[For food inspection] Prepared: August 2022 (2nd edition)

FASTKIT Slim Series

Handling information

*This information has been translated into English from the original Japanese version. If there are any differences in content between this English version and the Japanese version, the Japanese version shall take precedence.

*Please read this information before using the product.

Product features

(1) The kit is designed to detect specified ingredients or their equivalents (hereinafter referred to as "specified ingredients, etc.") in specimens based on immunochromatography.

(2) The kit can be used for both food testing and cleaning confirmation testing (surface swab tests, rinse water tests) with the following detection limits.

Inspected item	Food	Swabbed surfaces	Rinse water
Detection sensitivity	Sample solution 0.025 ppm (25 ng/mL) *5 ppm per food	Sample solution 0.025 ppm (25 ng/mL) (Note 1)	Sample solution 0.025 ppm (25 ng/mL) *Concentration in rinse water 0.05 ppm (50 ng/mL)

3) The simple one-step operation and easy determination make it possible for anyone to perform the test easily.

4) No special detection equipment is required, and the results can be obtained quickly, making it ideal for day to day control at manufacturing sites.

(Note 1) It has been found that the reactivity of some samples decreases when PBS or saline is used as a suspension.

Kit Contents

Components

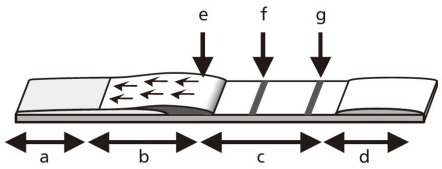
A: Test strips ……2 test strips x 10 packs
B: Dilution buffer ……50 mL x 1 bottle
C: Extraction buffer (10x concentrated)……100 mL x 1 bottle
D: Instruction manual (Japanese version)……1 copy
E: Plastic pouch bag……1

Ingredients

(1) Reagent-containing section
Gold-colloid labeled antibodies to specified ingredients, etc.
(2) Detecting section
Antibodies to specified ingredients, etc.
Anti-immunoglobulin antibodies

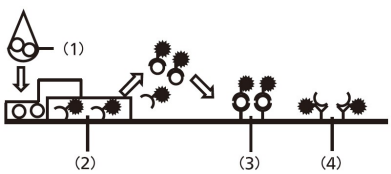
Test strip part names and detection principle

Test strip part names



a. Sample dropping area (be careful not to touch by hand)
b. Reagent-containing section
c. Detecting section (be careful not to crush or scratch it)
d. Absorption pad
e. Position of description of measurement items
f. Test line appearance position
g. Control line appearance position

Detection principle



[1] The sample solution is dropped onto the sample dropping area of the test strip.
[2] Proteins (1) from specified ingredients, etc. in the sample solution (1) form a complex with the gold colloid-labeled antibodies (2) in the reagent-containing section.
[3] The complex moves through the detecting section by capillary action.
[4] The complex is captured by antibodies (3) immobilized at the test line appearance position, and a reddish-purple line (test line) due to the gold colloid appears.
[5] Regardless of whether the sample solution contains proteins from specified ingredients, etc., excess gold colloid-labeled antibodies are captured by the anti-immunoglobulin antibodies (4) immobilized at the control line appearance position, and a reddish-purple line (control line) appears.

Sample solution preparation 1 (detection from food)

Equipment and materials

Grinder (food cutter), homogenizer ("Millser" in Japan), centrifuge (Note 1) (preferably capable of centrifugation at 3000 g or higher at 4°C), centrifuge tube, filter paper, graduated cylinders, beakers, micropipettes, tips, test tubes, disposable gloves, masks, etc.

Reagent Preparation

Dilution buffer: Bring to room temperature (20-25°C).
Extraction buffer: Dilute 10-fold with purified water.

Note 1) Testing can be performed even if a centrifuge is not available. A refrigerator can be used for cooling.
Note 2) If precipitation is observed in the extraction buffer, bring to room temperature and make sure the precipitates are dissolved before diluting with purified water.
Note 3) The compositions of the dilution buffer and extraction buffer are the same for all the FASTKIT Slim Series, so they can be used regardless of the specific product.

Extraction (example for common foods)

(1) After crushing each package unit of the food to be tested (specimen), grind the food to a uniform state using a food grinder, etc. (Note 1).
(2) Add 38 mL of the previously prepared extraction buffer to 2 g of the sample prepared in (1). Homogenize three times in a homogenizer, 30 to 60 seconds each time (Note 2).
(3) Centrifuge the sample at 3000 g or more at 4°C for 20 minutes and filter the supernatant (Notes 3, 4).
(4) Dilute the filtrate 10-fold with dilution buffer to produce the sample solution (Note 5).

Note 1) To prevent contamination via instruments, make sure they are thoroughly cleaned. In particular, clean grinders and homogenizers for each specimen (wash with a neutral detergent, then soak overnight in an alkaline detergent, or perform ultrasonic cleaning in an alkaline detergent).
Note 2) Check the pH at the time of extraction and adjust to near neutral (pH 6.0-8.0) if necessary. Extraction buffer should be added only at the time of the initial extraction and should not be added during the repeat operations.
Note 3) If a centrifuge is not available, let the sample stand in a refrigerator for about 30 minutes before filtration.
Note 4) If the sample solution contains a lot of unwanted substances such as lipids, etc., remove as much of them as possible; otherwise, incorrect results may be obtained.
Note 5) Store sample solutions at 4°C. The shelf life of the sample solution depends on the food, so testing should be done as soon as possible.

Sample solution preparation 2 (cleaning confirmation)

1. Swab test

Equipment and instruments

Cotton swabs (Note 1), test tubes, micropipettes, tips, disposable gloves, masks, etc.

Preparation of reagents and equipment

Phosphate buffered saline (PBS) or 0.9% sodium chloride solution (saline): room temperature (20-25°C).
Dilution buffer: bring to room temperature (20-25°C).

Note 1) Commercially available swab test kits for microbiological testing can be used. However, attention should be paid to the composition of the liquid contained therein.

Swabbing method

(1) Prepare a cotton swab moistened with PBS or saline solution (Note 1).
(2) Swab the target test area with the cotton swab prepared in (1) (Note 2).
(3) Suspend the contaminants adhering to the cotton swab in (2) in (e.g., 1 mL) supplied dilution buffer pre-dispensed into a test tube (Note 3).
(4) Use this suspension as the sample solution (Notes 4, 5).

Note 1) Do not swab with cotton swabs moistened with the supplied dilution buffer, due to concerns over contamination of manufacturing machinery and equipment.
Note 2) It is recommended to swab the areas where food residues, etc. are likely to remain or where it is difficult to wash, and to swab the entire surface of the target area.
Note 3) After suspending the swab, use the sides of the container to fully squeeze out the suspension soaked into the swab.
Note 4) If a large amount of impurities are found in the suspension, an incorrect test result may be obtained. Therefore, remove impurities as much as possible by centrifugation, filtration, or other means.
Note 5) When diluting the suspension, use the dilution buffer.

2. Rinse water inspection

Equipment and instruments

Test tubes, micropipettes, tips, vortex mixer, disposable gloves, masks, etc.

Preparation of reagents and equipment

Dilution buffer: Bring to room temperature (20-25°C).

Rinse water test method

(1) Mix equal volumes of rinse water and the supplied dilution buffer and homogenize with a vortex mixer or the like.

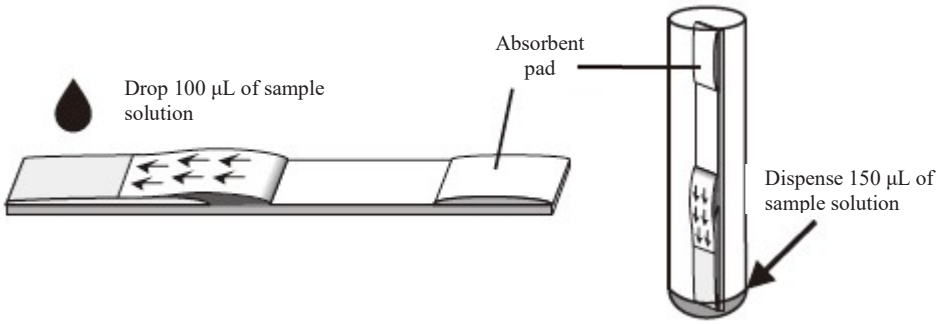
(2) Use this mixture as the sample solution.

Note 1) Rinse water may give incorrect results if detergents or other residues are present.

Note 2) Check the pH of the rinse water and adjust to near neutral (pH 6.0-8.0) if necessary.

Test procedure

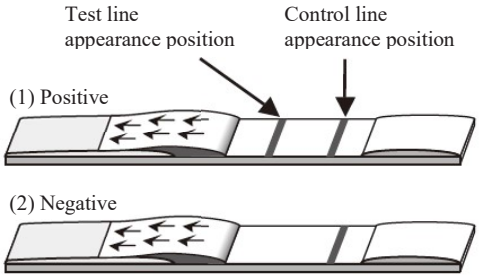
(1) Bring the test strips to room temperature while still in their aluminum packaging and remove from the packaging immediately before use (Notes 1, 2).
(2) Write the sample name or sample number on the absorbent pad of the test strip using an oil-based pen.
(3) Place the test strip on a horizontal table and drop 100 µL of sample solution onto the sample dropping area (left in the below figure). Alternatively, dispense 150 µL of sample solution into a test tube, and place the test strip in the test tube so that the sample dropping area is immersed in the sample solution (right in the below figure) (Notes 3, 4, and 5).



Note 1) Since moisture absorption may cause incorrect results, ensure that the test strips are brought to room temperature before removing them from the aluminum packaging. Unused test strips should be returned to the plastic pouch bag with desiccant and stored refrigerated. Unused test strips should be use as soon as possible.
Note 2) Be careful not to directly touch or scratch the sample dropping area and detection section of the test strip with the fingers or other objects. When holding the test strip, hold the absorbent pad.
Note 3) Pipettes or tips used for dropping or dispensing sample solutions must be replaced for each sample solution.
Note 4) When dropping 100 µL of sample solution, be careful not to overflow the test strip, and if necessary, divide into two drops.
Note 5) If using the method shown on the right, make sure that the sample solution is at or below the position where the sample name is indicated.

Determination of results

(1) Judge the test as positive if a reddish-purple line is observed at the test line appearance position and control line appearance position 15 minutes after the start of the test.
(2) Judge the test as negative if there is no reddish-purple line observed at the test line appearance position and a reddish-purple line is observed only at the control line appearance position.



Note 1) Judge the result at 15 minutes after the start of the test. As time passes, there may be deviations from the 15-minute result.
Note 2) Test lines may be identified as time passes if the sample solution contains proteins from specified ingredients, etc. at lower than the detection sensitivity or due to non-specific reactions.
Note 3) If a line is identified, judge the result as positive regardless of the strength of the reddish-purple color.
Note 4) If no reddish-purple line is observed at the control line appearance position, the detection of the sample solution may have been abnormal, and the test should be performed again.
Note 5) If only a portion of the test line is colored, reserve judgment, and retest with a new test strip and sample solution.
Note 6) Since the kit is for the qualitative confirmation of proteins from specified ingredients, etc., it cannot quantify the content of such proteins. An ELISA test should be performed if a quantitative confirmation of protein content is required.

Performance

Performance when the test is performed according to the [Sample solution preparation] and [Test procedure] described in this document.

Inspected item	Food	Swabbed surfaces	Rinse water
Detection sensitivity	Sample solution 0.025 ppm (25 ng/mL) *5 ppm per food	Sample solution 0.025 ppm (25 ng/mL) (Note 1)	Sample solution 0.025 ppm (25 ng/mL) *Concentration in rinse water 0.05 ppm (50 ng/mL)

(Note 1) It has been found that the reactivity of some samples decreases when PBS or saline is used as a suspension.

Reproducibility

When a sample solution positive for a protein from specified ingredients, etc. and a sample solution negative for a protein from a specified ingredient are tested three times simultaneously, all positive sample solutions indicate positive and all negative sample solutions indicate negative.

False Positive/Negative

(1) For information on food reactivity data, please refer to the website of the Research & Development Center, NH Foods, Ltd.
(2) For highly viscous food or in the presence of very high concentrations of protein, a false positive result may be obtained due to non-specific reactions. In such cases, perform the test after diluting the sample to an appropriate concentration.
(3) In the swab test, if a high concentration of protein from specified ingredients, etc. is contained in the sample solution, the test line may be faint or impossible to identify. In such cases, perform the test after diluting the sample to an appropriate concentration.

Precautions

General precautions

(1) When using the kit, read this handling information carefully and follow the described test method.
(2) Sample solution preparation and testing should be performed in a clean area. Wearing disposable gloves and a mask is recommended.
(3) Do not use the kit after the expiration date. The expiration date is indicated on the outer label of the kit and on the aluminum packaging containing the test strips.
(4) The kit is for the detection of proteins from specified ingredients, etc. in foods or solutions, and is not a reagent to diagnose the presence or absence of food allergy symptoms caused by specified ingredients, etc. No correlation between the test results from the kit and the onset of allergic symptoms has been confirmed.
(5) The presence or absence of protein from specified ingredients, etc. should be judged comprehensively in conjunction with other methods, such as by checking raw ingredients and manufacturing records, in addition to the results from the kit.
(6) The methods for using the equipment and instruments used with the kit should be confirmed with the respective manufacturers or distributors.
(7) This handling information is intended as a guideline for inspectors. The customer should verify the validity of each operating procedure and application for each food by themselves.
(8) The customer is fully responsible for the judgment and use of the results obtained from the kit. We shall not be liable for any damages or losses incurred as a result thereof.
(9) Product specifications are subject to change without notice.

Hazard Prevention

(1) Take care that the reagents and sample solutions in the kit do not adhere to skin, mucous membranes, clothing, etc.
(2) If reagents or sample solutions accidentally come in contact with the eyes or mouth, immediately take first aid measures such as rinsing thoroughly with tap water, etc., and seek medical attention if necessary.

Disposal

Disposal of the kit, samples, or leftover sample solution, should be carried out in accordance with local waste regulations and with due consideration for sanitation and the environment.

Storage method and expiration date

(1) Storage method: Store refrigerated (2-8°C) in light-shielded conditions. Avoid freezing.
(2) Expiration date: Indicated on the outer packaging and on the component labels.
*These expiration dates are for unopened items. Opened reagents should be used as soon as possible.

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