

# Vial Testing



The American Academy of Otolaryngic Allergy (AAOA) recommends that vial testing be performed on every patient prior to the initiation of subcutaneous allergy immunotherapy. We recommend vial testing be done on every new treatment vial to catch potential issues related to increased potency of new vials, mixing errors or lot changes of antigen, new or different agent supplier, testing for an antigen not previously introduced, and an increased antigen concentration. Vial testing is to maintain safety for the delivery of immunotherapy and is not a billable procedure. The National Correct Coding Initiative (NCCI) explains vial testing as follows<sup>1</sup>:

*“Physicians should not report allergy testing CPT codes for allergen potency (safety) testing prior to administration of immunotherapy. Confirmation of the appropriate potency of an allergen vial for immunotherapy administration is an inherent component of immunotherapy.”*

The vial test will improve the safety and may improve comfort of subcutaneous allergy immunotherapy. Vial testing serves as a biologic indicator of tolerance to the mixed antigen vial.<sup>2</sup> A large skin wheal after an intrader-

mal vial test may indicate the antigen concentration is too high for the patient. Although there is a paucity of data on this issue, a large local skin reaction may identify those that may be at a higher risk for developing a systemic reaction. In addition, a large response may result in pain and discomfort of immunotherapy injections that, if continued, may result in patient noncompliance to therapy.

Vial testing is the process of applying a much smaller dose (typically 5-fold less) of the treatment vial intradermally to assess for a skin wheal. Typically, a 4-mm wheal is applied as an intradermal injection. If after 10 minutes, the wheal size is 13 mm or less, then the first subcutaneous injection may be given during this visit. If the size is 13 mm in size, then the injection should be given on the next visit. If the size is greater than 13 mm, then the treatment vial needs to be diluted 5-fold and another vial test performed in a week.<sup>3</sup>

Persistently large wheals may indicate an error in the mixing of the treatment vial as noted above, or even a higher prevalence of the offending antigen in the environment. If large wheals persist after dilution, further dilution or selective retesting may be performed.

<sup>1</sup> NCCI Policy Manual, Chapter 11, Section K, 4

<sup>2</sup> Krouse, JH, Chadwick, SJ, Gordon, BR, Derebery, MJ. Allergy and Immunology - An Otolaryngic Approach. Lippincott 2002.

<sup>3</sup> King HC, Mabry RL, Mabry CS, Gordon BR, Marple BF. Allergy in ENT Practice: The Basic Guide. Thieme, 2004.

*Note: American Academy of Otolaryngic Allergy's (AAOA) Clinical Care Statements attempt to assist otolaryngic allergists by sharing summaries of recommended therapies and practices from current medical literature. They do not attempt to define a quality of care for legal malpractice proceedings. They should not be taken as recommending for or against a particular company's products. The Statements are not meant for patients to use in treating themselves or making decisions about their care. Advances constantly occur in medicine, and some advances will doubtless occur faster than these Statements can be updated. Otolaryngic allergists will want to keep abreast of the most recent medical literature in deciding the best course for treating their patients.*