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WHITE PAPER

Getting Allergen Testing Right – The Foundation

A food industry guide to developing an effective and compliant allergen testing procedure.

Getting Allergen Testing Right – The Foundation

Food manufacturers continue to invest heavily in allergen control, yet allergen-related recalls remain a persistent challenge across the industry.

An effective allergen testing programme depends on several factors, including defining the purpose of testing, selecting the right test kits, refining sample collection methods, and determining how results will be acted upon.

Misunderstandings around best practice and differing interpretations of auditor expectations can also result in inconsistent testing, misleading results, and an increased risk of contamination events or recalls.

This white paper outlines the key principles required to build a robust allergen testing programme and establish confidence in allergen control.

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The Allergen Testing Ladder

Much like climbing a ladder, each stage of your allergen verification programme needs to be completed in the correct order. Skipping steps can lead to unreliable results, unnecessary costs, and wasted time. As you move up the ladder, testing methods become more expensive and time-consuming. Additionally, if a stage fails, you will need to return to the previous step before moving forward again.

1. Visual Checks

The first step is a visual inspection. If visible debris remains on a surface, it is clear the cleaning has not been effective. There is little value in carrying out further testing until the surface has been cleaned again.

2. Hygiene Verification

Once a surface appears visually clean, hygiene verification can be carried out using ATP tests or protein swabs. Klipspringer recommends the A3 System, which measures ATP, ADP and AMP to provide a broader assessment of organic residue. Although hygiene verification methods are not intended for allergen detection, they can identify residues that may contain allergenic material. A failed result at this stage indicates cleaning has not been effective.

3. On-Site Allergen Verification

After hygiene verification has been successfully completed, allergen testing can begin. If hygiene verification and allergen testing are both carried out correctly, the results should generally align. Frequent unexpected failures at this stage may indicate that your site's hygiene verification methods are not fully representative of cleaning performance.

Rapid allergen tests are commonly used for routine verification and provide quick qualitative (positive/negative) results. In some cases, sites may choose to carry out ELISA testing immediately after hygiene verification, particularly if greater sensitivity or quantitative results are required.

4. Laboratory Validation

Where a higher level of confidence is required, for example during annual reviews or following a material change on site, laboratory testing should be used to support validation activities and investigate more complex risks. Laboratory testing provides the highest level of accuracy, but is typically reserved for this stage due to the time and cost involved.

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Understanding Allergen Testing Methods

Lateral Flow Tests

There are two main types of lateral flow allergen tests. Surface and rinse water tests are typically used for post-clean verification, while product sample tests are used to assess allergens within finished products or ingredients.

These lateral flow tests provide qualitative results, indicating whether the target allergen is present or absent to a predetermined level of accuracy. They are rapid, easy to use, and require less equipment than more complex methods.

Surface and rinse water tests can usually be completed without additional equipment, whereas product sample tests typically require more complex equipment, such as a boiling water bath as part of the extraction process.

ELISA Tests

ELISA tests are used to detect specific allergenic proteins and provide quantitative results. They report the level of allergen present in parts per million (ppm).

These tests are generally more sensitive than lateral flow methods and are commonly used during cleaning validation, product assessment, and investigations where a greater level of detail is required.

ELISA testing is more time consuming and needs to be conducted in a laboratory that has specialist equipment such as an incubator, stirrer, and dry bath.

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Key Questions to Consider

What is the purpose of your testing?

A clear objective helps to ensure your testing method, sampling process, and interpretation of results are appropriate for the risks being assessed. Common reasons for allergen testing include:

- **Cleaning validation:** demonstrating that a cleaning process is capable of removing allergen residues to an acceptable level.
- **Cleaning verification:** confirming that cleaning has been effective on a routine basis.
- **Environmental monitoring:** checking for the presence of allergens in the production environment.
- **Screening incoming ingredients:** assessing raw materials for potential allergen contamination.
- **Meeting customer or retailer requirements:** ensuring compliance with specific customer standards or specifications.
- **Substantiating free-from claims:** providing evidence to support allergen labelling.
- **Investigating consumer complaints:** identifying potential sources of allergen contamination following a reported issue.

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Why is effective sampling so important?

Sampling is just as important as the testing method itself, as an ineffective approach can cause misleading results and undermine the reliability of your entire testing programme. If samples are not collected correctly, your cleaning validation and verification results will not be valid. Careful consideration should be given to:

- Where samples are taken from
- How many samples are required
- Whether all relevant surfaces and risks are represented

In every case, the objective should be to maximise the likelihood of detecting the target allergen. Focus on areas that are difficult to access, prone to residue build-up, and particularly challenging to clean.

Another vital step is to establish a clear action plan for responding to positive results. Rapid decision-making can help to prevent further contamination, minimise unnecessary stock loss, and reduce the risk of product recalls.

What are the key steps for responding to a positive result?

A positive result during cleaning validation may indicate that a cleaning procedure requires further development before it can be considered effective. In this context, the purpose of testing is to challenge the cleaning process and identify potential weakness.

A positive result during routine verification is typically more concerning, as it may indicate that a validated cleaning procedure has not been followed effectively or that control has been lost during production.

The appropriate response will depend on the level of risk identified at each individual site. In many cases, measures will include:

- Assessing and, if necessary, placing affected product on hold.
- Repeating cleaning and re-testing where appropriate.
- Investigating the cause of the result through root cause analysis.
- Deciding if revalidation of the cleaning procedure is required.
- Documenting findings and actions taken.

Every site should ensure its response procedures are based on its own risk assessment, products, processes, customer requirements, and auditing standards.

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What is the difference between cleaning validation & verification?

When it comes to choosing the right testing methods for your site, it is important to understand the difference between cleaning validation and cleaning verification.

Cleaning Validation

Did we choose the right cleaning method?

The purpose of validation is to demonstrate that a cleaning procedure is capable of reducing allergen residues to an acceptable level. This process typically calls for ELISA testing, a quantitative method that measures how much allergenic protein is present, rather than simply reporting a positive or negative result.

Frequency

Cleaning validation is typically carried out:

- When a cleaning process is first introduced.
- Following significant changes to products, equipment, or cleaning procedures.
- Periodically in accordance with the requirements of a site, customer, or auditing body.

Cleaning Verification

Did the cleaning method work this time?

Cleaning verification is carried out routinely after cleaning to confirm the relevant equipment or surfaces have been cleaned effectively. Sites will typically use a qualitative test, such as a Lateral Flow Immunoassay (LFI), which provides a positive or negative result for allergen presence. These rapid methods should always be validated in advance to confirm they are accurate and reliable.

Frequency

Cleaning verification is carried out on an ongoing basis and is typically performed at defined frequencies based on risk assessment. This may include testing after changeovers, on a scheduled basis, or following events that could impact cleaning performance.

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Cleaning Validation: Best Practice

When validating the cleaning procedures at your site, the aim is to demonstrate that the process consistently removes or reduces allergen residues to an acceptable level. There are six key steps to work through:

1 Identify a target allergen

In the case of cleaning validation, sites handling multiple allergens do not always need to validate every allergen or product individually. Instead, a target allergen can be selected based on risk. This should be the allergen that is most difficult to remove, present at the highest concentration, or present within a particularly sticky or fatty product. The goal is to maximise the likelihood of detecting residue if cleaning has been ineffective. This approach applies to cleaning validation; however, routine allergen testing should cover all allergens on site.

2 Confirm the suitability of the testing method

The selected product should be sent to your chosen laboratory alongside details of the target allergen. The laboratory will need to confirm that your chosen testing method (e.g. ELISA test) can reliably detect the allergen. This assessment should involve quantitative analysis rather than a simple positive or negative result.

3 Conduct a routine clean

Cleaning should be completed according to a standardised procedure that is used routinely on site. Ideally, the clean should be inspected by someone who was not directly involved in the process.

4 Collect the right samples

Samples should be taken from *all* relevant surfaces, as materials can respond differently to cleaning. If your site relies on any clean-in-place procedures, final rinse water should also be sampled. These samples should then be submitted to the laboratory that assessed your chosen product.

The same samples can also be tested on site using rapid lateral flow tests, allowing results to be compared against the laboratory ELISA results. This will support validation and the ongoing verification of your rapid testing method.

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5 Assess allergen carry over

If your cleaning procedure is effective, the next product manufactured in that area should not contain the target allergen. To demonstrate this, a sample of the product will need to be sent away to your chosen laboratory to undergo the same form of testing. The laboratory should validate the testing process fully, carrying out cross-reactivity assessments and spike recovery testing where appropriate.

6 Demonstrate repeatability

Cleaning validation should be repeated at least three times to demonstrate consistent results. Ideally, the samples should be taken from cleans carried out by different hygiene teams and across different shifts to confirm the procedure is repeatable across normal production conditions.

Disclaimer: *The information within this white paper, including the cleaning validation process, is intended for guidance purposes only. It is essential that you conduct your own risk assessments, obtain specialist advice where appropriate, and develop procedures that reflect the specific risks and requirements of your site.*

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Choosing the Right Laboratory

The effectiveness of your allergen testing programme depends heavily on the capability of the laboratory that supports it. A suitable laboratory should be able to assist with sampling plans, recommend appropriate testing methods, and provide clear interpretation of results. Fast, reliable communication is equally important, helping to protect consumers while minimising operational disruption.

When selecting a laboratory, you will need to consider the following points.
For each, a question is provided to help you assess your potential partner:

- Appropriate external accreditations held by the laboratory. ISO 17025 is the core standard for testing laboratories. In the UK, UKAS is the main recognised accreditation body confirming compliance with ISO 17025.
  - ***What accreditations does the laboratory hold and are they relevant to allergen testing?***
- Proven expertise in allergen testing and analytical method validation.
  - ***What experience does the laboratory have in allergen testing and method validation?***
- Capability to evaluate cross-reactivity and matrix-related interference.
  - ***How does the laboratory assess cross-reactivity and matrix effects in different food types?***
- Robust internal quality control and assurance procedures.
  - ***What quality control and assurance systems does the laboratory have in place?***
- Availability and responsiveness of technical support.
  - ***How quickly can technical support be accessed when issues arise?***
- The speed and clarity of communication.
  - ***How clear and timely is the laboratory's communication of results and interpretation?***

Laboratory Requirements

At a minimum, a laboratory must operate under recognised accreditation. They must also participate in proficiency testing, measure uncertainty, and have robust quality control systems in place. These requirements ensure results are valid and traceable.

Best Practice

A good laboratory will advise on sampling plans and test selection. They should also help with the interpretation of results. Strong laboratories also assess method suitability for specific products, supported by cross-reactivity checks, along with recovery testing where appropriate.

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Questions to ask about your current testing programme

When evaluating your allergen testing programme, there are several key areas to address. The questions below provide a useful framework. Regularly reviewing them with your team will help to strengthen allergen control procedures and improve site-wide confidence in testing outcomes.

Question	Answer	Action	Who is responsible?
What is the purpose of our allergen testing?			
How do our sampling methods reflect real risks on site?			
How effective is our current approach to cleaning validation and verification?			
How confident are we that our rapid tests have been properly validated?			
Are we testing the most difficult to clean allergens and products at our site?			
How clear is our process for responding to positive or unclear results?			
How confident are we in the capability of our laboratory partner?			
How consistently are our procedures applied across different teams and shifts?			

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What are the next steps?

1. Meet with relevant stakeholders to review your current allergen testing programme. The questions on the previous page provide a useful starting point.
2. Connect with Klipspringer to review your existing processes and explore the range of available testing kits.
3. Our Technical Team will support you in developing the most effective approach for your operation, providing guidance on detection limits, storage requirements, best practice, and training.
4. Assess your current laboratory partner. You can discuss your options with our Technical Team. Alternatively, you can reach out directly to Reading Scientific Services (RSSL), a leading research, testing, and consultancy organisation.

EASY Rapid Allergen Test Kits
Suitable for surface swab samples and rinse water samples.

PRO Allergen Test Kits
Suitable for food samples in highly processed, processed, and unprocessed foods.

ELISA Allergen Test Kits
Suitable for highly sensitive detection of allergens in raw materials and processed foods.

Radek Tameczka
Allergen Testing Specialist

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Led by Allergen Testing Specialist Radek Tameczka, Klipspringer's Technical Team is available to help you select the most suitable tests for your site. They can also provide resources to support roll out and staff training.

If you have any questions or wish to discuss the specific requirements of your site, contact us at **01473 461 800** or **sales@klipspringer.com**

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Additional Resources

Via the Klipspringer Knowledge Hub, you can watch a dedicated industry webinar on best practice and the role of rapid allergen testing. For this resource and more, visit:
klipspringer.com/the-hub

WEBINAR:
Mastering Allergen Testing - Best Practice and the Role of Rapid Testing

Click here to watch

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