

These data provide the practicing allergist with more specific guidance than the manufacturers' recommendations.

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REFERENCES

1. Nath P, Freiler J, Gomez RA. Safety of multidose immunotherapy vials after routine use. *J Allergy Clin Immunol Pract* 2018;6:2110-1.
2. Hernandez CL, Waibel KH, Kosisky SE, Nelson MR, Banks TA. 15 years of allergen immunotherapy vial sterility testing. *Ann Allergy Asthma Immunol* 2017;118:374-5.
3. Letz AG, Tankersley MS, Dice JP, England RW. Monitoring bacteriostasis in allergen extract mixing: 10 years of culture data. *J Allergy Clin Immunol* 2009;123:1175-6.
4. Lay PC, Bass R, Lin SY. Allergen vial mixing and immunotherapy: risks of infections and vial contamination. *Otolaryngol Head Neck Surg* 2007;137:243-5.
5. Nelson MR, Petersen MM, Wolverson WO, Mikita CP. Allergen immunotherapy extract treatment set preparation: making a safer and higher quality product for patients. *Curr Allergy Asthma Rep* 2013;13:399-405.
6. ComforTen [package insert]. Spokane, WA: HollisterStier Allergy; 2010.

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Reply



To the Editor:

Atchley et al¹ present further arguments supporting the safety and sterility of allergen extracts. As noted, multiple studies, to include our study, have demonstrated the sterility of allergen extracts over time.² We presented evidence that our current practice of administration of multidose vials adheres to patient safety standards as well as US Pharmaceutical General Chapter <797> Pharmaceutical compounding – Sterile Preparations (USP <797>). After routine use of mixed-aeroallergen extract maintenance vials,

we found no risk of contamination and a lack of microbial growth 30 days past the 1-year manufacturer-recommended expiration date. Similarly, Atchley et al demonstrated the sterility of skin prick testing (SPT) systems used in routine patient testing. We believe the study presented by Atchley et al adds to the reservoir of data advocating for the sterility of allergen extracts by providing the practicing allergist with specific recommendations and reassurance about the use of SPT systems.

The United States Pharmacopeia released the final USP <797> standards on June 1, 2019. This revision details the personnel qualifications, appropriate facilities, and necessary documentation to continue in-office compounding of individual vial sets for allergen immunotherapy. These requirements allow allergists to compound extracts in an ISO Class 5 Primary Engineering Control (PEC) or in a dedicated Allergen Extract Compounding Area (AECA). Most importantly, allergen extracts continue to be a separate section of the chapter. Previous studies have bolstered arguments in support of the standards set forth by the current USP<797> with regard to allergen extract vials. The data presented by Atchley et al are unique in that it validates the safety profile of allergy extracts, whether as multidose vials or used in SPT systems.

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REFERENCES

1. Atchley T, Steigelman D, Trevino S. The sterility of extracts in skin prick testing reservoirs: a quality assurance initiative. *J Allergy Clin Immunol Pract* 2020;8:1472-3.
2. Nath P, Freiler J, Gomez R. Safety of multidose immunotherapy vials after routine use. *J Allergy Clin Immunol Pract* 2018;6:2110-1.

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