

XEMA_{TEST}FISH

Rapid immunochromatographic test for qualitative determination of common fish antigen in foods, kitchen and production facilities

Version I (009)

TEST PRINCIPLE

Fish proteins are among the eight major food allergens. Due to increased use of seafood in food industry, the consumers with fish allergies are at growing risk of serious reactions or even death due to mislabeled or undeclared fish derived products. Since 2004, the Food Allergen Labeling and Consumer Protection Act (FALCP) requires mandatory labeling of potential presence of this allergen in foods. XEMA_{TEST}FISH may be also used for fish storage monitoring to detect a "leakage" of fish muscle antigen caused by improper storage and/or freeze-thawing.

XEMA_{TEST}FISH represents an immunochromatographic rapid test (lateral flow) and may be used for qualitative or semi-quantitative determination of fish specific striated muscle associated antigen in foods, kitchen and production facilities. In immunochromatographic (lateral flow) method, the target antigens are bound by highly specific antibodies attached to colored microparticles. Then this complex migrates to the test line where binds to another fish-specific antibodies to form a colored line indicating positive result.

TEST SENSITIVITY AND SPECIFICITY

XEMA_{TEST}FISH utilizes an unique combination of antibodies which enables to detect an antigen common for ALL bone fishes. The test also detects a related antigen of cartilaginous fishes (sharks and sturgeons), though with significantly lower sensitivity. XEMA_{TEST}FISH does NOT detect the antigens of other seafood, including shrimp, lobster and crab. Detailed and updated data on specificity of are listed in our webpage (www.xema-medica.com)

A sensitivity of XEMA_{TEST}FISH (which may be described only approximately due to variability of the antigen among fish species) is ca. 5 ng/ml of target protein of cod (*Gadus*).

The sensitivity of XEMA_{TEST}FISH may be also very approximately compared to the dilution of allergen preparation used for skin testing (factor 10,000 to 100,000 for Cod allergen of different manufacturers).

If the visual test gives unclear results, we recommend to re-check the sample by the quantitative laboratory methods, e.g. Total Fish ELISA (XEMA, Cat# K363)

KIT CONTENTS

- 5 test strips individually packed into sealed aluminium foil pouches;
- 5 Specimen collection tubes;
- Instruction for use.

SPECIMEN HANDLING

The specimens should be brought to temperature range +15...+35 °C before use; testing of colder specimens diminishes the sensitivity of the assay; testing of hot specimens is NOT possible!

Liquid specimens – water samples, cooked brew, washouts from kitchen dishes or technological surfaces (eg cutting machines) may be tested directly. The limitation for liquid specimens is their viscosity (brew in particular) and turbidity (presence of particulate matter). If the specimen is viscous and cannot reach the test zone of the strip, it should be diluted by warm boiled water. In this case, the sensitivity level of the test should be adjusted by dilution factor. Turbid specimens should be filtered through textile or paper material, or allowed to sediment.

For testing of solid material we recommend the following procedure: using clean (preferably disposable) sharp tool, cut a small piece (0.1–0.5 grams) of the material and place it into the Specimen collection tube. Pour 2–2.5 ml of warm boiled water into the tube; thoroughly close the tube cap and shake the tube vigorously for 15–30 seconds. Put the tube on the table, let the particles set

down; the upper layer of the liquid is available for testing.

The specimens may be stored at +2...+8 °C within 24 hours. For longer storage we recommend to freeze the specimen or add the food specimen preservative available at XEMA (cat.# S075Z).

TEST PROCEDURE

1. If the test strips were stored below +20 °C, bring the required quantity of the strips to the room temperature before opening the pouches.
2. Carefully open the pouch with sharp instrument. TAKE CARE NOT TO DAMAGE THE TEST STRIP.
3. Dip the test strip into the liquid part of the specimen observing the right direction ("HAND" sign upwards) and depth (not deeper than the colored line marked by arrow signs) and keep for 5–10 seconds to ensure soaking.
4. Put the test strip onto a CLEAN horizontal surface; do not touch and move the test strip for 5–10 minutes.
5. Read the test result.



INTERPRETATION OF THE RESULTS

Test is considered POSITIVE if TWO colored lines appear in the test zone.



Test is considered NEGATIVE if only ONE colored line is clearly visible.



If NO colored line is formed, the test is INVALID.



Try to repeat it with another test strip, check the correct specimen handling and test procedure, expiry date and storage conditions.

PRECAUTIONS

- The test strips (dipsticks) should be stored at +18...+25 °C;
- Use the test within 10 minutes after opening the pouch because the test strips are very sensitive to moisture;
- DO NOT TOUCH the reaction membrane;
- Do not use the kit when its pouch is torn, or test strip is broken or damaged;
- All the components of the test kit are disposable; do not use them repeatedly;
- Do not use the test strips beyond the expiration date.

MANUFACTURER:

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