

# Flow CAST® Basophil Activation Test

Redefining Food Allergy Diagnosis

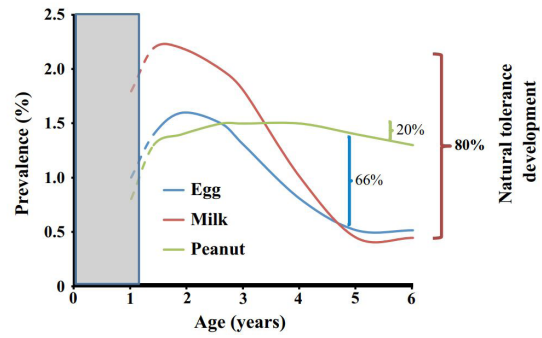


# Flow CAST® in Food Allergy Diagnosis

Food allergy affects millions of patients globally, significantly impacting their well-being and quality of life. Precise diagnosis and patient-tailored management are crucial to avoid unnecessary food avoidance and lifestyle changes. It is estimated that self-reported food allergy rates are up to 7 times higher than actual cases.

Current diagnostic methods, such as the Skin Prick Test and sIgE test, lack accuracy in determining true allergies, as they primarily measure sensitization to food allergens. According to these tests, over 10% of the global population is sensitized to at least one food allergen, whereas gold standard Oral Food Challenges (OFC) show a prevalence of less than 1-2%.

Beside their critical role in diagnosis, OFCs also play a central role in determining natural tolerance in food-allergic patients, particularly in a significant number of children. This information is vital for guiding the safe reintroduction of the food into the diet.



Adapted from Ponce et al., 2016

**Figure 1:** Prevalence of food allergy and natural tolerance development in children. While natural tolerance development to milk and egg is a common phenomenon during childhood, peanut allergy often persists to adulthood.

## Published data: The value of Flow CAST® in cow milk and egg allergy

### Flow CAST® shows high accuracy in determining patients with IgE mediated cow milk allergy

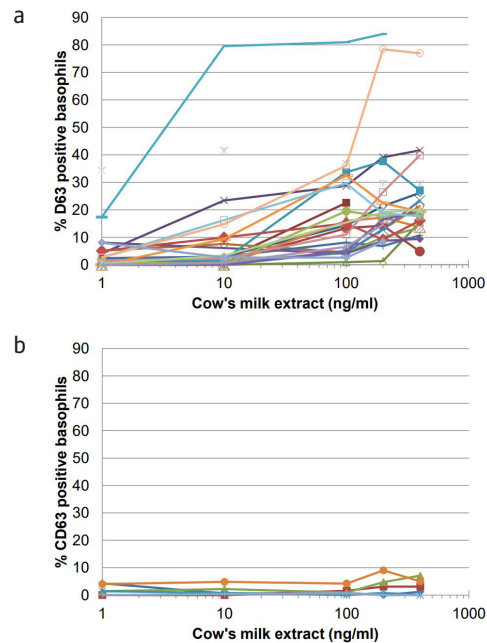
Ruinemans-Koerts et al. evaluated the reliability of the Basophil Activation Test (BAT) both for the initial diagnosis of cow's milk allergy in children and for determination of tolerance in children with cow's milk allergy. BATs and cow's milk specific IgE (sIgE) tests were performed in 86 infants/young children, suspected of cow's milk allergy. The results were compared to the gold standard Double-Blind Placebo-Controlled Food Challenge (DBPCFC) test.

The BAT had a sensitivity and specificity of 100% in IgE sensitized children (41% of the tested children).

The ROC curves for BAT and sIgE cow's milk show that the BAT is superior to sIgE (Figure 2).

**Benefit:**

BAT seems reliable and cost-effective to diagnose patients with an IgE-mediated cow's milk allergy. In IgE sensitized patients a BAT might replace a DBPCFC.



Adapted from Ruinemans-Koerts et al., 2019

**Figure 2:** Basophil activation to cow milk proteins, in allergic (a), and nonallergic (b)

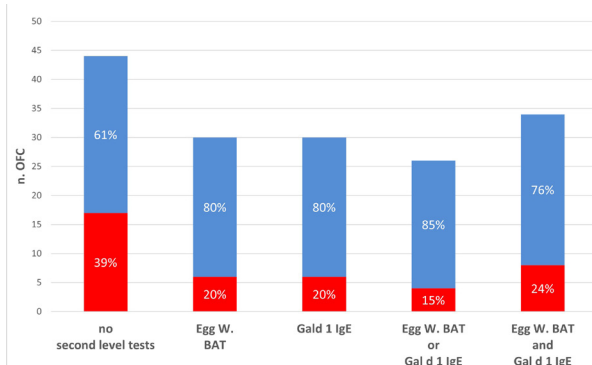
### Flow CAST® discriminates with high accuracy true egg allergy versus egg sensitization only

Licari et al. investigated the utility of the BAT test in discriminating patients with true allergy to egg versus individuals that are only sensitized but tolerated well the food. The study was carried out in a real-life setting offering BAT testing to patients needing OFC since with equivocal results from clinical history assessment and SPT and sIgE testing to egg components. Results from 75 BATs from the patient cohort showed high accuracy in discriminating egg allergy with the identification of an allergen specific clinical cut-off for BAT.

The introduction of BAT test as second line test could have resulted in a significant reduction of the positive OFC performed.

**Benefit:**

BAT is a reliable test for the high accuracy diagnosis of egg allergic patients with the potential of reducing the burden of OFC, especially the positive ones.



Adapted from Licari et al., 2023

**Figure 3:** The combination of BAT and Gal d 1-sIgE in the diagnostic workup would impact the need for OFC, with the best utility in reducing the challenge with a positive outcome.

# Flow CAST® in Food Allergy Diagnosis

Despite their critical role in diagnosing food allergies and monitoring natural tolerance, Oral Food Challenges raise safety concerns and require qualified healthcare personnel. Additionally, there is a notable lack of availability, preventing many individuals who require OFCs from accessing them.

Supported by a substantial body of evidence and clinical performance studies, the Basophil Activation Test has emerged as a reliable blood test and a safe alternative to OFCs. Its accuracy has been validated in systematic reviews and meta-analyses, leading to its inclusion for the first time in the EAACI guideline for the diagnosis of IgE-mediated food allergy.

Flow CAST®, the *in vitro* diagnostic BAT, is readily available in laboratories, representing a new standard for food challenges in a blood test. Offering immediate accessibility for patients, it carries no risk and allows for comprehensive testing of multiple allergens simultaneously.

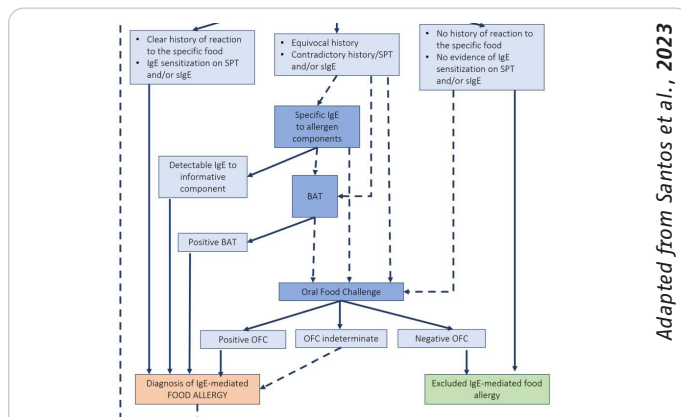


Figure 4: Algorithm for the recommended sequence of tests to support the diagnosis of IgE-mediated food allergy.

Adapted from Santos et al., 2023

## Published data: the value of Flow CAST® in peanut and nuts allergy

Flow CAST® discriminates patients allergic to one or multiple nuts or seeds (peanut, hazelnut, cashew nut, sesame, almond) to individuals that are only sensitized.

Santos *et al.* assessed the utility of the basophil activation test to predict the allergic status in children with potential 1 or more nut or seed allergies and reduce the need for an OFC. For the study were required patient from the Pronut study, specifically from the cohort of London and Geneva. BAT was performed in 90 patients and tested for 3 different doses of relevant nuts and seeds. Clinical cut-off and ROC curves for Flow CAST® were determined for each allergen showing superior accuracy over traditional testing methods. An effective use as second line test approach demonstrated utility of BAT testing in reducing the need of OFCs.

**Benefit:** The introduction of Flow CAST® test as a second step in the diagnostic workup of nut and seed allergy reduced the number of OFCs.

## Flow CAST® demonstrates high accuracy in the diagnosis of peanut and tree nut allergy

Duan *et al.* evaluated the clinical performance of the BAT test in the Markers Of Nut Allergy Study (MONAS) prospectively enrolling patients aged 0.5–17 years with confirmed peanut and/or tree nut (almond, cashew, hazelnut, pistachio, walnut) allergy or sensitization from Canadian (n = 150) and Austrian (n = 50) tertiary pediatric centers. The area under the ROC curve (AUROC) was 0.98 for peanut, 0.97 for cashew, 0.92 for hazelnut, 0.95 for pistachio, and 0.97 for walnut. The BAT outperformed sIgE testing for peanut or hazelnut and was comparable for walnut (AUROC 0.95, 0.94, 0.97) in a sub-analysis in sensitized patients undergoing OFC.

**Benefit:** Basophil activation test predicts allergic clinical status to peanut and tree nuts in multi-nut-sensitized children and may reduce the need for high-risk OFCs in patients.

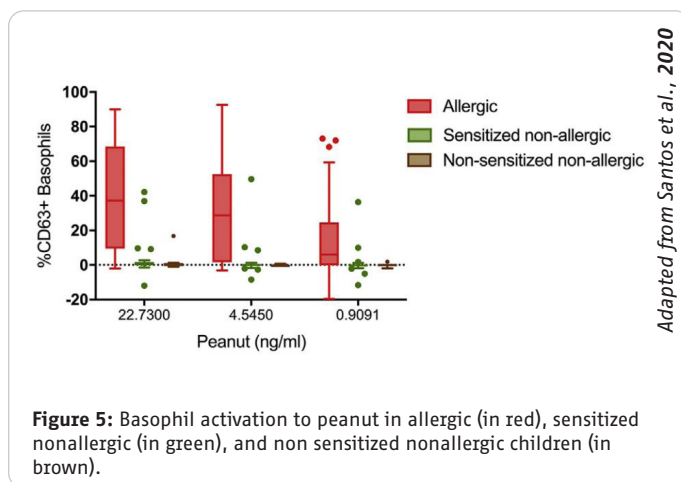


Figure 5: Basophil activation to peanut in allergic (in red), sensitized nonallergic (in green), and non sensitized nonallergic children (in brown).

Adapted from Santos et al., 2020

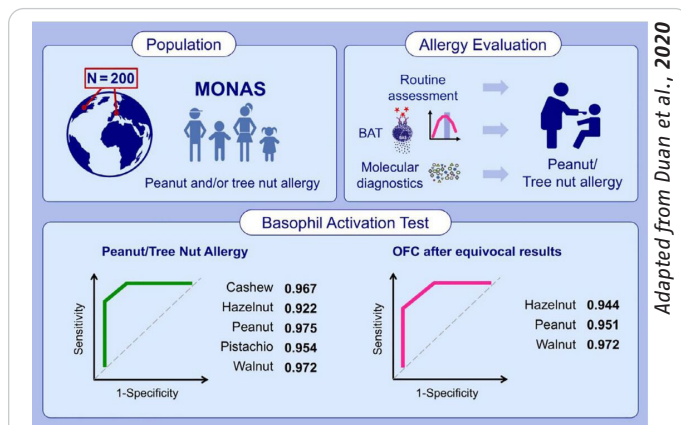


Figure 6: BAT performance in the MONA Study

Adapted from Duan et al., 2020

# Discover the broad range of CAST® allergens dedicated to food allergy

## Egg

BAG-F1  
BAG-F75

Egg White  
Egg Yolk

## Milk

BAG-F2  
BAG-F76  
BAG-F77  
BAG-F78

Cow Milk  
Alpha-Lactalbumin  
Beta-Lactoglobulin  
Casein

## Seeds, Beans & Nuts

BAG-F10  
BAG-F13  
BAG2-ARAH1  
BAG2-ARAH2  
BAG2-ARAH6  
BAG-F14  
BAG-F17  
BAG-F20  
BAG-F202  
BAG-F203  
BAG-F256

Sesame  
Peanut  
nAra h 1 Peanut  
nAra h 2 Peanut  
nAra h 6 Peanut  
Soybean  
Hazelnut  
Almond  
Cashew Nut  
Pistachio Nut  
Walnut

## Fish & Meat

BAG-F3  
BAG-F24  
BAG-F27  
BAG2-GAL

Codfish  
Shrimp  
Beef  
Alpha-Gal-HSA

## Cereals

BAG-F4  
BAG-F79  
BAG-F98  
BAG-F5  
BAG-F6  
BAG-F7  
BAG-F45

Wheat  
Gluten-Wheat  
Gliadin-Wheat  
Rye Flour  
Barley Flour  
Oat Flour  
Baker's Yeast

## Fruits & Vegetables

BAG-F25  
BAG2-MALD1

Tomato  
r Mal d 1, Apple

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