

Allergen Insider

Experts in the Field

2018

04 All Your Allergen Testing Needs in One Place



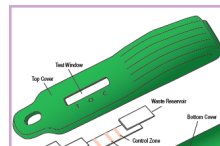
06

Which Solution Fits Best



10

Eliminating the Hook Effect



Tel: + 44 (0) 1292 525 627 • Fax: + 44 (0) 1292 525 602
Email: allergens_uk@neogeneurope.com
Web: foodsafety.neogen.com/uk/allergens



Contents

05

Behind the Scenes: Neogen's Technical Support Services

Read how our technical support team addressed the allergen testing issue of a seasoning manufacturer

06

Which Solution Fits Best?

Take our allergen testing quiz

11

Anaphylaxis Campaign

The charity working for allergy sufferers

12

Did You Know?

Check out some facts about cow's milk allergy

Allergen Testing Made Quick and Easy-to-Use



Simple and quick, Neogen's lateral flow tests provide the food industry with easy-to-use onsite allergen testing. Neogen's full line of quantitative ELISA test kits also provide food processors and laboratories with tools for the allergen-free verification of ingredients, in-process materials and finished products.

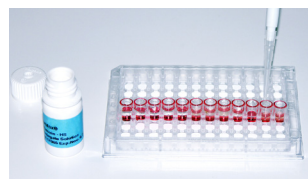
Reveal® 3-D tests are designed with three lines of detection and can be used to screen for the presence of low levels of allergen in rinses, environmental swabs and validated food products virtually anywhere. Reveal 3-D features an overload line designed to prevent saturation and alert the user to a high positive result (see page 10). These tests are simple to use and ideal for onsite analysis, with results available within 10 minutes or less, following sample preparation.

Our Veratox® ELISA test kits offer quantitative results within 30 minutes following extraction and require minimal

training and laboratory equipment. Veratox provides food processors and laboratories with a method of easily determining if an ingredient or product has been subjected to cross-contact with a food allergen.

Neogen's easy-to-use food allergen test kits offer quick results for real-time decision making. They can be used in all areas of the process and supply chain with minimal training required. Our teams are available to support customers in setting up onsite testing and deliver available training when necessary. From process control to auditing, inspection, troubleshooting and training, our food allergen testing solutions are a critical part of any food allergen risk assessment ■

For more information visit:
foodsafety.neogen.com/uk/allergens



Demonstrate Your Analytical Competence



When dealing with ingredients that pose a potential allergen risk, adequate testing is paramount. But how do you make sure that your laboratory methods are effective? Participating in a proficiency test, or ring trial, can give you assurance in the efficiency of your testing programme.

Neogen have partnered with DLA (Dienstleistung Lebensmittel Analytik GbR), an established provider of proficiency tests to offer a range of allergen detection proficiency tests across foods, cosmetics and contact materials.

Proficiency testing is an important

element of quality assurance in laboratory methods. Participation in ring trials enables a laboratory to prove their own analytical competence under realistic conditions. It also provides valuable data regarding the validity of the particular testing methods with respect to the requirements of ISO/IEC 17025 accredited laboratories.

Laboratories taking part in these proficiency tests will receive samples with known quantities of contamination, which they will then have to test according to their standard procedures. The results will be sent back to DLA and compared with the existing data to establish the effectiveness of the tests. The participants will receive a report which will outline how their performance compares to the

rest of the participants, thus providing an important tool to establish if allergen testing is performed adequately, or if procedures need to be reviewed.

Every year, DLA offers proficiency tests for between 50 and 60 matrices divided into seven categories. Registration for these tests is available all year round for any of the matrices. As is usually the case for proficiency tests, all results are anonymous ■

Contact us for more information on proficiency testing and internal evaluation materials.

Allergen Testing Solutions: We're With You Every Step of the Way

For over 25 years Neogen Europe has been a trusted partner for food manufacturers and testing laboratories providing an established range of allergen testing solutions, however we are much more than just a manufacturer of kits. Based at our European headquarters in Ayr, Scotland, our laboratory services, R&D department, technical support services, sales and customer service teams can help support your testing needs – every step of the way.

From rapid lateral flow kits that can be used onsite to deliver a qualitative result in seconds, to ELISA tests providing quantitative results in as little as 30 minutes after extraction, we've got a solution for you.

Our extensive range of allergen testing is complemented by our ISO 17025 accredited* laboratory services providing analysis of a wide variety of food matrices, CIP rinse waters and environmental swabs. We offer flexible turnaround times of ten, five, three and same day. This gives an alternative to onsite testing, as well as validation and verification of your own onsite test results.

A Dedicated Technical Support Team

Neogen is with you at every step of your testing process and our technical support teams work alongside sales to answer any questions users may have when testing with our kits, as well as evaluating new matrices and problem solving (check out our case study opposite). We also have R&D resources located

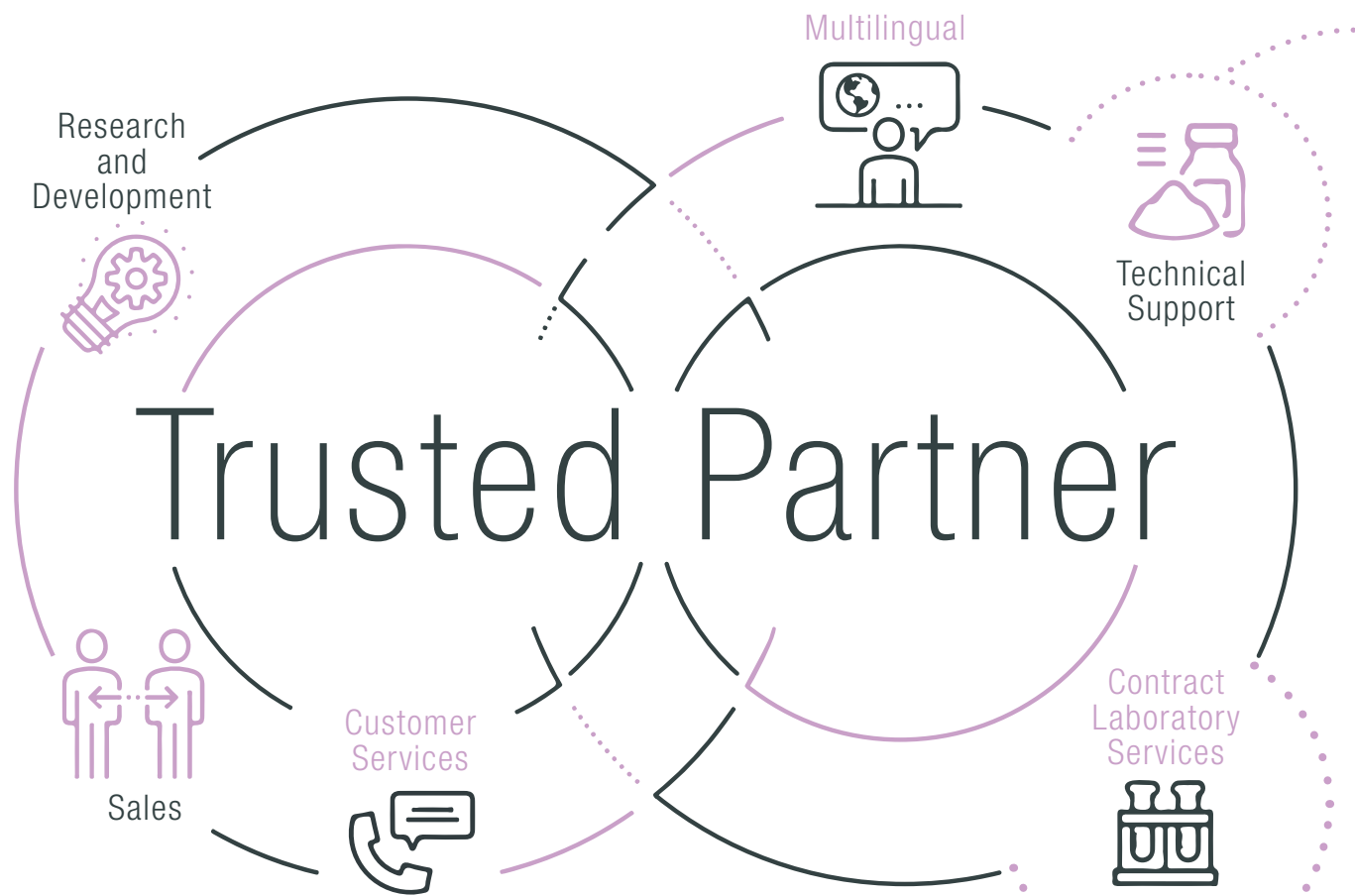
within our European headquarters in Ayr, Scotland, and in Lansing, Michigan, USA.

We collaborate closely with FARRP (Food Allergy Research and Resource Program) to develop the technology behind our ELISA and lateral flow kits. FARRP was established in 1995 within the University of Nebraska and works with the food industry to improve the safety of food

products for consumers suffering from food allergies and sensitivities.

Whether you test onsite or use an external laboratory, Neogen can be your trusted allergen partner every step of the way ■

For more information visit:
foodsafety.neogen.com/uk



CASE STUDY: Behind the Scenes with Neogen's Technical Support Services

When a seasoning manufacturer was looking to detect traces of residual milk in seasoning blends, their Quality Manager contacted Neogen to find out how we could help. The request was passed to Neogen's Technical Support team to investigate.

Firstly, the team had to find out exactly in what form was the milk present in the factory and how it was used in the blends. After it was identified the allergen was milk powder, it was agreed with the manufacturer to spike a total of four different seasonings with it. The team then proceeded to analyse the blank blends and the spiked blends with Reveal 3-D. This is a perfect option since it is easy to use and provides qualitative results in minutes.

For three of the seasoning blends, Reveal 3-D was able to show a product recovery of the milk at low detection levels of 5ppm. The concentration of spices in the fourth blend stained the strip of the kit, making the test unsuitable for the customer's needs. However, further analysis of this particular seasoning blend with Veratox, our ELISA test kit, provided the expected results. The seasoning manufacturer may use Reveal 3-D for qualitative assessment of seasoning blends 1 to 3 and either use our ELISA assay onsite or send their samples for analysis to our contract laboratory for blend 4 ■

Customer Comments:

- 'Neogen's Allergen Laboratory Services have played a key role in our allergen management programme over the past number of years and are the only service we use when carrying out our allergen and gluten free validations.'
- They offer a fast, friendly and reliable service and are always willing to accommodate any additional requests that we may have. Without doubt they are head and shoulders above anybody else within the industry.'

Callum McAllister
(Quality Supervisor, Avondale Foods)

Which Solution Fits Best?

With a choice of rapid onsite lateral flow tests, ELISA kits tests or contract laboratory services, it can be difficult to know where to begin if you don't currently test for allergens. We've broken down the decisions to help you choose the right solution.

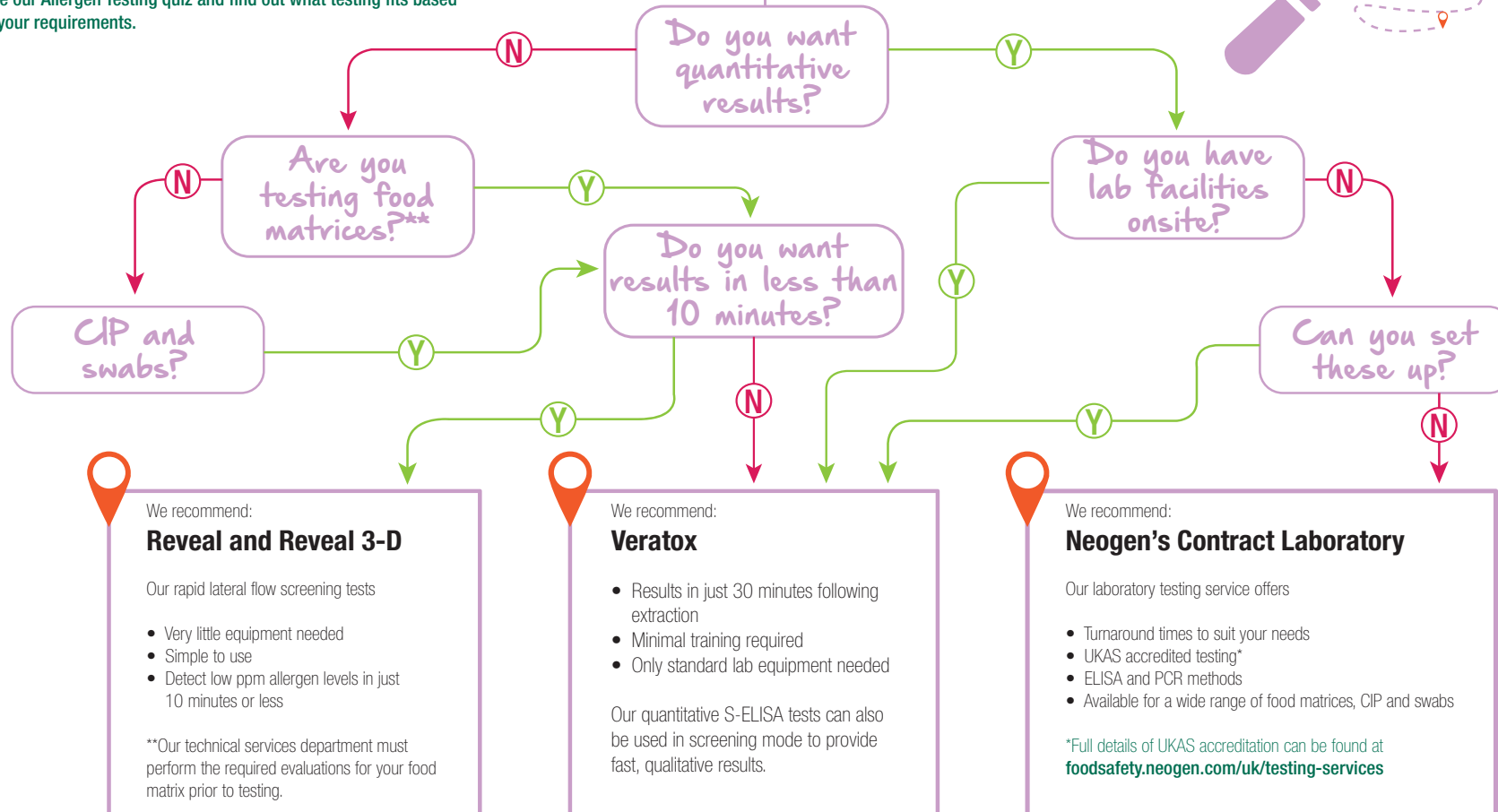
Take our Allergen Testing quiz and find out what testing fits based on your requirements.

Start Here



Neogen's allergen tests are available for the detection of:

Almond
Casein / BLG
Crustacea
Egg
Gliadin
Gliadin R5
Gluten
Hazelnut
Multi-Treenut
Mustard
Peanut
Sesame
Soy
Total Milk
Walnut



Contact us to see how we can help



Our Lab Services can also be used for validation and verification of your onsite results!

Contact us today for more information ■

Validation and Verification: The Cornerstones of Allergen Testing Programmes

Cleaning in a food production environment is a critical foundation to any food safety programme. The importance of an effective cleaning process cannot be overstated. Failures can result in biological, chemical (including allergens) or physical material contamination of future production. To prevent allergen cross-contamination, any cleaning programme must be validated for the removal of allergens then its effectiveness verified on a regular basis.

Allergen cleaning validation is specific to each unique product and so it is recommended to

perform a validation for each product risk profile. Rapid food allergen testing methods should be evaluated to determine their fitness for purpose under factory conditions. One approach would be to run a positive control (e.g. allergen containing product) to determine detection of the allergen and test surfaces after cleaning to establish if the cleaning regime is rigorous enough to effectively remove the allergen or if corrective actions need to be taken and incorporated into the cleaning procedures.

Given that some lateral flow devices may be interpreted as negative on high positive samples, it is preferable to use a three line test with an "overload" line, such as Neogen's Reveal 3-D range, for

the validation to avoid the hook effect (see page 10). Any sample with a result other than a positive should not be considered validated on the test kit. The validation steps should be repeated until the expected results are obtained for each surface and each food type.

Once the cleaning validation has been successfully completed, the monitoring programme is moved to a more routine check of adherence to the validated cleaning protocol. This verification is typically performed after each production run and associated cleaning event, and is designed to reflect whether the cleaning process was completed successfully relative to that standard. One of the objectives with routine monitoring and

verification is to achieve a representative sampling for each cleaning event.

Where to Test for Allergens?

Sampling areas for Environmental Monitoring Programmes (EMP) may be broken down into zones based on their proximity to the product. Zone 1 would typically be defined as surfaces that come into contact with the product. Zones 2, 3 and 4 would be non-contact surfaces of lessening probability that could contribute contaminants through some interaction with people, equipment or air and water circulation.

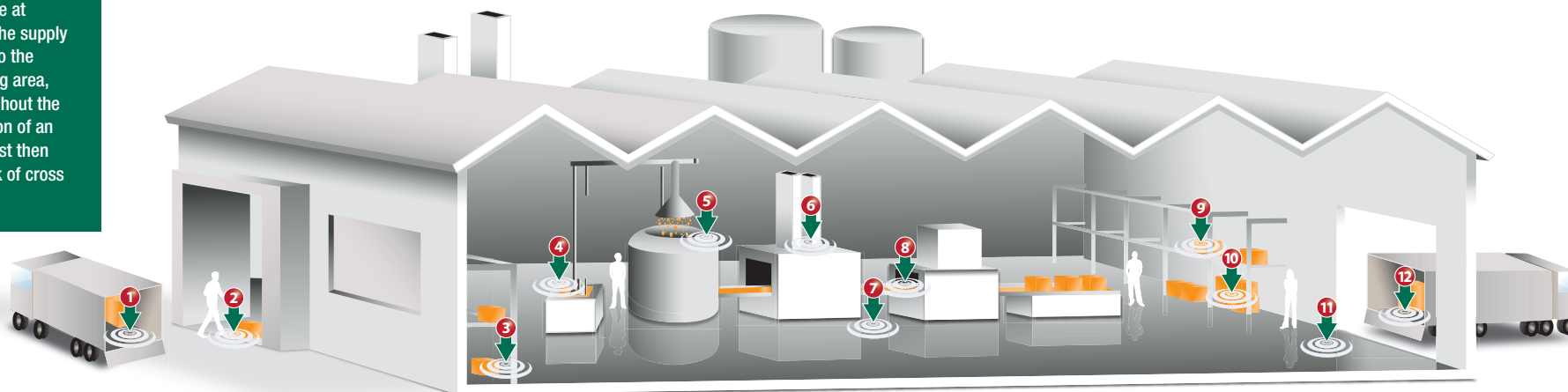
Zoning allows for monitoring to be conducted in environmental areas where the product and food contact surfaces are more susceptible to allergen cross-contact, to those areas that are far removed from the product, but may still have an impact on quality. Zone testing can help to identify areas in the plant environment that may be contributing to allergen cross-contact of the product or food contact surfaces. Through data trending and result interpretation, zone testing allows the site to identify environmental areas or traffic patterns that can be a source of allergen cross-contact.

For allergen cleaning verification, testing sites should be concentrated in Zone 1 as this is where the product is most

susceptible to allergen cross-contact. Testing these surfaces/areas will help to identify hot spots of allergen cross-contact that can directly affect the product and product contact surfaces. Testing in Zones 2, 3 and 4 can pinpoint allergen cross-contact sites outside of the production area. By identifying allergen cross-contact sites, facilities can minimise contamination that otherwise would be brought into the production room(s) through employee and equipment traffic ■

For more information please contact your Neogen representative or visit: foodsafety.neogen.com/uk/food-allergen-validation-and-verification-handbook to download our Allergen handbooks

Allergen testing can take place at every step of production: from the supply chain and the incoming goods to the finished product and the packing area, allergens can be present throughout the facility. Validation and verification of an allergen testing programme must then be performed everywhere a risk of cross contamination is present.



Incoming Goods and Warehouse

- 1 AUDITING SUPPLY CHAIN**
Verify allergen controls
- 2 INCOMING GOODS**
Confirm supplier specifications

- 3 WAREHOUSE**
Ensure robust ingredient segregation and packaging integrity

Processing and Packaging

- 4 FOOD PREPARATION SURFACE**
Validate cleaning and detect cross-contamination
- 5 6 PROCESS EQUIPMENT AND UTENSILS**
Validate cleaning and detect cross-contamination

Finished Product and Warehouse

- 7 SPILLAGES**
Ensure verification of cleaning
- 8 IN-PROCESS AND RE-WORK**
Detect potential cross-contamination

- 9 FINISHED PRODUCT**
Verify product labelling claims
- 10 WAREHOUSE**
Ensure robust final product segregation and packaging integrity

- 11 SPILLAGES**
Ensure verification of cleaning
- 12 FINISHED PRODUCT SUPPLY CHAIN**
Auditing and enforcement

Eliminating the Hook Effect in Allergen Testing

When testing for allergens with rapid methods such as lateral flow test kits, there is always a risk that a grossly contaminated sample returns a false negative result by overloading the strip. Known as the hook effect, this occurs when the amount of target allergen exceeds the amount of colour-labelled antibody material present in the strip's reagent pad.

The mechanics of the hook effect are simple: excess target allergen migrates across the membrane quicker than the colour-labelled antibody-antigen complex and saturates the binding sites on the capture antibody at the test line. When the colour-labelled complex arrives, it has no binding sites available so it continues to travel up the membrane to the waste reservoir at the end of the device. Without binding sites available, the

colour-labelled antibody-antigen complex cannot create the coloured test line indicative of a positive result. This presents the user with a false negative result, despite high levels of the target allergen.

Neogen's Reveal 3-D lateral flow device includes a third line in addition to the test (T) and Control (C) lines used in conventional lateral flow devices (see fig. 1). This overload (O) line is simply a reagent striped onto the device that

does not form in the presence of a highly positive sample. This means that it is possible to instantly and easily differentiate a high positive result from a negative result: if the O line doesn't show up, the sample is overloaded with the target allergen. A negative result will show the O and C lines, while a positive result will show the T, O and C lines (see fig. 2) ■

For more information visit:
foodsafety.neogen.com/uk/reveal-3-d

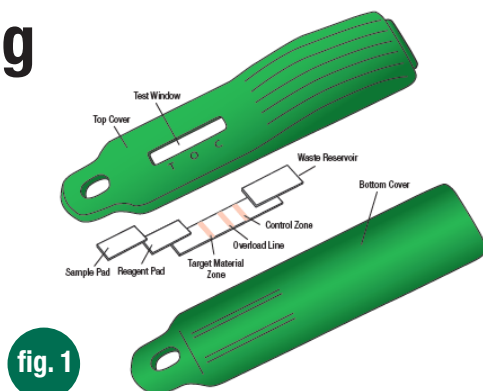
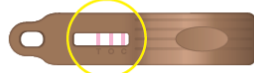


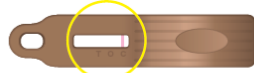
fig. 1

Reveal 3-D Device

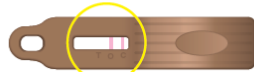
Test Device
Low Positive Result



Grossly Contaminated Sample, Positive Overload Result – "Hook Effect"



Negative Result



Conventional Lateral Flow Device

Test Device
Low Positive Result



Grossly Contaminated Sample, False Negative Result – "Hook Effect"



Negative Result



fig. 2

Anaphylaxis Campaign: Supporting Allergy Sufferers Everyday



Industry involvement is key to staying updated with development and Neogen has been working closely with the Anaphylaxis campaign for the past 5 years in the UK.

The Anaphylaxis Campaign, is the only UK wide charity dedicated to those at risk of severe allergies. The Anaphylaxis Campaign works alongside the food industry, schools, pre-schools, colleges, health professionals, parents groups and other key audiences. Its aim is to educate

them on medical facts, food labelling risk reduction and allergen management in order to create a safe environment for people with allergies.

Throughout the year, we participate in events, including this year's Orange Wig Day on Friday 18th May (as shown on the left). We are also the gold sponsors of this year's Anaphylaxis Campaign Corporate's Conference on Tuesday 18th September ■

For more information visit,
www.anaphylaxis.org.uk

Gluten in Food: Research from the Working Group on Prolamin Analysis and Toxicity

The Working Group on Prolamin Analysis and Toxicity (WGPAT) is an international group of physicians, chemists, food scientists, and nutritionists. Their aim is to perform and coordinate research on the analysis of gluten in food and on the evaluation of clinical and nutritional aspects of coeliac disease.

To achieve this goal, the WGPAT cooperates with producers of gluten-free food such as the starch-producing industry and manufacturers of

gluten-free products. The group also works closely with producers of test systems for gluten analysis in food, with national and international coeliac societies and with official organisations such as the Codex Alimentarius Committee on Nutrition and Food for Special Dietary Uses.

Neogen is proud to be hosting their 32nd annual meeting in Ayr, from 27th to 29th September ■

For more information visit,
<http://www.wgpat.com>



Did You Know?

COW'S MILK IS PROBABLY THE MOST COMPLEX OF ALL THE FOOD ALLERGIES



THERE ARE MANY VARIATIONS OF COW'S MILK ALLERGY:

- IMMEDIATE ONSET COW'S MILK ALLERGY (IGE MEDIATED)
- DELAYED COW'S MILK ALLERGY
- MIXED DELAYED AND IMMEDIATE COW'S MILK ALLERGY
- LACTOSE INTOLERANCE



IMMEDIATE ONSET IGE MOST COMMONLY OCCURS IN INFANCY



MOST CHILDREN OUTGROW IT BY 5 YEARS OF AGE



1 IN 200 ADULTS WILL STILL SUFFER FROM THE ALLERGY

TYPICAL SYMPTOMS OF IGE MEDIATED CAN AFFECT



SKIN



THE GUT



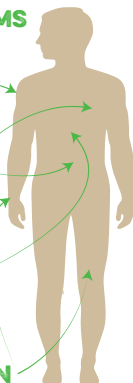
THE HEART



THE AIRWAYS



CIRCULATION



SURPRISINGLY, MILK IS ADDED TO OTHER THINGS SUCH AS:



SUFFERERS NEED TO RELY ON CLEAR FOOD LABELLING IN ORDER TO AVOID ALLERGENS



AND ACTIVELY READ FOOD LABELS



THEREFORE A STRONG ALLERGEN CONTROL PLAN IS ESSENTIAL

Contact us today



Tel: + 44 (0) 1292 525 627 • Fax: + 44 (0) 1292 525 602
Email: allergens_uk@neogeneurope.com
Web: foodsafety.neogen.com/uk/allergens