

Revision Date 01-Jul-2018 (ver.2)

SAFETY DATA SHEET

High Sensitivity Human L-FABP ELISA Kit

A kit for the quantitative determination of human L-FABP in urine

1. PRODUCT AND COMPANY IDENTIFICATION

| | |
|---|--|
| Product name : | High Sensitivity Human L-FABP ELISA Kit A kit for the quantitative determination of human L-FABP in urine |
| | KIT COMPONENT : |
| | ① L-FABP Antibody Coated Microplate |
| | ② Pretreatment Solution |
| | ③ Assay Buffer |
| | ④ The 2nd Ab-POD Conjugate |
| | ⑤ Substrate Solution |
| | ⑥ Wash Agent (×40 concentrate) |
| | ⑦ Stop Solution |
| | ⑧ Standard Diluent (0ng/mL) |
| | ⑨ L-FABP Standard (400ng/mL) |
| Recommended use and restrictions on use: | For research use |
| Supplier: | CMIC HOLDINGS Co., Ltd. Hamamatsucho Bldg.,1-1-1 Shibaua, Minato-ku Tokyo 105-0023, JAPAN |
| Emergency Phone | +81-3-6779-8017 (Monday-Friday, 9:00-17:00 Japan time) |

2. HAZARD IDENTIFICATION

② Pretreatment solution

GHS classification

Health Hazard:

Serious eye damage/eye irritation ; Category 2A
Reproductive toxicity ; Additional category: effects on or via lactation
Specific target organ toxicity - single exposure ; Category 2 Central nervous system

Hazardous to the environment:

Hazardous to the aquatic environment - acute ; Category 2

Pictograms:



Signal word: Warning

Hazard Statements:

H319 Causes serious eye irritation
H362 May cause harm to breast-fed children
H371 May cause damage to central nervous system
H401 Toxic to aquatic life

Precautionary statements:

Prevention Obtain special instructions before use. Do not breathe mist/fume/spray. Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Wear protective gloves/
protective clothing/eye protection/face protection.

Response IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. If exposed or concerned: Call a POISON CENTER/doctor.
If exposed or concerned: Get medical advice/attention. If eye irritation persists: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container to an approved waste disposal plant.

⑦ **Stop Solution**

GHS classification

Health Hazard

Skin corrosion/irritation ; Category 1A
Serious eye damage/eye irritation ; Category 1
Specific target organ toxicity -Single exposure ; Category 2 respiratory system

Specific target organ toxicity - Repeated exposure ; Category 2 respiratory system

Pictograms:



Signal word: Danger

Hazard Statements

H314 Causes severe skin burns and eye damage

H371 May cause damage to respiratory system

H373 May cause damage to respiratory system through prolonged or repeated exposure

Precautionary statements:

Prevention Do not breathe mist/fume/spray. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves, protective clothing/eye protection/face protection.

Response IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Wash contaminated clothing before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Call a POISON CENTER/doctor. Get medical advice/attention if you feel unwell.

Storage Store locked up.

Disposal Dispose of contents/container to an approved waste disposal plant.

Other reagents in the kit component mentioned above are classified "Not applicable" or "Classification not possible".

3. COMPOSITION/ INFORMATION ON INGREDIENTS

Single Substance or Mixture Mixture

| Kit component | Chemical Name | PRTR Law | ISHA | PDSCL | Weight-% |
|----------------------------|--|----------|---|-----------------------|----------|
| | CAS No. | | | | |
| Pretreatment Solution | Ethylenediaminetetraacetic acid ^{※1)} | × | — | — | 0.29% |
| | 60-00-4 | | | | |
| Solution | Lithium hydroxide monohydrate | — | Chemical Substances requiring Deliver of Documents | Deleterious Substance | 0.3% |
| | 1310-66-3 | | | | |
| Assay Buffer | Sodium azide ^{※2)} | × | × | × | 0.1% |
| | 26628-22-8 | | | | |
| The 2nd Ab-POD Conjugate | — | — | — | — | — |
| Substrate Solution | Hydrogen peroxide ^{※3)} | — | × | × | < 1% |
| | 7722-84-1 | | | | |
| Wash Agent | — | — | — | — | — |
| Stop Solution | Sulfuric acid ^{※4)} | — | • Chemical Substances requiring Labeling and Deliver of Documents, etc. • Group - 3 substances | × | 4.9% |
| | 7664-93-9 | | | | |
| Standard Diluent (0ng/mL) | Sodium azide ^{※2)} | × | × | × | 0.05% |
| | 26628-22-8 | | | | |
| L-FABP Standard (400ng/mL) | Sodium azide ^{※2)} | × | × | × | 0.05% |
| | 26628-22-8 | | | | |

—···Not Applicable.

×···Exclusion from Application

※1) PRTR Law does not apply to Ethylenediaminetetraacetic acid since the concentration is below 1%.

※2) PDSCL does not apply to Sodium azide since the concentration is below 0.1%.

PRTR Law and ISHL do not apply to Sodium azide since the concentration is below 1%.

※3) ISHL does not apply to Hydrogen peroxide since the concentration is below 1%.

PDSCL does not apply to Hydrogen peroxide since the concentration is below 6%.

※4) PDSCL does not apply to Sulfuric acid since the concentration is below 10%.

4. FIRST - AID MEASURES

- **Inhalation** Remove immediately person to fresh air and wrap person in a blanket. Get medical advice/attention.
⑦: Remove person to fresh air and keep comfortable for breathing.
- **Skin contact** Rinse skin with plenty of water. Get medical advice/attention, if necessary.
⑦: Take off immediately all contaminated clothing. Rinse skin with water or shower. Wash contaminated clothing before reuse.
- **Eye contact** Rinse immediately eyes with plenty of water. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
②, ⑦: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
②: If eye irritation persists: Get medical advice/attention.
- **Ingestion** Rinse mouth with water. Get medical advice/attention immediately.
⑦: Rinse mouth. Do NOT induce vomiting.

5. FIRE - FIGHTING MEASURES

- **Suitable extinguishing media** Water, carbon dioxide, powder, water spray, chemical foam
- **Extinguishing method** Extinguish fire by extinguishing agent. Move container from fire area. If it's difficult, extinguish fire by sprinkling water to container and surroundings.
- **Specific hazards** There is a stimulus characteristic or a poisonous or corrosive gas and a possibility of generating the gas depending upon fire.

6. ACCIDENTAL RELEASE MEASURES

- **Personal precautions, protective equipment and emergency procedures** Wear protective equipment (e.g. gloves, mask, clothing, goggles) to prevent exposure. If exposed or concerned: Call a doctor. Get medical advice/attention.
- **Methods and material for contaminant and methods and materials for cleaning up** Sweep dust by non-flammable absorbent to collect it into a container. Clean contaminated objects and areas with plenty of water.
- **Environmental precautions** Avoid release to the environment.

7. HANDLING AND STORAGE

1) Handling (contact avoidance)

- Avoid contact with eyes, skin or clothing. Use suitable protective equipment as required. After handling, wash hands and face thoroughly.
- Some reagents contain component of animal blood. Handle reagents carefully.
- Stop Solution is a strong acid substance. Keep your skin and clothes away from Stop Solution.
- ②, ⑦: Wear suitable protective gloves, protective clothing, eye protection or face protection.
After handling, wash hands thoroughly. Do not eat, drink or smoke when using this product. Do not breathe mist, vapours or spray.

2) Safe storage conditions

Store at 2-8°C (avoid freezing).

②, ⑦: Store locked up.

3) Others

Handle and Store this product in conformity with related laws.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Component Exposure Limits:

1) Ethylenediaminetetraacetic acid

Control limits: N/A

Exposure Limits:

JSOH (Japan): N/A

ACGIH: N/A

2) Lithium hydroxide monohydrate

Control limits: N/A

Exposure Limits:

JSOH (Japan): $1\text{mg}/\text{m}^3$

ACGIH: N/A

3) Sodium azide

Control limits: N/A

Exposure Limits:

JSOH (Japan): N/A

ACGIH: $0.29\text{mg}/\text{m}^3$

4) Hydrogen peroxide:

Control limits: N/A

Exposure Limits:

JSOH (Japan): N/A

ACGIH: $1\text{ppm}/\text{m}^3$

5) Sulfuric acid

Control limits: N/A

Exposure Limits:

JSOH (Japan): $1\text{mg}/\text{m}^3$

ACGIH: $0.2\text{mg}/\text{m}^3$

Exposure controls/personal protection

Personal protective equipment

Respiratory protection: protective mask

Hand protective: protective gloves

Eye protective: protective eye glasses or goggles

Skin and body protection: protective mask (Long-sleeved work clothes)

Engineering controls

Use exhaust ventilation to keep airborne concentrations below exposure limits.

General hygiene considerations

Wash hands and face thoroughly after handling

9. PHYSICAL AND CHEMICAL PROPERTIES

① L-FABP Antibody Coated Microplate

Appearance: Solid (molded product)

Odor: Not available

pH: Not available

Boiling point: Not available

Flash point: Not available

Explosive limits: Not available

Vapour pressure: Not available

Specific gravity (relative density) : Not available

Solubility: Not available

n-Octanol/water partition coefficient: Not available

② Pretreatment Solution

Appearance: liquid

Odor: Not available

pH: Not available

Boiling point: 100°C

Flash point: Not available

Explosive limits: Not available

Vapour pressure: Not available

Specific gravity (relative density) : Not available

Solubility: Soluble

n-Octanol/water partition coefficient: Not available

③ Assay Buffer

Appearance: liquid

Odor: Not available

pH: 7.5

Boiling point: 100°C

Flash point: Not available

Explosive limits: Not available

Vapour pressure: Not available

Specific gravity (relative density) : Not available

Solubility: Soluble

n-Octanol/water partition coefficient: Not available

④ The 2nd Ab-POD Conjugate

Appearance: liquid

Odor: Not available

pH: 7.2

Boiling point: Not available

Flash point: Not available

Explosive limits: Not available

Vapour pressure: Not available

Specific gravity (relative density) : Not available

Solubility: Soluble

n-Octanol/water partition coefficient: Not available

⑤ Substrate Solution

Appearance: liquid

Odor: Not available

pH: 3.35 - 3.75

Boiling point: Not available

Flash point: Not available

Explosive limits: Not available

Vapour pressure: Not available

Specific gravity (relative density) : 1.01

Solubility: Soluble

n-Octanol/water partition coefficient: Not available

⑥ Wash Agent

Appearance: liquid

Odor: Not available

pH: 7.5

Boiling point: 100°C

Flash point: Not available

Explosive limits: Not available

Vapour pressure: Not available

Specific gravity (relative density) : Not available

Solubility: Soluble

n-Octanol/water partition coefficient: Not available

⑦ Stop Solution

Appearance: liquid

Odor: Not available

pH: Not available

Boiling point: Not available

Flash point: Not available

Explosive limits: Not available

Vapour pressure: Not available

Specific gravity (relative density) : Not available

Solubility: Soluble

n-Octanol/water partition coefficient: Not available

⑧ Standard Diluent (0ng/mL)

Appearance: liquid

Odor: Not available

pH: 7.4

Boiling point: 100°C

Flash point: Not available

Explosive limits: Not available

Vapour pressure: Not available

Specific gravity (relative density) : Not available

Solubility: Soluble

n-Octanol/water partition coefficient: Not available

⑨ L-FABP Standard (400ng/mL)

Appearance: liquid

Odor: Not available

pH: 7.4

Boiling point: Not available

Flash point: Not available

Explosive limits: Not available

Vapour pressure: Not available

Specific gravity (relative density) : Not available

Solubility: Soluble

n-Octanol/water partition coefficient: Not available

10. STABILITY AND REACTIVITY

Stability: This product is stable for 24 months under the recommended storage condition at ambient temperatures of 2-8 °C.

Reactivity: Not self-reactive mixture

Hazardous decomposition products: When sodium azide contacts with metal surfaces, explosive metallic azide are formed. Sodium azide rapidly hydrolyzes in acids and forms toxic hydrogen azide.

11. TOXICOLOGICAL INFORMATION

Ethylenediaminetetraacetic acid

| | |
|-------------------------------------|---|
| Acute toxicity (oral) | : LD50(rat): 2580 mg/kg |
| Acute toxicity (skin) | : No data available |
| Acute toxicity (inhalation vapor) | : Not expected to be an acute toxicity (rat 8 hours) |
| Acute toxicity (inhalation mist) | : Classification not possible |
| Skin corrosion/irritation | : Not expected to be an skin corrosion/ irritation (rat) |
| Serious eye damage/irritation | : Based on the description in the report on rabbit eye irritation tests (CERI-NITE Hazard Assessment No.14 (2004)): Edema, reddening and corneal opacity are observed, each of which disappears after eight days of exposure or earlier. |
| Respiratory or skin sensitization | : No data available |
| Skin sensitization | : No data available |
| Germ cell mutagenicity | : Based on the absence of data on germ cell multi-generation mutagenicity tests in vivo/ mutagenicity tests, somatic cell mutagenicity tests in vivo (Some chromosome aberration tests show positive, which, however, is not reliable enough for use in classification), and germ cell genotoxicity tests in vivo, described in CERI-NITE Hazard Assessment |

No.14 (2004). Dominant lethal tests show negative and germ in vivo/somatic cell micronucleus tests show both positive and negative, according to EDTA-2Na (CAS: 6381-92-6).

| | |
|------------------------|---|
| Carcinogenicity | : No data available |
| Reproductive toxicity | : Maternal toxicity was observed in a teratogenicity study (rat). |
| STOT-single exposure | : No data available |
| STOT-repeated exposure | : Suspected renal tubular dysfunction |
| aspiration hazard | : No data available |

Lithium hydroxide monohydrate

| | |
|-------------------------------------|---|
| Acute toxicity (oral) | : Classification not possible |
| Acute toxicity (skin) | : Classification not possible |
| Acute toxicity (inhalation vapor) | : Not expected to be acute toxicity (inhalation vapor) |
| Acute toxicity (inhalation mist) | : Inhalation LC ₅₀ Rat 0.96 mg/kg |
| Skin corrosion/irritation | : Causes severe skin burn by contact with anhydrous form of this substance. |

Serious eye damage/irritation : No data available

The following is the information about anhydrous form of this substance (CAS: 7580-67-8).

Low exposure causes eye irritation. High exposure to eyes causes an irreversible damage.

| | |
|-----------------------------------|-------------------------------|
| Respiratory or skin sensitization | : Classification not possible |
| Skin sensitization | : Classification not possible |
| Germ cell mutagenicity | : Classification not possible |
| Carcinogenicity | : Classification not possible |
| Reproductive toxicity | : No data available |

The following is the information about Lithium Litium was contraindications for the woman with possible pregnancy. breastfeeding mothers should be avoided due to a breast milk transfer, and breastfeeding should be stopped if a patient has no choice but to receive this substance

STOT-single exposure : Cause respiratory tract irritation and corrosion of human.
Inhalation exposure by rats: sloughing of the bronchiolar

| | |
|------------------------|--|
| | mucosa and pulmonary emphysema change caused by persistent cough and sneeze |
| STOT-repeated exposure | : No data available However, it is likely that this substance has same toxic effect caused by lithium ion as Water-soluble lithium salts. It was classified to as Category 1 (nervous system, respiratory, cardiovascular system, kidney, thyroid gland, digestive tract) |
| Aspiration hazard | : Classification not possible |

Sodium azide

| | |
|-----------------------------------|---|
| Acute toxicity (oral) | : LD ₅₀ Rat 45 mg/kg (DFGOT vol.20(2003)) |
| Acute toxicity (skin) | : LD ₅₀ Rabbit 20mg/kg |
| Acute toxicity (inhalation) | : Inhalation vapor LC ₅₀ Rat 37 mg/m ³ |
| Skin corrosion/irritation | : Based on a report that application to rabbit skin caused corrosion after 4-hour. |
| Serious eye damage/irritation | : Since the substance is classified into Category 1 for skin corrosion, Category 1 was also applied for the eyes. |
| Respiratory or skin sensitization | : No data available |
| Germ cell mutagenicity | : No data available |
| Carcinogenicity | : No data available |
| Reproductive toxicity | : Classification not possible |
| STOT-single exposure | : Causes damage to circulatory system |
| STOT-repeated exposure | : Cause damage to organs through prolonged or repeated exposure (circulatory system, liver) |
| Aspiration hazard | : No data available |

Hydrogen peroxide

| | |
|-----------------------------------|----------------------------------|
| Acute toxicity (oral) | : LD ₅₀ Rat 311 mg/kg |
| Acute toxicity (skin) | : Toxic in contact with skin |
| Acute toxicity (inhalation) | : Toxic if inhaled |
| Skin corrosion/irritation | : Causes severe skin burns |
| Serious eye damage/irritation | : Causes serious eye damage |
| Respiratory or skin sensitization | : No data available |

| | |
|------------------------|---|
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Suspected of damaging fertility or the unborn child |
| STOT-single exposure | : Causes damage to organs (respiratory system, central nervous system) |
| STOT-repeated exposure | : Cause damage to organs through prolonged or repeated exposure (lung). May cause damage to organs through prolonged or repeated exposure (blood) |
| Aspiration hazard | : No data available |

Sulfuric acid

| | |
|-----------------------------------|---|
| Acute toxicity (oral) | : LD ₅₀ Rat 2140 mg/kg |
| Acute toxicity (skin) | : No data available |
| Acute toxicity (inhalation) | : Inhalation mist LC ₅₀ 0.375 mg/m ³ |
| Skin corrosion/irritation | : Corrosive substances (GHS classification) |
| Serious eye damage/irritation | : Example of accident in human: the critical ; damage to the eye accompanied by solutions of anterior chamber of eye The eye of Rabbit: moderate irritation with 5% liquid and severe irritation with 10% liquid |
| Respiratory or skin sensitization | : No data available |
| Germ cell mutagenicity | : Classification not possible |
| Carcinogenicity | : Classification not possible |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Based on the descriptions that in the inhalation exposure of low concentration by humans, airway irritation such as cough and breath shortness is identified (DFGOT, 2001), and at high exposure levels, acute effects such as cough, breath shortness and hemoptysis shedding etc., and permanent effects such as functional depression of lungs, fibrosis and emphysema were identified (ATSDR, 1998), and that hemorrhage in lungs and dysfunction were identified by 8-hour inhalation exposure in guinea pigs (ATSDR, 1998). |
| STOT-repeated exposure | : In the 28-day inhalation exposure test using rat , cell proliferation in laryngeal mucosa is acknowledged in |

guidance value of Category 1(SIDS (2001)), and in the 14 to 139-day repetition inhalation exposure test using the guinea pigs of the concentration of guidance value within the limits of Category 1, respiratory and lung disorder, such as nasal-septum dropsy, pulmonary emphysema, atelectasis, hyperemia, dropsy, bleeding and thrombosis of bronchioles are recognized (ATSDR(1998)), and further in the 78-week inhalation exposure test using a cynomolgus, histological change as hyperplasia of a cell, the wall thickening, etc. in bronchioles of lungs was acknowledged in the dosage (0.048 mg/L, 23.5 Hr/Day) of the range of the guidance value of Category 1, so it was classified to as Category 1 (respiratory systems).

Aspiration hazard : No data available

12. ECOLOGICAL INFORMATION

Component Analysis - Aquatic Toxicity

1) Ethylenediaminetetraacetic acid

Fish LC₅₀: Bluegill 41 mg/L 96h (EU-RAR, 2005)

Hazardous to the aquatic environment (Long-term):

Crustacea NOEC: Daphnia magna 5.5 mg/L 21d (aquatic toxicity tests of chemicals conducted by Ministry of the Environment in Japan, 2002)

Classified into Category 3 since its acute toxicity is Category 1 (LC₅₀: Bluegill 41 mg/L 96h) and it is not rapidly degradable (the decomposition by BOD: 0%(Existing Chemical Safety Inspections Data)).

2) Sodium azide

Algae ErC₅₀: Pseudokirchneriella subcapitata 348 μg/L 96h(AQUIRE, 2010)

Hazardous to the aquatic environment (Long-term):

Classified into Category 1 since its acute toxicity is Category 1 and it is not rapidly degradable (Degradation rate by direct measurement (HPLC): 1% (Biodegradation and Bioconcentration of Existing Chemical Substances under the Chemical Substances Control Law, 2000)).

3) Hydrogen peroxide

Crustacea ErC₅₀: Water flea 2.4 mg/L 48h

Hazardous to the aquatic environment (Long-term): Rapidly degrading in water

4) Sulfuric acid

Fish LC₅₀: Bluegill 16-28 mg/L 96h

Hazardous to the aquatic environment (Long-term): Toxicity factor is considered to be strong acid as aqueous solution, but toxic effect is eased by the buffer action in the environmental water.

13. DISPOSAL CONSIDERATIONS

- Stop Solution is a strong acid substance. Therefore, pay attention to in disposal of this material.
- Assay Buffer, Standard Diluent and L-FABP Standard contain Sodium azide. Therefore, dispose these materials after diluting them with large quantity of water to avoid production of explosive metallic azide.
- Dispose of contents/container to an approved waste disposal plant after wash with plenty of water.

14. TRANSPORT INFORMATION

- Transport this product avoiding direct sunlight at 2-8 °C
- Load this product to prevent from overturning, falling or damage.
- Transport this product in accordance with Ship Safety Act or Civil Aeronautics Act or other regulations.

15. REGULATORY INFORMATION

| | |
|-------|---|
| CSCCL | Sodium azide |
| ISHA | Sulfuric acid Sodium azide (Not available, < 1%) Lithium hydroxide monohydrate (Not available, < 0.3%) Hydrogen peroxide (Not available, < 1%) |
| PDSCA | Lithium hydroxide monohydrate Sodium azide (Not applicable, < 0.1%) |

| | |
|----------|---|
| | Hydrogen peroxide (Not applicable, < 6%) Sulfuric acid (Not applicable, < 10%) |
| PRTR Law | Sodium azide (Not applicable, < 1%) Ethylenediaminetetraacetic acid (Not applicable, < 1%) |

16. OTHER INFORMATION

Key/Legend

NITE - National Institute of Technology and Evaluation (JAPAN)

<https://www.nite.go.jp/index.html>

CSCL: Chemical Substances Control Law

PRTR Law - Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof;

ISHA - Industrial Safety and Health Act;

PDSCA - Poisonous and Deleterious Substances Control Act

JSOH - Overview of the Japan Society for Occupational Health

Disclaimer

The information set forth in this Safety Data Sheet does not purport to be all-inclusive and should be used only as a guide. While the information and recommendations set forth herein are believed to be accurate, the company makes no warranty regarding such information and recommendations and disclaims all liability from reliance thereon.