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Pharmaceutical Value Creator

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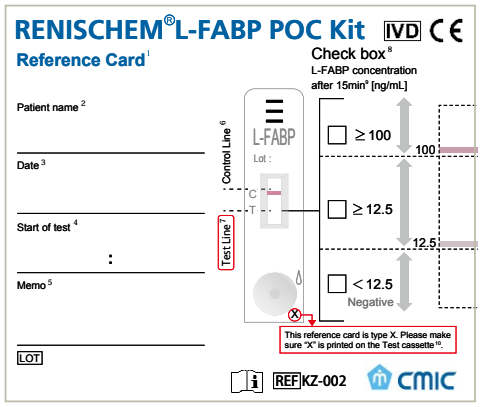
FOR EARLY DETECTION OF ISCHEMIC EVENTS ON **ACUTE KIDNEY INJURY**

RENISCHEM®
L-FABP POC Kit



Assay specifications

Size:	10 test kits
Intended User:	Lab professional
Store Temperature:	1-30°C
Method:	Immunochromatographic test for detection and semi-quantitative determination
Sample:	Human urine
Assay time:	15min.
Shelf life:	18 months
Reference range:	L-FABP < 12.5ng/mL L-FABP ≥ 12.5ng/mL- and < 100 ng/mL L-FABP ≥ 100 ng/mL

Kit components

Aluminum Pouch	x 10
Reference Card	
Instruction For Use	

In Aluminum Pouch

L-FABP Test Cassette	x 1
Pre-treatment Micro Tube	x 1
Dropper	x 1
Dry Sheet	x 1

L-FABP BIOMARKER WEBSITE OPENED!

fabp web search

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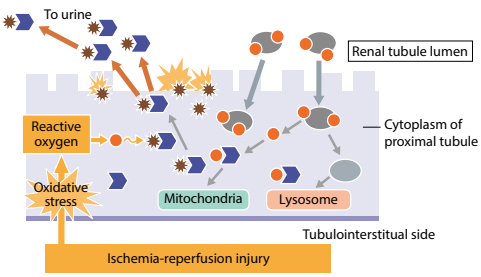
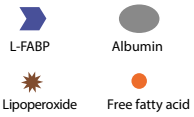
L-FABP excretion of mechanism

Free Fatty Acids (FFAs) are bound to serum albumin filtered through glomeruli and reabsorbed into the proximal tubule along with albumin. FFAs up-regulate the expression of L-FABP gene. L-FABP, a carrier protein or 14kDa expressed in the proximal tubule plays a role in the intracellular transport of FFAs to mitochondria and/or peroxisomes for metabolism.

Lipoperoxides are accumulated in proximal tubules during renal ischemia/re-perfusion. L-FABP is excreted from the proximal tubules into urine by binding these cytotoxic lipids.



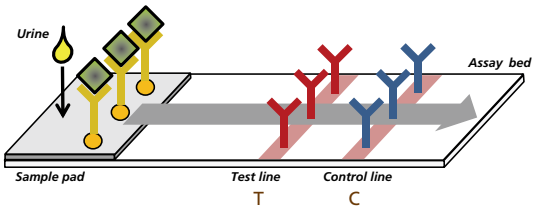


Reactive oxygen generated due to peritubular ischemia/reperfusion injury change free fatty acids to fatty acid peroxides(lipoperoxides), which are highly toxic to cells.
L-FABP binds with these lipoperoxides, and is excreted outside of cells. Thus, it is thought that L-FABP is "renoprotective"—it works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

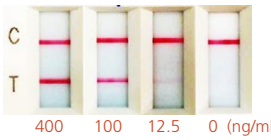
PRINCIPLE

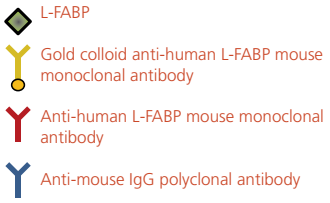
RENISCHEM® L-FABP POC Kit is an immunochromatographic test for detection and semi-quantitative determination of L-FABP. Urinary L-FABP levels can be visualized within 15 minutes after the specimen is added to the sample pad. L-FABP in the urine samples reacts to a gold colloid anti-human L-FABP mouse monoclonal antibody (CloneL), forms an antigen-antibody complex, move through the membrane by a capillarity action, and reacts to the anti-human L-FABP mouse monoclonal antibody on the Test Line (Clone2), visualizing a burgundy color. RENISCHEM® L-FABP POC Kit allows semi-quantitative measurement by comparing the color density of Test Line with that on reference card.

Additionally, the gold colloid anti-human L-FABP mouse monoclonal antibody (CloneL) moves further on the membrane and binds with the anti-mouse IgG polyclonal antibody on the Control Line, visualizing a burgundy color. This line is an index for checking that the test is performed properly.



Urinary L-FABP level displayed on testline





Accuracy of test

As shown in Table 1, this product shows strong correlation with L-FABP ELISA (CE-marked). The concordance rate is 92.6% (125/135).

※The reference range, which are determined by the distribution of urinary L-FABP corrected by urinary creatinine levels in 431 healthy adults is 8.4ug/gCr or below. The quantitative assay kit for L-FABP, RENISCHEM®L-FABP ELISA kit was used for the trial. The reference range of urinary L-FABP concentration, which is not corrected by urinary creatinine levels, is 10.1ng/mL or below.

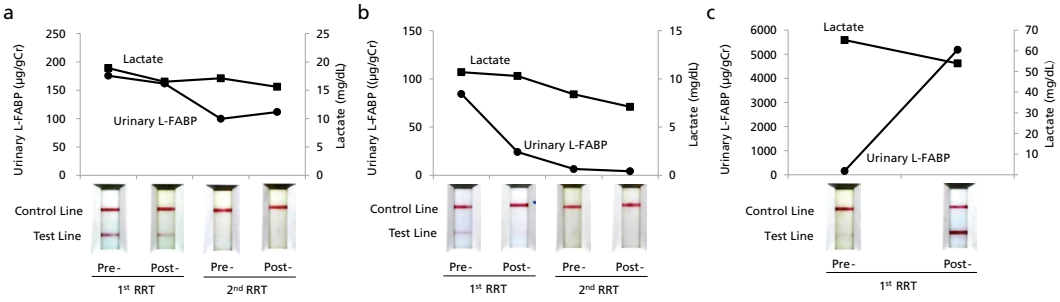
Table 1 Results of correlation test

Urine		RENISCHEM® L-FABP POC Kit			Total
		<12.5	≥12.5, <100	≥100	
RENISCHEM®	<12.5	62	1	0	63
	≥12.5,<100	6	32	0	38
	≥100	0	3	31	34
Total		68	36	31	135

Clinical evaluation

Clinical evaluation of L-FABP POC kit was performed in renal replacement therapy (RRT) setting. The POC kit and ELISA were performed on urine samples from 3 patients who were admitted to the ICU at Shinmatsudo Central General Hospital (Chiba, Japan) as critically ill patient with sepsis. The lactate level which was described as the new criteria of sepsis in third international consensus definition for sepsis and septic shock (Sepsis-3) was also evaluated at pre- and post-RRT by the blood gas analyzer. As a result, lactate (mg/dL) and urinary L-FABP/creatinine (μg/gCr) were decreased in 2 patients after RRT. The results of POC kit were assessed as score 3: 100 ng/mL at Pre-1st RRT, and as score 1: < 12.5 ng/mL at Post-2nd RRT (Figure 1a, b). These 2 patients discharged from the hospital. In another patient, the lactate level was decreased slightly, whereas the urinary L-FABP was increased in a patient after RRT. Also, the result of POC kit was assessed as score 2: ≧12.5 ng/mL and <100 ng/mL at Pre-RRT, and as score 3: ≧ 100 ng/mL at Post-RRT (Figure 1c). The patient died after 3 days of RRT. Thus, when the score of POC kit for urinary L-FABP and lactate level were decreased in the patients after RRT, the patient tends to improve the condition. On the other hand, when the score of POC kit and lactate were sustained high level in the patient even after RRT, the patient tends to deteriorate the condition. Therefore, these results suggested that POC kit for urinary L-FABP can be useful to evaluate therapeutic efficacy of RRT in sepsis patient.

Figure 1 Correlation between the ratio of urinary L-FABP to urinary creatinine, POC kit results and lactate levels in RRT treated patients. Urine samples from 3 patients who were admitted to the ICU were measured with the ELISA test and POC kit. The test lines obtained with the POC kit were scored using three-score method. Lactate levels measured by the blood gas analyzer. 2 patients discharged from the hospital (a, b). Another patient died after 3 days of RRT. (c).



[Contact]

[Manufacturer]

CMIC HOLDINGS Co., Ltd.

Address: Hamamatsucho Bldg., 1-1-1 Shibaura, Minato-ku, Tokyo 105-0023, JAPAN

URL: https://www.cmicgroup.com/e/

E-mail: l-fabp@cmic.co.jp

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