

## BasoFunction Test

### An Ex Vivo Blood Challenge Test for Allergy

**Test Name:** BasoFunction HRT (Histamine Release Test)

**Test Codes:** See Individual Allergens

**CPT Codes:** 86343, 83088

**Test Name:** Basophil Activation Test (fMLP)\*

**Test Code:** 501250

**CPT Code:** 86343, 83088

\*(Automatically included with BasoFunction Test)

**Clinical Utility:** The BasoFunction test may be useful with patients who have a suggestive history and for whom skin testing and/or in vitro specific IgE testing is not appropriate or available.

#### Specimen Requirement:

- Whole blood preserved with Sodium Heparin (8-10 mL) and maintained at 18 - 25 °C (room temperature) in an insulated container. Do not use lithium heparin tube.
- Specimen to arrive within 48 hours of the draw. Samples are to be shipped by overnight delivery. Samples are accepted **Monday through Friday**.
- Hemolyzed blood will be rejected.

**Background:** Adverse reactions to drugs and chemicals are common problems that the allergist is often asked to evaluate. The immunological basis and the clinical symptoms in response to these antigens may vary from patient to patient. Both true allergic and pseudo-allergic reactions can result in anaphylactoid-type symptoms<sup>1-4</sup> because common mediators are released (e.g. histamine leukotrienes, etc.). It is often not possible to implicate IgE in a direct role for many adverse reactions and thus the usual diagnostic tools of skin testing or *in vitro* allergen-specific IgE testing may not be useful. The Basophil Activation Test assesses the ability of the patient's basophils to release histamine when activated by a non-specific stimulus (fMLP). The BasoFunction test measures histamine released *in vitro* following challenge with the suspected allergen.

#### Report Format and Interpretive Comments:

**Basophil Activation Test:** The amount of histamine (ng/mL) released following fMLP stimulation is reported. The Basophil Activation Test (fMLP) result is an indicator of the activation potential of the patient's basophils. A low response indicates the basophils are hypo-responsive; this occurs in 5 to 10 percent of individuals. Reference ranges were determined on a population of healthy controls that had responsive basophils.

**BasoFunction:** The amount of histamine (ng/mL) released following specific allergen stimulation is reported. Reference ranges were determined on a population of healthy individuals without a history of adverse reactions to the

indicated allergens. The reference range varies for each allergen (see report). Patients with values above these thresholds are sensitized and should be further evaluated before therapeutic administration of the drug. Since placebo controlled challenge studies are difficult to perform, the true predictive value of the test is unknown for most drugs, and caution must be exercised with regard to patients who are non-responders to a suspected allergen. The sensitivity of the test is not known, and the allergen may still cause a clinically significant adverse reaction.

#### Method:

- (1) **Cell Setup:** Peripheral blood leukocytes are enriched from heparinized whole blood and stimulated with fMLP Basophil Activation Test), allergen (BasoFunction Test) or buffer alone. Following a brief culture the supernatant containing secreted histamine is separated from the cells.
- (2) **Histamine Test:** A validated histamine ELISA<sup>5,6</sup> quantifies histamine that was secreted by any stimulated basophils in response to the antigen and the stimulating control. IBT Laboratories determined the performance characteristics of this test. It has not been approved or cleared by the FDA.

#### Antigen List (Please call Client Services for other antigens)

<b>Analgesics:</b>	<b>Antibiotics:</b>	<b>Food Additives:</b>
Acetaminophen	Amoxicillin	Amaranth
Diclofenac	Ampicillin	Brilliant Black BN
Dipyron/Metamizole	Cefamandole	Chromotrope B
Ibuprofen	Cefazolin	Erythrosine
Indomethacin	Cefuroxime	Indigo Carmine
Lys-Aspirin	Cephalosporin C	Monosodium Glutamate (MSG)
Mefenamic Acid	Ciprofloxacin	New Coccine
Phenylbutazone	Penicillin; Benzylpenicil-	Patent Blue V
Propyphenazone	loyl-ploylysine	Potassium-Metabisulphite
	Penicillin; minor det. mix	Quinoline Yellow
<b>Anesthetics:</b>	Sulfamethoxazole	Sodium-Benzoate
Atracurium	Tetracycline	Sodium-Nitrite
Lidocaine	Trimethoprim	Sodium-Salicylate
Mivacurium		Sunset Yellow FCF
Pancuronium		Tartrazine
Propofol		
Rocuronium		
Suxamethonium		
Vecuronium		

#### References:

1. Gruchalla, R S. *J Allergy Clin Immunol* 2001, 108 (4):475-488.
2. Winther, L et al. *Allergy* 1999, 54: 436-445.
3. Zia, P. K. et al. *Clinical Chemistry* 1998, 44: 2063-2065.
4. Sainte-Laudy, J et al. *Inflammation Research* 1998, 47: 401-8.
5. Histamine EIA Test Kit, Ref 2015, Pack. Insert. Immunotech, Beckmann Coulter Company 1999.
6. Morel, A M and Delaage, M A. *JACI* 1988, 82: 646-654.

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