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WHITE PAPER

Rapid Allergen Testing - A Practical Guide for Food Manufacturers

How to select, use, and maximise the effectiveness of Rapid Allergen Tests.

Rapid Allergen Testing - A Practical Guide for Food Manufacturers

Rapid allergen tests are widely used across the food manufacturing industry, yet many sites continue to struggle with uncertainty around best practice.

Rapid allergen testing plays an important role in food manufacturing. When applied correctly, it helps sites to prevent cross contamination, verify allergen control measures, and protect consumers with allergies.

However, misunderstandings around test capabilities, limitations, and best practice also mean that rapid allergen tests are frequently misused. This can result in inconsistent data and false confidence in allergen control measures.

This white paper provides a practical guide to rapid allergen testing. It explains how different testing methods work, when they are most effective, and the key considerations for generating reliable and meaningful results.

For readers looking to build a stronger foundation in allergen management, a companion white paper, Getting Allergen Testing Right - The Foundation, is also available through the Klipspringer Knowledge Hub. It covers the core principles of an effective allergen testing programme, best practice for cleaning validation, and expert guidance on selecting the right laboratory.

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The Allergen Testing Ladder

A useful way to view allergen testing is through a simple ladder structure, where each method occupies a different level, from quick, cost-effective checks through to more complex and sensitive analysis.

Within this framework, rapid allergen tests represent just one step in the allergen testing process. They deliver the most value when supported by visual inspection, hygiene verification, and laboratory analysis. Understanding how these methods work together helps sites to apply rapid testing more effectively and avoid over-reliance on a single control measure.

1. Visual Checks

Visible debris or product residue is a clear indication that cleaning has been ineffective. When contamination remains visibly present, proceeding to hygiene verification or rapid allergen testing offers limited value and may result in the unnecessary use of time and resources.

2. Hygiene Verification

If a surface appears visibly clean, hygiene verification can be performed using ATP testing or protein swabs. Klipspringer recommends the A3 System, which measures ATP, ADP, and AMP, providing a more comprehensive assessment of organic residue than ATP testing alone.

While hygiene verification methods are not designed to detect allergens directly, they can identify residual organic material that may contain allergenic substances. A failed result at this stage indicates further cleaning is required and allergen testing should not be undertaken yet.

3. On-Site Allergen Testing

Once hygiene verification has been successfully completed, allergen testing can begin. When both processes are implemented correctly, the results should generally be consistent. Repeated allergen test failures following satisfactory hygiene verification may indicate that the site's hygiene verification programme is not fully representative of cleaning effectiveness.

There are two main types of rapid allergen tests: one primarily used for product testing and another for routine verification of surfaces and rinse water samples. These tests provide rapid qualitative results, indicating the presence or absence of the target allergen.

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4. Laboratory Validation

Laboratory testing provides quantitative results, offering a more detailed assessment than the qualitative positive/negative results generated by rapid allergen tests. ELISA tests are typically used when a higher level of assurance is required, such as during annual validation reviews or following significant changes to processes, ingredients, or equipment.

Laboratory analysis can help to verify the effectiveness of allergen control measures and support the investigation of more complex allergen-related risks. However, due to the additional time, cost, and expertise involved, it generally sits at the highest level of the allergen testing ladder.

Understanding Allergen Testing Methods

Rapid allergen tests use lateral flow technology to detect the presence of target allergenic proteins within a sample. They are quick and easy to use, providing qualitative positive/negative results that indicate whether an allergen is present or absent at a defined limit of detection.

There are two main types of rapid allergen tests. Surface and rinse water tests are typically used for post-cleaning verification, helping to confirm that allergenic residues have been effectively removed or reduced to an acceptable level. These tests can often be completed without the need for additional equipment.

Product sample tests are used to assess the presence of allergens in raw ingredients and finished products. They typically require additional equipment, such as a boiling water bath, but are still significantly less complex than ELISA tests.

How do Rapid Allergen Tests differ from ELISA Tests?

While rapid allergen tests provide qualitative results, ELISA methods deliver quantitative measurements, reporting allergen concentrations in parts per million (ppm).

ELISA tests are commonly used in applications that require greater analytical accuracy such as cleaning validation, detailed product assessment, and investigations that call for numerical results.

ELISA testing is more time-consuming and costly than rapid allergen testing. It also involves analysis within a laboratory environment that is equipped with specialist instrumentation such as incubators, stirrers, and dry baths.

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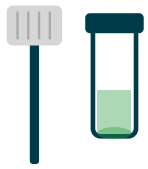
How Do Rapid Allergen Tests Work?

Understanding how Rapid Allergen Tests work is important for reducing the risk of incorrect or unreliable results. Individual test formats vary based on brand, but the process for testing surface and rinse water samples generally follows the same principles:

1

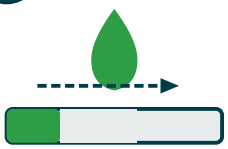


A surface is swabbed or a rinse water sample is collected. The sample is then mixed with an extraction buffer to release the proteins for testing.

2

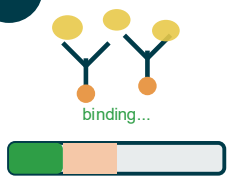
The required number of drops from the prepared sample are applied to the dedicated pad on the test strip.

3



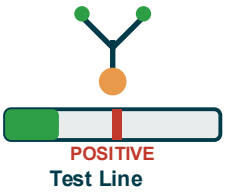
The liquid moves across the test strip through capillary action, working along the porous material without the need for external force.

4



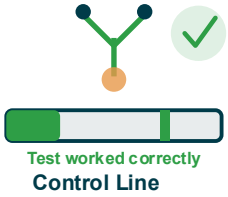
The detection antibodies rehydrate and are released. If the target allergen is present, the antibodies bind to it, forming immune complexes.

5



The immobilised antibodies at the **test line** capture these complexes. The appearance of a visible coloured line indicates a positive result.

6



Excess detection antibodies continue to the **control line** where they are captured. If a coloured line appears, this confirms the test has worked.

7

The absorbent pad draws the remaining liquid through the test device, maintaining a consistent flow across the strip.

NOTE: *The test result should be interpreted at the 10-minute mark. Changes observed after this time (e.g. 12-15 minutes) may occur due to continued movement of the test solution and should be disregarded.*

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Sensitivity and Rapid Allergen Tests

The performance of rapid allergen tests can vary depending on the product being tested and the surrounding food matrix. A test may perform well in one application but deliver different levels of sensitivity in another. This is influenced by several factors, including:

- Processing methods
- Ingredient combinations
- Product composition

For example, a test kit may be capable of detecting peanut protein at a specified level in a dry ingredient blend, but its sensitivity may be reduced when testing peanut residues in a chocolate product due to the high fat content affecting allergen extraction.

It is important to remember that a test kit capable of detecting an allergen at a specific level (e.g. 5 ppm) may not achieve the same level of sensitivity across all product types. Food manufacturers should therefore work with a laboratory to confirm that the chosen method is suitable for their specific products and processes.

Cross-Reactivity and Rapid Allergen Tests

Cross-reactivity occurs when a rapid allergen test reacts not only to the target allergen, but also to other ingredients with similar protein structures. This can lead to false positives or misleading results.

While test suppliers often provide information on known cross-reactivities, it is not always possible to predict every potential interaction. If there is uncertainty about test performance, manufacturers should work with the suppliers of their rapid allergen tests or consult an accredited laboratory.

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Detection of Native and Denatured Proteins

Native proteins retain their original structure and are typically easier to detect. Examples include allergenic residues from raw ingredients such as milk, egg, wheat, or peanut.

Denatured proteins have been altered by processing conditions such as heat, exposure to cleaning chemicals, or changes in pH. For example, milk proteins in baked products, roasted peanut proteins, or allergenic residues exposed to caustic cleaning solutions may be more difficult for some test methods to recognise.

The suitability of rapid allergen tests depends on the specific application and the type of residues likely to be present in the testing environment. It is recommended to work with the test supplier or an accredited laboratory to confirm that the chosen method is capable of detecting allergenic proteins under relevant real-world conditions.

If consistent or reliable results are difficult to achieve, certain advanced test methods combine enhanced extraction approaches with specialised antibodies to improve the detection of both intact and modified protein residues across a wider range of applications.

Validation of Rapid Allergen Tests

The appropriate interval for validating allergen tests depends on a site's risk assessment, the nature of the products being manufactured, and any specific requirements set by customers or certification bodies.

However, most sites validate allergen testing methods when they are first introduced, then revalidate at least annually and whenever a significant change occurs, such as:

- Introduction of new products or allergens
- Changes to ingredients or suppliers
- Changes to manufacturing processes
- Changes to cleaning procedures

Validation should cover all relevant allergens, products, and processes used on site and should include any rapid allergen tests that form part of the allergen control programme.

If laboratory-based ELISA testing is already being used for validation, it can be beneficial to assess the performance of rapid allergen tests at the same time. For example, adjacent areas of the same surface can be sampled following cleaning, with one sample analysed using a rapid allergen test and the other submitted to an external laboratory for ELISA analysis. Comparing the results can help to demonstrate whether the rapid test performs as expected.

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Six Key Factors to Consider When Selecting Rapid Allergen Tests

The following six factors provide a useful starting point when assessing rapid allergen tests:

1. The Target Allergen

Start by identifying which allergen needs to be detected. Remember, different rapid tests are designed for different allergens, and not all tests are suitable for every product type or production environment.

At this stage, some sites consider using composite swabs, where material from multiple swabbed locations is combined into a single test sample in an attempt to reduce costs. However, this is generally a false economy. Combining swabs can dilute any contamination present, potentially reducing it below the detection limit and leading to a false negative result.

Furthermore, if a combined sample returns a positive result, it is not possible to determine which of the original sampling locations was responsible, limiting the usefulness of the result for corrective action.

2. Detection Sensitivity

Rapid allergen tests vary in sensitivity, with typical detection limits ranging from around 2 ppm to 10 ppm. If greater sensitivity is required, extraction methods can sometimes be adjusted to increase sample concentration. However, this process must be validated to ensure results remain reliable.

3. Validation

It is important to understand how the rapid allergen tests have been validated by the supplier or manufacturer. This should include evidence of repeatability, quality control, and consistency across different batches.

Sites will also need to work with a laboratory to confirm the tests are suitable for their specific product types and processing conditions. It remains the responsibility of the site to validate the test against their exact products and processes.

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4. Storage Requirements

Many rapid allergen tests require chilled storage. This can limit the number of kits that can be held on site at one time. It can also make stock management more complex.

These temperature-controlled conditions must also be maintained during transportation and delivery. On receipt, storage temperatures must be verified, introducing an additional step and potentially delaying use. In contrast, tests that are stable at ambient temperatures typically offer greater flexibility.

5. Supply Chain Reliability

Due to the validation requirements associated with allergen testing, it is not recommended to frequently change test brands and suppliers. Instead, it is important to choose partners that can consistently deliver the same test kits.

Establishing a contract or standing order can help to reduce disruption and ensure continuity of supply through service level agreements.

6. Ease of Use

Rapid allergen testing should be as simple and practical as possible. Reducing complexity helps to streamline training and supports consistency across different shifts.

Some rapid tests require additional preparation steps or reagent mixing, which can introduce unnecessary variables and require a higher level of operator skill. This, in turn, increases the potential for human error and the associated consequences.

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Six Common Mistakes Associated with Rapid Allergen Tests and How to Avoid Them

The effectiveness of rapid allergen tests is reliant on their correct use and interpretation. Below are six common mistakes to avoid:

1 Using Rapid Tests as the Sole Means of Allergen Testing

Rapid allergen tests provide qualitative positive/negative results. They do not indicate specific allergen levels, and therefore provide an incomplete view of risk when used alone. Instead, they should be incorporated into a broader allergen control and validation strategy.

To learn more about establishing an effective strategy at your site, refer to our companion white paper, *Getting Allergen Testing Right – The Foundation*, also available through the Klipspringer Knowledge Hub.

2 Overuse of Positive Controls

Positive controls are samples known to contain a target allergen. They are used to confirm that rapid tests are working correctly. However, they do not reflect real production conditions or actual allergen levels. Positive controls can be over-relied upon as a form of routine validation rather than periodic checks.

3 Overloading the Tests

Rapid tests are designed to detect very low levels of allergens. Applying too much sample can overwhelm the system and lead to incorrect results. This is known as the *High Dose Hook Effect* and is often misinterpreted as a test failure instead of a sampling issue. To avoid overloading, a small representative sample should be taken and any visible residue should be removed prior to testing.

4 Premature Testing

Visual checks and hygiene verification should be completed prior to the rapid allergen testing of surfaces and rinse water samples. However, some sites may skip these steps under time pressure and proceed directly to allergen testing.

In many cases, this results in the use of a more complex and costly test when earlier checks could have confirmed that the surface or rinse water was not yet suitable for allergen testing.

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5 Poor Swabbing and Sampling Technique

For reliable results, a defined 10 cm x 10 cm area should be swabbed, with sampling focused on areas identified through risk assessment as the most likely to harbour allergen residues.

Limiting sampling to low-risk or easily accessible areas can create a false sense of security and increase the likelihood of contamination going undetected.

6 Mishandling and Storage Errors

The accuracy of rapid allergen tests can be affected by how the kits are stored, transported, and prepared. For example, some tests require reagent mixing, where incorrect technique can significantly impact results. Others require chilled storage, which introduces additional constraints during transport and delivery. Selecting simpler test formats can help to reduce these risks.

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Protein Swabs, ATP Tests, and the A3 System

Allergen testing is essential for confirming the presence of specific allergenic proteins and should not be replaced. However, many sites continue to use rapid allergen tests in situations where hygiene verification tools could provide an effective intermediate step.

Hygiene verification methods such as protein swabs, traditional ATP tests, and the A3 System are typically faster and lower cost than rapid allergen tests, making them well suited to the initial stages of cleaning verification. When used correctly, these tools can help to ensure allergen testing is only carried out once effective cleaning has been demonstrated.

Protein Swabs

Protein swabs are used to assess the effectiveness of cleaning by detecting residual protein contamination on surfaces.

Benefits

- Simple, rapid, and cost-effective.
- Provides a quick indication of whether general protein contamination has been effectively removed during cleaning.
- Can be used as an initial screening tool before more costly and time-consuming allergen-specific testing.

Limitations

- Detect total protein rather than specific allergenic proteins.

Conventional ATP Tests

ATP tests have traditionally been used for hygiene verification. However, ATP can degrade into ADP and AMP during processes such as heating, fermentation, and cleaning. A growing number of sites are moving away from conventional ATP testing due to its limited ability to detect these additional forms of organic residue.

Benefits

- Simple, rapid, and cost-effective.
- Detects ATP, a form of organic residue, providing a partial indication of cleaning effectiveness.

Limitations

- Cannot detect ADP or AMP, which reduces accuracy in assessing overall cleaning effectiveness.
- Inability to detect all organic residue may lead to premature allergen testing or conflicting results with allergen-specific tests.
- Cannot confirm the presence or absence of specific allergens.

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The A3 System

The A3 System is a hygiene monitoring tool that detects all forms of organic residue (ATP + ADP + AMP). In a study conducted by Kikkoman Biochemifa Company, the system demonstrated greater sensitivity to organic residue than both traditional ATP tests and protein swabs.

Benefits

- Quick, easy to use, and cost-effective.
- Greater sensitivity than traditional ATP tests and protein swabs, providing a more accurate indication of cleaning effectiveness.
- Improved accuracy helps align hygiene monitoring results more closely with allergen testing outcomes.

Limitations

- Detects organic residue rather than specific allergenic proteins.

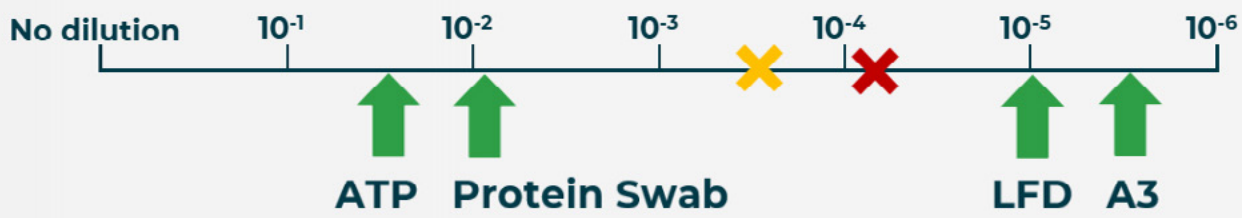
Evaluating the Sensitivity of Hygiene Verification Tools

A study conducted by Kikkoman Biochemifa Company compared the sensitivity of protein swabs, conventional ATP tests, lateral flow detection methods (LFDs), and the A3 System for the detection of peanut residue.

The study found that protein swabs detected peanut residue only at relatively low dilution levels, performing only marginally better than conventional ATP tests.

In comparison, the A3 System demonstrated greater sensitivity, detecting peanut protein at concentrations as low as 10 ppm. These results were consistent with those obtained using ELISA tests and a Bradford protein assay.

Overall, the findings suggest that the A3 System provides a more sensitive and reliable method for verifying cleaning effectiveness prior to allergen-specific testing.



Disclaimer: The A3 System is highly sensitive to organic residues, but cannot be used to confirm the presence or absence of a particular allergen. The system should be viewed as a hygiene verification tool rather than a replacement for rapid allergen testing.

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Rapid Allergen Testing Checklist

This checklist is a practical guide to help support the selection and use of rapid allergen tests. However, allergen management procedures should always be based on site-specific risk assessments, validated methods, and specialist advice.

Before Selecting a Rapid Allergen Test

Task	Tick
Define the target allergen(s) that need to be detected.	
Confirm the test is suitable for the relevant product types and processing conditions.	
Review the stated detection sensitivity and ensure it aligns with site requirements.	
Assess the potential impact of processing, heat treatment, cleaning chemicals etc...	
Review supplier validation data, including repeatability and batch consistency.	
Consider the risk of cross-reactivity with ingredients used on site.	
Confirm storage requirements and transportation conditions can be maintained.	
Assess ease of use and training requirements for operators.	
Select suppliers capable of providing long-term continuity of test kits.	

Before Carrying Out Rapid Allergen Testing

Task	Tick
Complete a visual inspection to confirm no visible residue remains.	
Carry out hygiene verification (protein swabs, ATP testing, or the A3 System).	
Confirm cleaning has been effective before progressing to allergen testing.	
Identify the highest-risk sampling locations based on risk assessment.	
Ensure staff are trained in correct swabbing and sampling techniques.	
Confirm all test kits are within expiry date and have been stored correctly.	
Ensure clear testing procedures are established, understood, and consistently followed.	

During Rapid Allergen Testing

Task	Tick
Avoid overloading tests with excessive sample material.	
Follow extraction and preparation steps exactly as instructed by the kit manufacturer.	
Use the correct sample volume and timing requirements.	
Confirm the control line appears correctly on the test device.	
Record results clearly and consistently.	

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Interpreting Results

Task	Tick
Remember that rapid allergen tests provide qualitative results only.	
Do not use rapid tests as the sole means of allergen control.	
Investigate unexpected or inconsistent results before releasing equipment or product.	
Consider ELISA testing if quantitative data or additional confirmation is required.	
Review trends over time to identify recurring cleaning or process issues.	

Ongoing Validation and Best Practice

Task	Tick
Periodically review sampling locations, sampling strategies, and risk assessments. (At least annually, or whenever a significant change occurs.)	
Revalidate testing methods and sampling procedures when products, ingredients, suppliers, equipment, processes, or cleaning procedures change.	
Periodically compare rapid allergen test results with laboratory analysis, where appropriate, to maintain confidence in test performance.	
Use positive controls appropriately without over-reliance.	
Maintain documented procedures for storage, handling, testing, and interpretation.	
Provide refresher training to maintain consistency across operators and shifts.	
Work with test suppliers or specialist laboratories when uncertainty exists.	

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What are the next steps?

1. Review current allergen testing practices, including where and when rapid allergen tests are used.
2. Work with Klipspringer's Technical Team to identify and discuss opportunities for improvement.
3. Assess the sensitivity and cross-reactivity of your testing methods. This can be undertaken in collaboration with your laboratory or an independent research, testing, and consultancy organisation.

   For guidance on selecting a laboratory, refer to our companion white paper Getting Allergen Testing Right - The Foundation, available through the Klipspringer Knowledge Hub.
4. Ensure rapid allergen tests are used correctly across your site by reviewing procedures, expected detection capabilities, supply agreements, and storage requirements. This should be reinforced through regular, targeted training sessions.

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. You can also access a second white paper on developing an effective and compliant allergen testing procedure. For these resources and more, visit:
klipspringer.com/the-hub

WEBINAR:

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

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WHITE PAPER:

Getting Allergen Testing Right - The Foundation

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