

Read instructions carefully before starting test

BioKits

Allergen Swabbing Kit

*Store at room temperature
For the collection of environmental samples for analysis*

INTRODUCTION

The problem of undeclared or unintentional allergen content in foods for human consumption is rising in importance with the increase in prevalence of sufferers who experience severe reactions to one or more of the key food allergens. Similarly the high prevalence of Celiac Disease (gluten intolerance), which is only treatable by avoidance of cereal gluten in the Celiac diet, has increased the importance of knowing that foods are truly gluten-free.

Increasingly, food manufacturers and caterers are adopting HACCP-based Allergen Control Plans which require thorough audits of manufacturing/preparation processes to ensure that allergenic protein that may be present in a manufacturing or processing facility is not incorporated into allergen- or gluten-free foods. Part of this process involves the validation of cleaning and cleaning-in-place routines to ensure thorough protein removal. Such validations often require the collection of test samples from processing line surfaces and equipment in order to prove that protein has been effectively cleaned to below specified levels.

PRINCIPLE OF TESTING

The BioKits Allergen Swabbing Kit is intended to be used for the collection of environmental swab samples, from which allergenic protein may be estimated. Information on contamination levels is useful in order to ensure adequate cleaning and/or to identify problem areas (e.g., unwanted build-up of allergens in processing equipment).

The kit provides all the materials required to collect and preserve proteins from environmental surfaces, processing machinery, etc. The surface is swabbed using a generic swabbing and preserving solution and the swabs placed in plastic transport tubes containing more of the solution. This swabbing solution can then be returned to a laboratory for testing using BioKits allergen detection ELISA kits. The swabs collected using the BioKits Allergen Swabbing kit are validated for use with the range of allergen assay kits listed below. Use of the BioKits allergen swabbing kit with other allergen test kits would require validation by the user for suitability:

BioKits assay	Wells	Catalog number	BioKits assay	Wells	Catalog number
BLG	48	902061Y	Peanut	96	902048Q
Egg	48	902072T	Walnut	48	902085J

SAFETY / COSHH NOTE

“Good laboratory practice” techniques should be employed when using this kit. If such practices are used, the reagents constitute a very low potential risk to health. Safety clothing (lab coat, glasses and gloves, if necessary) should be worn and skin contact with reagents avoided. Do not ingest. Any contact with skin/eyes should be treated by washing/irrigation. It also is important to be aware of the allergic, toxic or infectious potential of analytical samples.

NOTE: After swabbing, wipe the swabbed area with a clean, damp cloth to remove any swabbing solution residue.

KIT COMPONENTS

Each kit contains sufficient material for 20 swabs.

The following components are provided in each kit:

Component	Detail	Amount
Sterile swabs	With break-off tips	20
Sterile Pasteur-pipettes	Individually packaged	3
Transport tubes		20
Transport tube caps		20
Tube labels		20
Swabbing solution	Ready to use (mix by repeated inversion, do not shake)	1x 25 mL bottle
Package insert		1
Swabbing sample record sheet		1

MATERIALS REQUIRED BUT NOT PROVIDED

1. Indelible pen for labeling transport tube labels
2. Clean damp cloth for cleaning swabbing site after swab collection

SHELF LIFE

Swabbed samples: The swabbed samples may be stored at room temperature or below for up to four hours prior to testing. If prolonged storage or shipping is required, the swabbed extracts must be kept refrigerated or frozen between -20°C and 8°C and should be shipped under these conditions to preserve integrity. Due to diminished protein solubility through time, Neogen recommends testing within **24 hours** from the time of collection. This is considered optimum for peak recovery of allergenic residues. In situations where this is not logistically feasible, the samples can be analyzed up to **72 hours** from the time of collection with valid results.

Kit reagents: The kit should be stored at room temperature, preferably 22°C or below. The shelf life of unopened kit components is indicated by the expiry date on the respective labels.

SWABBING PROCEDURE

Details of swabs taken and test results may be recorded on the swabbing sample record sheet.

NOTE: This swabbing procedure can detect allergens at extremely low levels. It is important to ensure that hands, clothing, etc. are not contaminated with food materials. If in doubt, wash hands and/or wear gloves and change into clean protective clothing.

1. Remove the required number of components and the swabbing solution from the kit before starting the procedure.

2. Place a label onto the required number of transport tubes and label with an indelible pen to preserve sample (swab solution) identity.
3. Mark out or estimate a swabbing area of approximately 10 cm x 10 cm. Alternatively, the swab may be used to collect samples of contamination from problem areas of processing equipment.
4. Using one of the clean, 1 mL graduated Pasteur pipettes add approximately 1 mL of swabbing solution into clean, labeled transport tube. **NOTE:** Fill several tubes at once so that the three pipettes required are sufficient to fill all 20 transport tubes during the life of the kit. Unused, filled tubes can be stored with the kit for extended periods.
5. Remove a sterile viscose swab from its packaging and wet the end by dipping into the swabbing solution in the first transport tube.
6. Use the wetted swab to wipe the entire swabbing area using side-to-side movements of the swab and revolving the viscose end on the surface. Repeat this swabbing procedure using movements at right angles to those used in the first swabbing to create a crosshatch pattern.
7. Return the swab to the solution in the transport tube and carefully break off the viscose end at the prescored mark so that it remains in the tube. Carefully secure the cap of the transport tube taking care to ensure that the stem of the swab does not prevent the tube from being properly sealed.
8. Mix the swabbing solution in the transport tube well. Return the tube to the laboratory, with the completed record sheet, for analysis using one or more BioKits ELISAs for allergenic proteins.

MEASUREMENT OF SWAB ALLERGEN CONTENT

The collected swab solution is tested directly in the relevant BioKits assay kit for the allergens of choice. 1 mL of swab solution is sufficient to test for two separate allergens in duplicate (assuming that repeat measurements are not necessary).

When tested directly in the BioKits assay kits the following ranges of quantification apply:

BioKits assay	Range of quantification (ng/mL)	Units of measurement
BLG	25–400	BLG
Egg	5–100	Egg white protein
Peanut	10–200	Peanut
Walnut	120–6000	Walnut

See individual BioKits inserts for further details.

INTERPRETATION / LIMITATIONS

Because of the variability of the swabbing process, the amount of detectable protein in the swabbing solution may vary considerably. Recoveries of various allergens from a swabbed area vary quite widely and detection of allergens from complex and/or highly processed food sources can be difficult.

Even if the allergen is undetectable in the swabbing solution using BioKits ELISAs, the solution may still contain protein that may be allergenic, either because it is undetectable (below the limit of detection of the test) or because processing of the food reduces or prevents reaction in the test. These factors must be taken into consideration when interpreting results. For these reasons, it is generally agreed that the determination of allergen content from a swabbed area can never be truly quantitative.

CUSTOMER SERVICE

Neogen Customer Assistance and Technical Services can be reached by using the contact information on the back of this booklet. Training on this product, and all Neogen test kits, is available.

SDS INFORMATION AVAILABLE

Safety data sheets (SDS) are available for this test kit, and all of Neogen's test kits, on Neogen's website at www.neogen.com, or by calling Neogen at 800/234-5333 or 517/372-9200.

TERMS AND CONDITIONS

Please visit www.neogen.com/Corporate/termsconditions.html for Neogen's full terms and conditions.

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TESTING KITS AVAILABLE FROM NEOGEN

Natural toxins

- Aflatoxin, DON, ochratoxin, zearalenone, T-2/HT-2 toxins, fumonisin, histamine

Foodborne bacteria

- *E. coli* O157:H7, *Salmonella*, *Listeria*, *Listeria monocytogenes*, *Campylobacter*, *Staphylococcus aureus*, *Salmonella enteritidis*

Sanitation

- ATP, yeast and mold, total plate count, generic *E. coli* and total coliforms, protein residues

Food allergens

- Almonds, crustacea, eggs, gliadin, hazelnut, milk, mustard, peanut, sesame, soy, walnut, multi-treenut

Genetic modification

- CP4 (Roundup Ready®)

Ruminant by-products

- Meat and bone meal, feed

Species identification

- Raw and cooked meat samples, feed



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