Assay Procedure

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

Sample (urine*) 4 μL + R1 150 μL → 37℃ approx. 5 min → R2 50 μL → 37℃ approx. 50 sec → measurement 1 (absorbance 1**)
→ 37℃ approx. 4 min → measurement 2 (absorbance 2**)
→ Concentration Calculation

* Spot or pooled urine(No acidified pooled or toluene-preserved urine)
** The difference in absorbance between 570 nm and 800 nm.
Calibrator: L-FABP Calibrator(Manufacture's assigned value)
Reagent blank: Saline

Basic Performance Data

(Example : Hitachi 7180)

Within-run Reproducibility

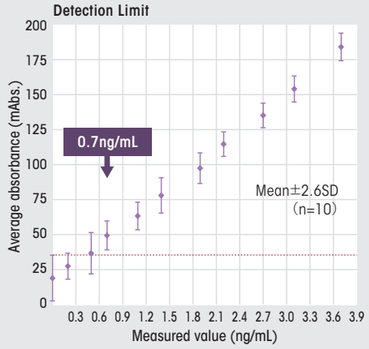
	Measurement Value (ng/mL)		
	Level 1	Level 2	Level 3
N	10	10	10
Mean	4.1	51.7	118.7
S.D.	0.08	0.26	0.71
CV(%)	1.94	0.51	0.60
Max.	4.2	52.0	120.0
Min.	4.0	51.1	117.9

Interference

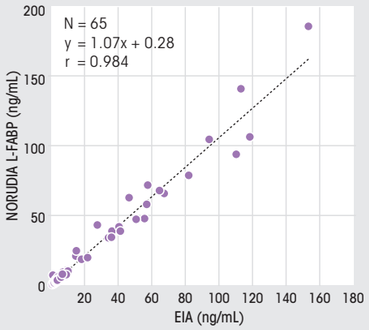
	added volume	measured value (ng/mL)	
		Without interferent	With interferent
Bilirubin F	20 mg/dL	4.7	4.9
		46.1	44.7
Bilirubin C	20 mg/dL	5.1	4.9
		47.8	46.1
Hemoglobin	500 mg/dL	4.4	4.7
		44.8	46.3
Chyle	2400 Formazin Turbidity Unit	4.6	4.4
		46.1	42.4
Glucose	4000 mg/dL	5.3	4.9
		49.4	47.8
Ascorbic acid*	100 mg/dL	4.4	4.8
		44.7	45.2

* Ascorbic acid may interfere with the L-FABP assay from around 100 mg/dL depending on the sample.

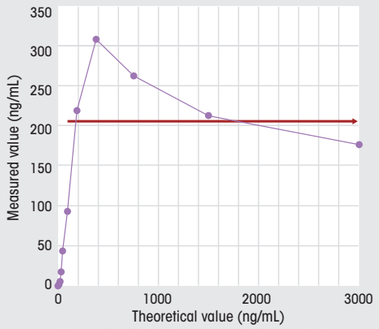
Detection Limit



Correlation



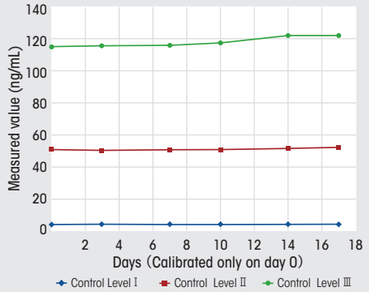
Prozone



* Parameters to check for prozone effect are required.

On-board Stability

Please note the On-board stability may differ depending on the type of analyzer and measured environment. When use of this product please preform accuracy control, and calibrate as necessary.



Measurement Range	1.0～200 ng/mL(Hitachi 7180)
Assessment of Assay Results	1. The assay range is calculated using the L-FABP concentration (μg/gCr) within 1 g of Urine Creatinine, and corrected with the Urine Creatinine value. Conversion Formula: L-FABP (μg/gCr) = L-FABP (ng/mL)/Cr (mg/dL) × 100 2. Reference Range: 8.4 μg/gCr and below (Ref: Kamijo A, et al. Diabetes Care 34 (3), 691, 2011)

For more information contact:

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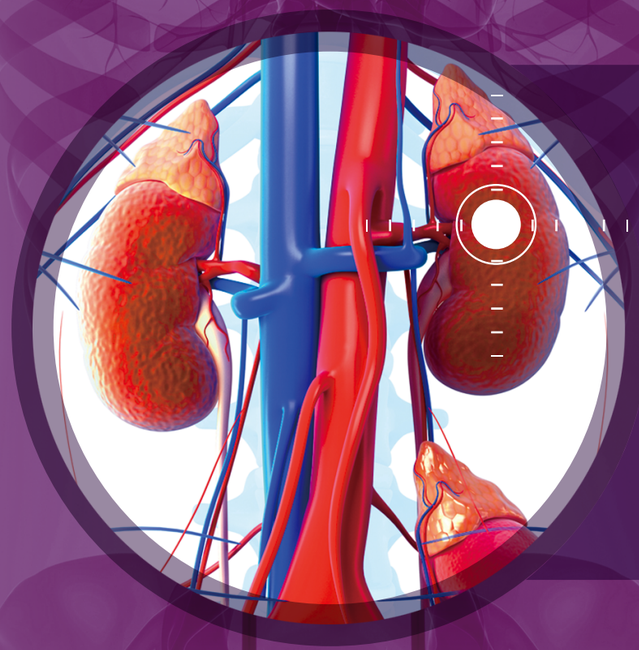
LF-103
1808 JBA1000

Liver - type Fatty Acid Binding Protein (L-FABP) Reagent

NORUDIA L-FABP



For the early detection of kidney injury

Features

1. Ready-to-use liquid reagent
2. Applicable to various automated analyzers

Reagent Kit

Name	Assay Principle	Package		Storage
NORUDIA L-FABP	Latex Agglutination Turbidimetry	L-FABP Buffer Solution 1	1 bottle × 18 mL	2℃ – 10℃
		L-FABP Latex Reagent 2	1 bottle × 7 mL	

Sold Separately

Name	Package	Storage
L-FABP Calibrator	5 concentrations × 1.0 mL	2℃ – 10℃
L-FABP Control	2 concentrations × 1.0 mL × 3 vials each	

Other package sizes are available upon request

SEKISUI MEDICAL CO., LTD.

Marker for the early stage detection of kidney injury

What is L-FABP ?

- A fatty acid binding protein found in the renal proximal tubule
- Excreted in the urine due to oxidative stress or renal tubule ischemia before kidney injury
- A useful marker for the early diagnosis of renal disease that involves tubular disorder

Conventional Renal Disease Markers

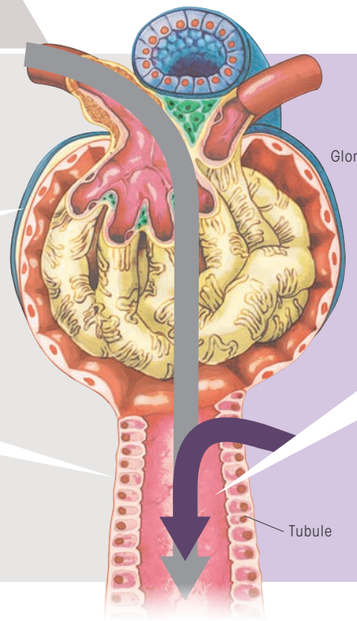
Mainly reflects signs of Renal Dysfunction

Glomerular injury
↓
Failure of filtration function
↓
Albumin, Type IV collagen

Tubular reabsorption dysfunction
↓
α1-MG, β2-MG

Injury/Inflammation of renal tubule
↓
NAG

Reflects the **RESULT** of Kidney Injury



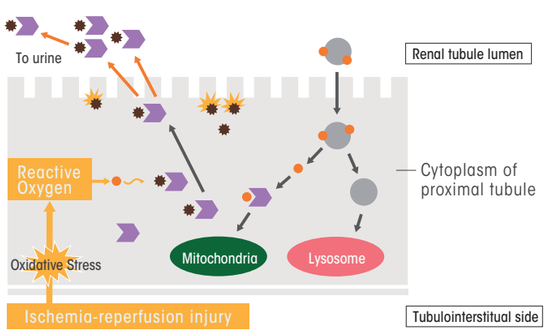
L-FABP

Reflects signs of stress on to renal tubule before cytotoxicity

Renal tubule ischemia
↓
Oxidative stress
↓
Excretion of L-FABP

Reflects the **CAUSE** of Kidney Injury

L-FABP Urinary excretion within the proximal tubule cytoplasm



L-FABP　Albumin　Lipid peroxides　Free fatty acid

1. Reactive oxygen, generated due to peritubular ischemia/reperfusion injury, changes free fatty acids to lipid peroxides which are highly toxic to cells.
2. L-FABP binds with these lipid peroxides and is excreted outside of cells. Thus, it is thought that L-FABP is "renoprotective", and works to protect the kidneys.

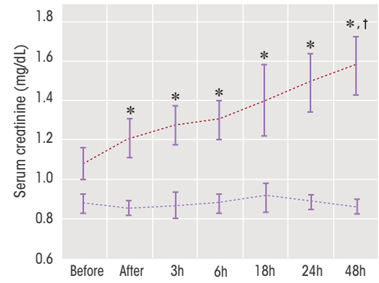
↓

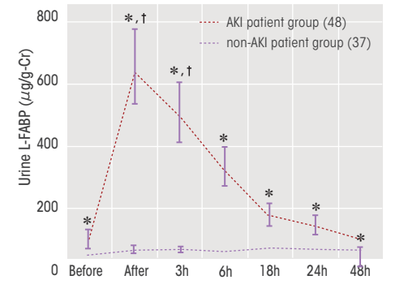
Urinary L-FABP values reflect the level of stress given to the kidneys

Acute Kidney Injury (AKI) - Prediction of onset

Process: 85 cardiovascular surgery patients were divided into AKI and non-AKI cohorts based on the AKIN criteria. Urine L-FABP and Serum CRE were measured immediately before and at several after points surgery.

Results: With the conventional AKI diagnosis method which uses serum creatinine as an indicator, AKI symptoms were confirmed 24 hrs after surgery. However, Urine L-FABP shows a significant increase within the AKI patient cohort immediately after surgery. This indicates that Urine L-FABP is a useful marker for predicting AKI at an early stage.





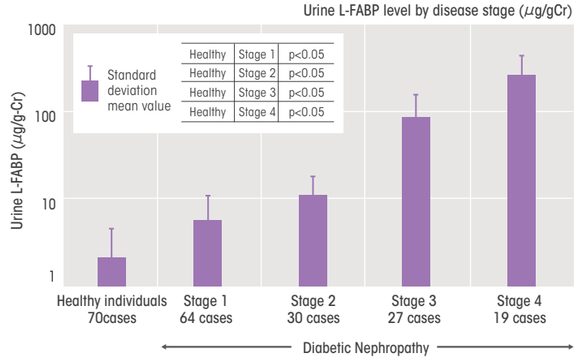
∗:p < 0.05 [vs.non-AKI]　†:p < 0.05 [vs. before surgery]

Katsuomi Matsui,et al.Circulation Journal 76:213-220,2012

Diabetic Nephropathy - Early stage diagnosis

Process: The Urine L-FABP levels of 140 Diabetic nephropathy patients were subdivided based on disease stage. The mean and standard deviation values were calculated and compared to those of healthy individuals.

Results: The Urine L-FABP levels of Diabetic nephropathy patients increased with the progress of disease stage. As it shows a significant increase compared to healthy individuals even from the early stages of nephropathy, it can be inferred that L-FABP has utility in the early diagnosis of Diabetic nephropathy.

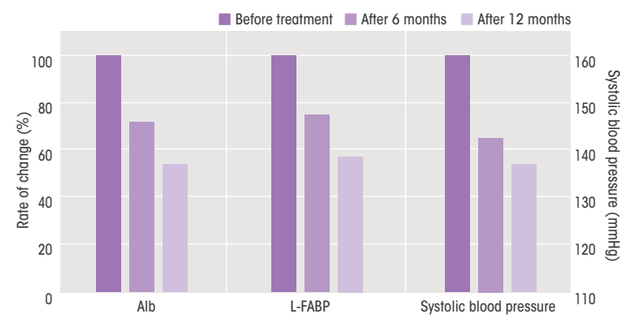


Based on Kamijo-Ikemori A,et al.Diabetes Care 34:691-696,2011

Chronic Kidney Disease - Monitoring and assessment of treatment

Process: Diabetic nephropathy patients with microalbuminuria were given ARB for 12 months. The Urine Albumin levels, Urine L-FABP levels, and systolic blood pressure were monitored to deternire the effects of medical treatment.

Results: Large decrease of Urine Albumin levels, Unine L-FABP levels, and systolic blood pressures were observed after 6 months and 12 months when compared to the start of treatment. Similar to Urine Albumin, Urine L-FABP is effective for the monitoring and assessment of treatment, such as antihypertensive therapy for early-stage diabetic nephropathy.



Tsukasa Nakamura,et al.Diabetologia 50(2):490-492,2007