In Vitro Diagnostics
Certification No. 226ADAMX00212000
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This package insert must be read carefully prior to use.

Human L-type fatty acid-binding protein (L-FABP) assay kit
(Classification No.: 84051000)

NORUDIA L-FABP

General Precautions

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. For the effects of an administered drug on the measured value, carefully read the Precautions for Use in the package insert of the drug, especially the section about the effects on laboratory test results.
4. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
5. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
6. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
7. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components)

Component: Ingredients
L-FABP Buffer Solution 1
L-FABP Latex Reagent 2:
Anti-human L-FABP mouse monoclonal antibody-coated latex※

※ Anti-human L-type fatty acid-binding protein mouse monoclonal antibody-coated latex

Intended Use

Measurement of L-type fatty acid-binding protein (L-FABP) in urine

Urinary L-FABP levels are considered to reflect the severity of renal tubular dysfunction, thus being useful for evaluation of peritubular microcirculatory disturbance (ischemia),[1] staging of diabetic nephropathy and evaluating of the treatment effects,[2] assessment of the risk of severe acute kidney injury (AKI) [3], and prediction of contrast nephropathy .[4]

Assay Principle

1. Assay Principle

In samples, an antigen-antibody reaction occurs between L-FABP and anti-human L-FABP mouse monoclonal antibody-coated latex , resulting in aggregation of the latex. The L-FABP concentration in the sample is determined by measuring the aggregation as the change of absorbance.

2. Features

1) Liquid reagents, ready-to-use.
2) Applicable to various automated analyzers.

Procedural Precautions

1. Properties of Samples and Sampling Methods

1) Samples

Use spot or pooled urine as the sample. However, do not use acidic urine or pooled urine containing toluene as the sample, because the measurement system will be affected.

Measure spot and pooled urine samples immediately after collection.

If suspended matter is seen in the sample, centrifuge the sample (500*g* for 5 minutes[5]) and use the supernatant.

2) Storage of samples

If the sample cannot be measured immediately after collection (after completion of collection if the sample is pooled urine), store it in a refrigerator or freezer as soon as possible. Measure refrigerated samples within 1 day of collection. Measure frozen samples immediately after thawing and mixing the sample at room temperature or in a water bath. It has been confirmed that samples are stable for 1 year when stored at -80°C and for 2 weeks when stored at -30°C. Avoid freezing and thawing the sample more than once.

2. Interfering substances[7]

Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), hemoglobin (up to 500 mg/dL), or glucose (4000 mg/dL). Depending on the sample, ascorbic acid may affect the assay results when present at a concentration of approximately 100 mg/dL.

3. Others

1) Always use L-FABP Calibrator for multipoint calibration.
2) Precautions for assay range

If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

3) It is known that urinary L-FABP may increase after administration of an angiography contrast medium.[4]

Dosage/Administration (Assay Procedure) * * *

1. Preparation of reagents

Reagent (1): L-FABP Buffer Solution 1 is ready to use.

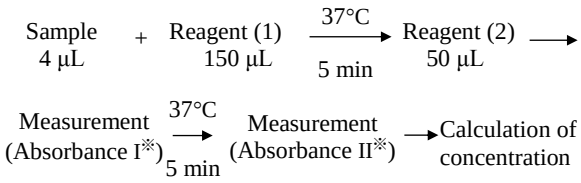
Reagent (2): L-FABP Latex Reagent 2 is ready to use.

Before using this product, gently invert the L-FABP Latex Solution 2 bottle to mix it

thoroughly, and check that there are no bubbles.

2. Assay Procedure

This product is compatible with various types of automated analyzer. An example of the assay procedure is indicated below.



※Absorbance I and II: The difference in absorbance between the dominant wavelength (570 nm) and the complementary wavelength (800 nm).

Calibration material: L-FABP Calibrator (manufacture's assigned value)

Reagent blank: Saline

Assessment of Assay Results

1. Correction of assay results

Correct the assay results for the urinary creatinine level, and calculate the amount of L-FABP (μg/gCr) per g of urinary creatinine.

2. Reference standard range

The reference range was calculated from the urinary L-FABP levels in 412 healthy volunteers, and was been reported to be ≤ 8.4 μg/gCr.[6]

3. There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance ＊＊

1. Sensitivity

a) The absorbance of physiological saline is 0.0459 or less.

b) The absorbance per 5 ng/mL of L-FABP is ≥ 0.0048 (L-FABP 4–6 ng/mL).

2. Accuracy: 85–115 % of the expected assay value

3. Within-run Reproducibility:

Coefficient of variation ≤ 15 %

(Test methods used for 1.–3. are in-house methods.)

4. Measurement Range[7]: (On Hitachi 7180 automated analyzer)

1.0–200 ng /mL

5. Correlation[7]

Sample: Spot and pooled urine

Control method: Approved in vitro diagnostic

Control method (1): Enzyme immunoassay

N=87 r=0.979 y=1.04x–2.32

Control method (2): Enzyme immunoassay

N=67 r=0.984 y=1.02x–1.32

6. Standard Material

Recombinant Human L-FABP Protein (in-house reference standard)

Precautions for Use or Handling ＊

1. Precautions for Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.

2) Proclin 300, which possesses skin-irritative potential, is added as an antiseptic agent in the L-FABP Buffer Solution 1 and L-FABP Latex Reagent 2. Therefore, if the reagent comes in contact with skin or clothes, rinse immediately with ample water, and consult the doctor if skin irritation develops.

2. Precautions for use

1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.

2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.

3) Do not replenish the reagents.

4) Do not combine L-FABP Buffer Solution 1 and L-FABP Latex Reagent 2 with different lot numbers on the outer box.

5) Do not perform the assay under direct sunlight

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121 ºC for 20 minutes.

2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.

3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.

4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.

4. Other precautions

Do not use the containers for other purposes.

Storage and Shelf Life ＊

1. Storage temperature: 2–10 °C

2. Shelf life: 1 year from the date of manufacture

(The expiration date is printed on the outer package.)

Packaging

Name		Package
NORUDIA L-FABP	L-FABP Buffer Solution 1	1 × 18 mL
	L-FABP Latex Reagent 2	1 × 7 mL

Constituent reagents are available in other configurations. For further details please contact SEKISUI MEDICAL CO., LTD.

References

1) Sugaya K. et al.: Modern Physician, 28(8), 1159, 2008.

2) Ikemori A. et al.: J Jpn Soc Clin Chem, 43(1), 20, 2014.

3) Matsui K. et al.: Circ J, 76(1), 213, 2012.

4) Nakamura T. et al.: Am J Kidney Dis, 47(3), 439,

2006.
5) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 33th ed. 130, 2010.
6) Kamijo A. et al.: Diabetes care, 34(3), 691, 2011.
7) In house data, SEKISUI MEDICAL CO., LTD.

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