immediately apply the specimen at the test device within 1 minute at least.
14. Use the STANDARD F U-Albumin FIA at 15-32°C / 59-90°F.
15. Mix well to avoid bubble forming and do not put bubbles in the specimen well of the test device.
16. All kit components are must be at room temperature (15-30°C/59-86°F) at least 30 minutes before running the assay.
17. Do not write on the barcode or damage the barcode of the test device.

SPECIMEN COLLECTION AND PREPARATION

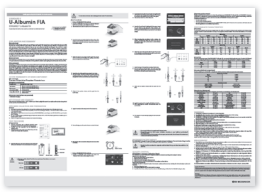
[Urine]

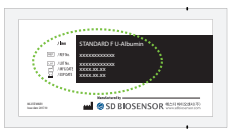
1. Urine specimens should be collected in a clean and dry container and collected at any time of the day may be used.
2. Urine specimen may be stored at room temperature (15-30°C/59-86°F) for up to 3 days or at 2-8°C/ 36-46°F for up to 2 weeks prior to testing.
3. For prolonged storage, specimens may be frozen and stored at -40°C/ -40°F. The frozen specimens are stable up to 3 months at -40°C/ -40°F.
4. Frozen urine specimens should be thawed and fully mixed before testing.
5. If the urine specimen exhibits visible precipitates, it should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

TEST PROCEDURE

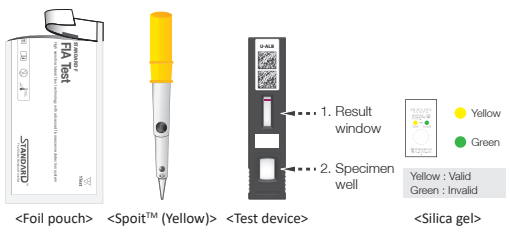
[Preparation]

1. Allow kit components and collected specimen to room temperature (15-30°C/ 59-86°F) at least 30 minutes before starting the test.
2. Carefully read instructions for the STANDARD F U-Albumin FIA.
3. Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.





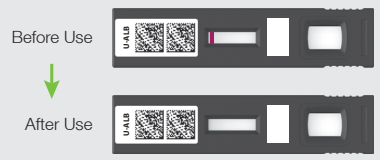
4. Open the foil pouch, and check the test device and a Spoit (Yellow) with anti-albumin fluorescent tablet in the foil pouch.



<Foil pouch> <Spoit™ (Yellow)> <Test device> <Silica gel>

CAUTION

- If there is no violet colored Check Band on membrane of test device, do not use it.
  * Check Band



CAUTION

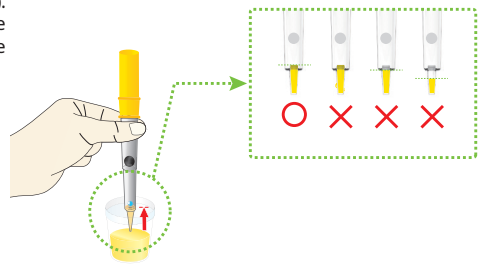
- Do not write on the barcode or damage the barcode of the test device.

[Analysis of specimen]

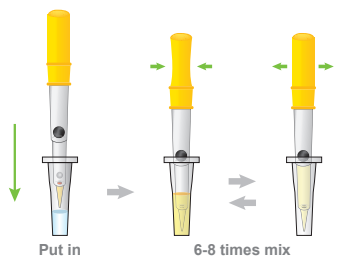
- **Using a 'STANDARD TEST' mode**
  - **Applying STANDARD F100, F200 or F2400 analyzer**

1. Prepare a STANDARD F Analyzer and select the 'Standard Test' mode according to the analyzer's manual. In case of STANDARD F2400 analyzer, go to the 'Workplace' in the main screen. And select the 'Run Test'
2. In case of STANDARD F200 and F2400 analyzer, input patient ID and/or operator ID on the analyzer.
3. Take the test device out of the foil pouch.
4. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and validate the test device.

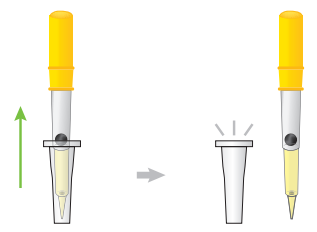
5. Collect the 3µl of urine specimen with the Spoit (Yellow). The specimen will be collected automatically by the capillary action when the end of Spoit is put on the specimen.



6. Insert the edge of the Spoit into an extraction buffer tube. Mix the specimen, fluorescent tablet, and extraction buffer by carefully pressing and releasing the rubber at the top of the Spoit for 6-8 times. Mix well to avoid bubble forming.



7. Collect all the specimen mixture with the Spoit from the tube.



8. Apply the specimen mixture at the specimen well of the test device.

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

<F100> <F200> <F2400>

10. The analyzer will automatically display the test result within 5 minutes.

Read
After 5 mins

CAUTION

- Do not put bubbles in the specimen well of the test device.
- Discard the used test kit in proper container, according to your healthcare professional's recommendation.
- If you feel the test result is inaccurate or do not agree your test result, do not change the treatment and contact your healthcare professional.

NOTE

- The mark on the label between specimen well and result window is scanned by the STANDARD F Analyzer and displayed on the screen.

INTERPRETATION OF TEST RESULTS

The STANDARD F U-Albumin FIA can measure U-Albumin concentration between 5.0-250mg/L. If the result is below 5.0mg/L, it will be reported as "↓5.0mg/L". If the result is above 250mg/L, it will be reported as "↑250mg/L".

CAUTION

- Results should be considered in conjunction with the clinical history and other data available to the physician.
- If an error message appears on the analyzer's screen, refer to the analyzer's manual.

[Reference Range]

UAC (mg/L)	Interpretation of results
〈 20mg/L	Normal
20~200mg/L	Microalbuminuria
〉200mg/L	Macroalbuminuria

QUALITY CONTROL

[STANDARD F Analyzers Calibration Check]

The calibration set test of STANDARD F Analyzers should be conducted according to the analyzers' manual.

When to use calibration set

1. Before using the analyzer for the first time
2. When you drop the analyzer
3. Whenever you do not agree with your result
4. When you want to check the performance of an 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.

1. Select the 'Calibration' menu.
2. The specific calibration set is included with the analyzer.
3. Insert the CAL-1 first, and then insert the CAL-2 for UV-LED testing and the CAL-3 for RGB-LED testing in order.

NOTE

- The 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 CAL devices. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

[External quality control]

Quality control testing should be run to check the performance of STANDARD F U-Albumin FIA and STANDARD F Analyzers. STANDARD F U-Albumin Control manufactured by SD BIOSENSOR should be used for quality control testing. Control test should be conducted in accordance with instructions of STANDARD F U-Albumin Control.

Control test should be run:

- once for each new lot.
- once for each untrained operator.
- as required by test procedures in instructions of STANDARD F U-Albumin Control and in accordance with local, state and federal regulations or accreditation requirements.

PERFORMANCE CHARACTERISTICS

[Precision]

The precision evaluation was done at 3 hospital sites. The within-run using the 3 levels of urine specimens and the Day-to-Day using the 2 levels of control materials for 20 days. The acceptance criterion is within 7% (CV) for both within-run CV and total-run CV.

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
Ref.	23.1	22.2	23.3	127	123	123	223	226	226
AVG.	24.7	23.7	25.0	135	131	131	236	241	240
CV (%)	4.1	4.9	4.5	4.5	4.5	4.1	4.7	4.2	4.6
Diff (%)	6.9	6.9	7.2	6.5	6.8	6.9	5.6	6.8	6.3

Day-to-Day						
	Level 1			Level 2		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
Ref.	25.4	25.6	25.3	223	222	224
AVG.	27.2	27.3	27.1	236	236	237
CV (%)	3.5	3.8	3.5	3.9	3.7	3.6
Diff (%)	6.9	6.6	6.9	5.8	6.0	6.1

[Linearity]

To set the measuring range of the STANDARD F U-Albumin FIA, we evaluated the linearity test using 13 points (4.0-300mg/L) and 3 LOTs comparing the reference equipment. The measuring range of the STANDARD F U-Albumin FIA is 5.0-250mg/L.

	LOT 1	LOT 2	LOT 3
Slope	0.9938	0.9843	0.9981
Intercept	0.0379	1.4103	1.2116
R	0.9978	0.9963	0.9964
R^2	0.9955	0.9927	0.9928

[Accuracy (Method comparison)]

Results comparing the STANDARD F U-Albumin FIA with the reference method are presented at the below;

Regression Analysis	
Slope	0.9941
Y-intercept	0.2120
R	0.9991
R^2	0.9983
N	210

System Accuracy	
below -1.96SD	3/210 (1.4%)
within ±1.96SD	200/210 (95.2%)
over 1.96SD	7/210 (3.3%)

[Interfering Substances]

The following materials with up to the indicated concentration do not interfere with the test result.

Acetaminophen	30 mg/dL	IgA	50 mg/dL
Acetone	240 mg/dL	Hemoglobin	50 mg/dL
Bilirubin	5 mg/dL	Ascorbic acid	250 mg/dL
Creatinine	700 mg/dL	Calcium	200 mg/dL
Glucose	900 mg/dL	Ibuprofen	0.5 mg/dL
Sodium chloride	2900 mg/dL	Urobilinogen	50 mg/dL
Sodium nitrate	85 mg/dL	Uric acid	150 mg/dL
Urea	20000 mg/dL	Furosemide	80 mg/dL
Myoglobin	50 mg/dL	Trichloromethiazide	5 mg/dL
β-microglobin	25 mg/dL	Glybenclamide	3 mg/dL
IgG	50 mg/dL	Metformin HCL	0.8 mg/dL

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Product Disclaimer

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning

The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

CE IVD

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IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
To indicate the temperature limitations in which the transport package has to be kept and handled.
Note
Do not re-use.
Use by
LOT Batch code
Manufacturer
Date of manufacture
CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices