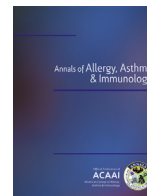




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Factors related to histamine concentrations for positive control in prick-puncture skin testing

The Public Health Service (PHS) publication 86–1685 (National Health and Nutrition Examination Survey), which involves multiple centers and is funded by the National Institute of Environmental Health Sciences and the National Institute of Allergy and Infectious Diseases, established that histamine at a concentration of 1 mg/mL was the optimal concentration for use as positive control when conducting prick-puncture skin testing.¹ Findings from PHS publication 86–1685, regarding the optimal concentration of histamine positive control, were updated in the *Journal of Allergy and Clinical Immunology* in August 2005.² Histamine at 1 mg/mL was again considered the optimal concentration for prick-puncture skin testing.

Through the Freedom of Information Act, Lincoln was able to obtain a copy of the new drug application for histamine at a concentration of 6 mg/mL. We were not able to find any studies to support this concentration for clinical use as positive control. When the license was issued, the Food and Drug Administration mandated that the manufacturer could not represent 6 mg/mL as superior to any other concentrations of histamine. However, the manufacturer has promoted the 6-mg/mL product as superior, and as a result, many allergy practices are using this high concentration.

Use of histamine at a concentration of 6 mg/mL raises the following issues for careful consideration:

1. Wheal reactions will occur with the use of histamine at 6 mg/mL even when the patient's ability to respond to diagnostic extracts

is impaired. Under this condition, underdiagnosis and false-negative results are likely to occur.

2. The probability of the following scenario would not likely be high, but it could happen. If a patient were highly allergic to an antigen and the allergy was missed because the positive control of 6 mg/mL indicated that the patient's ability to react was not suppressed, who would be liable if this patient later experienced anaphylaxis and died?

We hope that those who update practice parameters will classify the 6-mg/mL dose of histamine for research only.

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- [2] Arbes SJ Jr, Gergen PJ, Elliott L, Zeldin DC. Prevalences of positive skin test responses to 10 common allergens in the U.S. population: results from the Third National Health Examination Survey. *J Allergy Asthma Immunol*. 2005;16:377–383.