

What AllerGiene® Can Do for Your Allergen Control Program



Adenosine tri-phosphate (ATP) is present in all foodstuffs, including foods containing allergenic proteins. The Charm AllerGiene test delivers exceptional sensitivity to the presence of ATP, so much so, that its removal assures exceptional cleaning relating to food crosscontact has been achieved. Food and beverage manufacturers no longer have to face the difficult choice of holding product before release, or waiting for tardy test results, as AllerGiene performs sensitive pre-operational surface monitoring in seconds.

Allergen contamination can occur through food cross contact, supplier error, or manufacturing/labeling error. As consumer's tastes expand, manufacturers are faced with new challenges to reduce the risk of allergens in their finished product.

Up until recently, there were few allergen test options available to the food industry. In 2003, the US FDA announced that three allergen ELISA (enzyme linked immunosorbent assay) test kits for the detection of peanut proteins in breakfast cereal, cookies, ice cream and milk chocolate had received Performance Tested^{SM*} approval by the AOAC (Association of Official Analytical Chemists). All three test methods have been proven to be reliable, i.e., 80% level of confidence, for the detection of peanut protein. In 2006, a fourth ELISA test for gliadin achieved AOAC Research Institute's Performance Tested Method.

The food industry is faced with the dilemma of confronting other allergens of concern without the safety net of using approved methods, as none exist for allergenic milk, soy, egg, tree nut, fish, and crustaceans. The four approved methods for specific allergens are based on ELISA, which are time and labor intensive as the allergen must be extracted and purified. ELISA kits are not available for all known allergens. This may be costly to some food manufacturers as there may be more than one allergen of interest, an inadequate supply of specific allergen tests on hand, or they are faced with a difficult choice of holding product before release, or recalling product after it is released to distribution.

Charm Sciences has approached this issue head-on by setting new standards in validating cleanliness of surfaces which strengthens both allergen and microbial control programs. The AllerGiene test offers a pro-active approach to strengthening allergen control programs by testing surfaces or rinse waters for the presence of ATP, at levels low enough to coincide or be lower than protein levels detected by specific allergen methods. It accomplishes this in just 30 seconds, and has complete data traceability and tracking with the novaLUM[®] instrument and novaLINK software. AllerGiene is not a replacement for existing test methodologies, rather a complementary risk assessment tool that fits the HACCP model because it anticipates and helps eliminate potential hazards allowing for remediation before product overlay.

ATP and allergenic proteins are harder to remove if surfaces have pits, cracks, corrosion, recesses, open seams, gaps, rivets, bolts, or protruding threads, so proper cleaning is critical to their removal. Thermal treatment is ineffective in ridding equipment of the proteins that are the basis of food allergens. To remove protein, sanitarians must implement thorough protocols and cleaning chemicals of sufficient concentration. The AllerGiene test is the most sensitive test available to validate surface hygiene. The limit of detection to ATP is 500–1000 times more sensitive than typical ATP hygiene systems commercially available.

A positive AllerGiene result may indicate that ATP from food residuals is present, empowering the food manufacturer to reclean and re-validate before product is produced. Side by side sensitivity testing between the AllerGiene and the specific allergen test is critical to integrating AllerGiene within an allergen control program. The pre-requisites for a successful AllerGiene program include companies who:

- Manufacture products with and without allergens on shared equipment
- Manufacture on equipment that is wet cleaned e.g., CIP
- Manufacture foods containing allergens that contain ATP at critical level pre and post process
- Achieve acceptable levels achieved with conventional ATP tests (PocketSwab® Plus or equivalent)
- Provide SSOP validation data demonstrating AllerGiene and specific allergen surface test results

In keeping with HACCP principles, the food industry trend continues towards a pro-active approach to allergen control which allows for remediation before product loss. Ultimately, an allergen control program that integrates the AllerGiene test effectively yields returns by way of a safer product, improved product quality, improved productivity, and increased consumer acceptance.

*Performance Tested MethodSM Multiple Laboratory Validation Study of ELISA-Based Assays for the Detection of Peanuts in Food, Journal of AOAC International, 2005, Vol. 88, Issue 1, pages 156 - 160

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