

bioavid Diagnostics Lateral Flow Tests for the Detection of Allergen-Residues – General Instructions for Use



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Brief information

Antibody based rapid test (lateral flow) for the detection of allergen residues. The extracted sample is transferred to a Reaction Vial that contains specific antibodies ready to use. If the sample contains the target antigen, an antigen-antibody complex will form in the tube. This complex is subsequently detected by means of the test strip. The test is very rapid and reliable and does not require laboratory equipment for most applications

A number of different tests are available. Please find the offer [here](#).

Sample preparation

Homogenize and filter

Time required

Extraction	ca. 5 minutes
Test implementation	max. 10 minutes
Detection Limit	ca. 1 ppm allergen-Residue in buffer
Specificity/Cross-reactivity	click here for an actual list

Intended Use

Immunological rapid test (lateral flow) for the detection of allergen residues in food, raw materials, or environmental samples (e.g. industrial lines in food manufacturing), as well as in rinsing water.

Principle of the test

A solid sample is homogenized in a mixer for 5 min. The extract is then centrifuged or filtered. After adding 0.2 ml of Running Buffer into a Reaction Vial that contains specific antibodies, 0.1 or 0.2 ml of the prepared extract is added (please refer to the test kit instructions in the test kit). When the target antigen is in the sample extract, an antigen - antibody complex will form. After 5 minutes of incubation, a dip stick is added into the Reaction Vial to detect the formed immune complex. The result can be read latest after another 5 minutes (see kit instructions).

Test kit content

(Test kits are available for 25 , 50 or 100 determinations)

Each Test kit contains:

25 (50, 100)	Test strips in a Tube
25 (50, 100)	Reaction Vials
1	Positive Control (colored cap)
1 (2)	Dropper bottle(s) with 10 ml Running Buffer
1	Instructions for Use (compact version)

Reagents required but not provided

For solid samples

Water, salt
Mixer
Measuring cylinder
Filter paper (coarse), syringe filter with glass wool, or centrifuge
Pipet (0.1 – 0.2 ml)

For liquid samples

Pipette (0,1 – 0.2 ml)

For swab samples

Phosphate buffered saline with Tween (PBS-T, 20 mM phosphate, 150 mM saline), add 0.2 % Tween 20
Sample vials, 5 ml
Cotton swabs
Pipet (0.1 – 0.2 ml)

Test kits for 25 oder 100 swabbings including all materials required are available with the product numbers BS 800-25 and BS 800-100, respectively.

Storage

Store the test kit at 2 – 25 °C (36 – 77 °F, room temperature or refrigerator). Do not freeze. The expiration date is printed on the outer label of the test kit. Do not use beyond the expiration date.

Test preparation

Bring the test kit to room temperature before use. Do not open the tube with test strips when it is colder than the environment, since deterioration may result from moisture.

Extraction of solid samples

for 50 g sample
4.0 g Sodium Chloride (NaCl, Salt)
450 ml distilled water (alternatively fresh tap water)

Extraction solution for swab samples

Phosphate buffered saline, per liter:
8.0 g Sodium chloride (NaCl)
0.2 g Potassium chloride (KCl)
1.44 g Di sodium hydrogen phosphate (Na₂HPO₄)
0.24 g Potassium di hydrogen phosphate (KH₂PO₄)

The pH-value should be between 7 and 8, ideally between 7.2 und 7.4

Add 2 ml Tween 20 per liter of PBS

Positive Control (when needed)

Add 1 ml water to the Positive Control and leave for 5 minutes. Then apply 0.1 ml as a sample into the assay. The Positive Control can be further diluted 1 in 10 with water and frozen in aliquots at -20 °C (-4 °F) for a year at least. Do not repeatedly freeze and thaw. Use dissolved or thawed controls within 2 days.

Test implementation – Sample preparation

solid samples

Add 450 ml water and 4 g salt to 50 g sample and homogenize for 5 minutes in a mixer (equivalent volumes can be applied, e.g. 5 g sample in 45 ml water and 0.4 g salt). Filter the homogenate using a coarse paper filter or a syringe filled with glass wool until 0.1 ml filtrate is available, at least. Alternatively centrifuge at ca 2000 x g for 5 minutes.

Remark:

Centrifuging may result in a fat layer on top of the sample. Puncture the fat layer with the pipet tip and take the sample from the aqueous phase below. Use the extract within 2 days, store refrigerated. Longer storage is possible at -20°C (-4 °F).

liquid samples

0.1 ml of the sample can be applied directly into the assay. For some tests use 0.2 ml sample volume. Please see the instruction for use in the kit.

Remark:

strong acidic or alkaline samples (4 > pH > 9) should be diluted 1:10 in phosphate buffer or neutralize with NaOH or HCl before use.

swabbing samples

Fill 1 ml PBS-T in a Sample Vial, moisture a cotton swab therein and swab the area thoroughly. Twist the swab on the surface in order to get all sides the swab in contact with the surface.

Wash the used swab out thoroughly in the remaining PBS-T in the sample vial, squeeze the swab in order to release the sample into the buffer. Use 0.1 ml of the extract in the assay.

When using the swabbing test kit, fill 1 ml water into a sample vial and add 3 drops of the buffer concentrate from the test kit. Moisten the swab therein and transfer the sample into it.

Test procedure – Detection

Open a Reaction Vial and add 0.2 ml (7 drops) Running Buffer.

Add 0.1 ml extracted sample.

Incubate for 5 min at RT; shake sporadically.

Take an Allergen Test Strip out of the container close the tube.

Touch the test strip only at the plain plastic upper end and enter it to the bottom of the Reaction Vial containing the sample.

After ca. 1 min the red colored liquid can be seen moving upwards. Latest after 2 minutes the upper control line is visible.

After 4 - 5 min the test strip is taken out of the vial and the result is read. The test line is exposed 3 mm (0.12 inches) below the control line. Please learn the time to read the result for the test you have in hand from the kit instructions. Positive samples may color the test line even after 2 minutes.

Evaluation

The results are read after 2 – 5 minutes (see instructions in the test kit for specific information).

The result is valid, when the (upper) control line is clearly visible.

The result is read as **negative** if only the control line was visible.

The result is read as **positive** if 2 lines were visible.

Remark: Should a test strip be stored for documentation purposes, cut with a scissors the lower part from the test strip, 4 cm (1.6 inches) from the bottom right after reading the result. With this measure, the result remains nearly constant. After complete drying, the strips can be stored dry and in the dark for a year.

Limitations/Remarks

When testing samples with 10% or higher content of the analyte the detection can be suppressed. Such a sample may appear as weakly contaminated only or even as negative. If there is a concern, a high concentration of analyte was present, dilute the sample at least 1:100 (dilute the extract again 1:10 with water and then apply into the assay).

A number of food matrices may introduce difficulties when being extracted for immunoassay applications. Therefore, please consider the following:

- Intensely colored food, e.g. red wine, must be decolorized. Please inquire for methods and reagents.
- Neutralize strong acidic or alkaline samples after extraction with NaOH oder HCl (adjust pH from 7 to 8).
- Fatty samples should be centrifuged refridgerated. A fat layer then is formed upon the sample, which easily can be punctured with a pipet tip in order to withdraw from the aqueous phase. Defatting chemicals like hexane can interfere with immunoassays, if they are not removed completely.
- Blood containing samples may interfere with immunoassays. Please inquire.
- Food containing polyphenols (beer, wine, cocoa, chocolate, spices, herbs) should be absorbed before use. Please inquire methods and reagents.
- It is possible to use the test kits for the detection of product falsification (e.g. penut in hazelnut). For that purpose, samples should be diluted another 1:100 with water after the first extraction (final dilution 1:1000). The detection limit for falsification thus will change to 0.1 – 0.5 %.
- Cleaners and disinfectants recimmeded for use in food production lines, in general to not interfere with bioavid tests. Therefore, rinse water obtained after cleaning/disinfection can be applied into the bioavid assays directly.
- Cleaners for dish washers that with a high pH (> pH 10) may interfere with immunoassays and should be neutralized before used. Rinse water obtained from the final rinse can be applied directly into the bioavid tests.
- If swab samples are visually contaminated and if there is concern they might contain the allergen of interest in high concentrations, the sample should be analyzed in a further dilution to exclude an inhibitory effect of the sample.
- bioavid lateral flow tests are qualitative tests. They do not allow for a quantitative evaluation.
- If an immediate estimation of the allergen contents is required, the sample can be further diluted serially (e.g. 3 further 10 fold dilutions) and retested.

Food allergens usually are proteins. Processing during food manufacturing (heating, extrusion, mixing) may modify these proteins, making them extractable for immunoassays by chemical methods only. This may increase the detection limit for such allergens.

Food matrices may influence the detectability of allergens. Therefore our statements regarding sensitivity of our tests can be applied only to those foods, for which they are listed. In case your type of sample is not listed, please inquire.

It is possible to use the bioavid allergen test kits for the detection of product falsification (e.g. peanut in hazelnut). For that purpose, samples should be diluted another 1:100 with water after the first extraction (final dilution 1:1000). The detection limit for falsification thus will change to 0.1 – 0.5 %.

Warranty

These specifications are based on our current state of knowledge and are designed to provide information about our products and their possible applications. They are not intended to guarantee certain product properties or their suitability for a specific application. Bioavid does not accept any liability except for the standard quality of the reagents. Replacement will be provided for any defective products. Bioavid is not liable for any other claims concerning direct or indirect damage or cost arising from the use of the products.

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Status: Oct. 2010