

XEMAtest SESAME

Rapid immunochromatographic test for qualitative determination of sesame antigen in foods, kitchen and production facilities
Version of the test 1 (2003)

Sesame is an herbaceous plant belonging to the family *Pedaliaceae*; most common species are *Sesamum indicum* (white sesame) and *Sesamum radiatum* (black sesame).

Allergy to sesame seeds as well as products based on them can display the variety of symptoms from mild oral allergy or hives to severe life-threatening systemic reactions, i.e. anaphylactic shock or bronchial asthma. Allergy to sesame seeds is estimated 0.1 - 0.9% prevalence in population, it is more common in Asian countries. Sensitized organisms may cross-react with peanuts, walnuts, hazelnuts, rye and poppy seeds.

In EU, sesame seed is included into the list of allergens established by European Food Safety Authority, which must be indicated in foods according to EU Law No 1169/2011 Annex II. UK, Australia, Canada and Israel are among the regions where sesame is considered as major food allergen and must be specifically declared on the labels. In the USA, sesame seed rates number 9 by frequency among food allergies, especially affecting young children.

The test is applicable for **qualitative detection** or **semiquantitative measurement** of target antigens in the samples of complex foods and swabs from the surfaces. The qualitative detection is usually done for screening and the semiquantitative measurement is applied for monitoring or comparative studies.

TEST SENSITIVITY AND SPECIFICITY

XEMAtest SESAME utilizes a combination of monoclonal antibodies which enables to detect all major forms of target antigen.

XEMAtest SESAME does NOT detect the antigens of cereals, legumes and nuts.

The sensitivity of XEMAtest SESAME (LOD, limit of detection) in the extract prepared according to present instruction is approximately 10 ppm by dry weight of ground raw nuts in model extract; the range of detection (ROD) is 10-80000 ppm.

In dry spots or other types of the material collected by wet swabs according to present instruction, the LOD is approximately square centimeters.

PLEASE NOTE: the sensitivity is calculated for the target antigenic material content in solid material extracted by the method described below, (solid/liquid ratio 1:10 wt/vol). The sensitivity of the test may be upgraded by lowering of the solid/liquid ratio, however this may result in thick liquid which will not penetrate into the test strip. The LOD data for liquid samples are 5x lower with standard procedure, ie with regular liquid specimens the test reaches higher sensitivity.

The sensitivity of the test decreases in fat-rich environment (e.g. in presence of oil or cream).

More details of test performance (sensitivity, specificity, variability, influence of matrix and processing) are available on request or online at www.xematest.com.

If the visual test gives unclear results, we recommend to recheck the sample by the quantitative laboratory methods, e.g. Sesame antigen EIA (XEMA, Cat# K389), or PCR.

CONTENTS

- 2 test strips individually packed into sealed pouches;
- 2 Specimen collection tubes;
- 1 vial of Specimen extraction buffer, 10 ml;
- Instruction for use.

SPECIMEN HANDLING

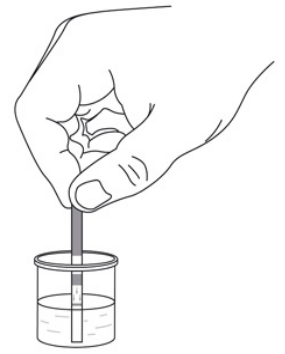
The specimens should be brought to temperature range +18...+35 °C before use; testing of colder specimens diminishes the sensitivity of the assay; testing of hot specimens is NOT possible!

The test is designed to detect the target antigen in different types of the material, please select the relevant section of the text below.

TEST PROCEDURE FOR SOLIDS

1. Allow the test strips to reach room temperature for 5-10 minutes before opening the pouches.
2. Put a small piece of tested material (0.1-0.5 g) into a Specimen collection tube. If the balances are available, record the actual weight in grams.
3. If the accurate volume measurement tool (pipette) is available, calculate required Specimen extraction buffer volume as 10x actual weight (for example, if the weight is 0.23 g, add 2.3 ml of the buffer). Otherwise, add not more than half of tube volume of Specimen extraction buffer. Adjust the sensitivity of the assay if the weight/volume ratio is different from 1:10.
4. Screw the cap securely onto the tube and shake vigorously for 15 – 30 seconds or use the vortex mixer. Allow to settle for 2 minutes.
5. If the liquid is thick and cloudy, it may not penetrate into the test strip, and testing fails. To avoid it, allow to settle for longer period (up to 6 hours). The extract may be also filtered by textile material or centrifuged.

- Open the pouch, taking care not to damage the test strip. Dip the test strip into the liquid layer, do not touch the solid settled down on the bottom.
- Allow the strip to remain in the solution for 5 – 10 seconds. Remove the test strip and place onto a clean horizontal surface; do not touch or move the test strip for 10 minutes. Read the test result.



CAUTION: ENSURE THE TEST STRIP IS DIPPED AS SHOWN IN A FIGURE. THE DIRECTION AND THE DEPTH OF IMMERSION MUST BE AS SHOWN FOR CORRECT OPERATION.

TEST PROCEDURE FOR LIQUIDS

The limitation for liquid specimens is their viscosity and turbidity (presence of particulate matter). If the specimen is viscous and cannot reach the test zone of the test strip, it should be diluted by Specimen extraction buffer right in the Specimen collection tube or separately. In this case, the sensitivity of the test should be adjusted by dilution factor. Cloudy specimens should be allowed to settle, filtered through textile material, or centrifuged.

- Allow test strips to reach room temperature for 5-10 minutes before opening the pouches.
- Collect 1 ml of liquid specimen into a Specimen collection tube (by first marker on the tube wall or using a pipette).
- Add an equal volume of Specimen extraction buffer, screw the cap securely onto the tube and mix by shaking or use the vortex mixer. If the liquid is cloudy, allow to settle, then follow the instructions from point 5 of test procedure for solid materials outlined above.

TEST PROCEDURE FOR SURFACE SWABS

- Allow test strips to reach room temperature for 5-10 minutes before opening the pouches.
- Add 1 ml of Specimen extraction buffer to the tube into a Specimen collection tube (by first marker on the tube wall or using a pipette).
- Place the swabbing tool (for example, cotton tip) into the tube, rinse the swabbing tool in the buffer.
- Squeeze off any excessive liquid off the swabbing tool against the tube wall.
- Swab the tested surface with special attention to suspected spots.
- Put the swab back into the tube containing the rest of the buffer and shake vigorously for 15 – 30 seconds or use the vortex mixer.
- Remove the swab from the tube and follow the instructions from point 5 of test procedure for solid materials outlined above.

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 should be stored at +10...+30 °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 test strip if its pouch is torn, or test strip is broken or damaged.
- The test strips are disposable; do not use them repeatedly.
- Do not use the test strips beyond the expiration date.

MANUFACTURER:

XEMA group of companies

www.xematest.com