

## Measurement of natural rubber latex allergen levels in medical gloves by allergen specific IgE-ELISA inhibition, RAST inhibition, and skin prick test.

Palosuo, Timo  
Mäkinen-Kiljunen, Soili  
Alenius, Hari  
Renuala, Timo  
Yip, Esah  
Turjanmaa, Kristiina

National Public Health Institute, Helsinki, Finland;  
University Hospital for Skin and Allergic Diseases, Helsinki, Finland;  
Rubber Research Institute of Malaysia, Kuala Lumpur, Malaysia;  
University of Tampere, Tampere, Finland.

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Exposure to natural rubber latex (NRL) medical gloves poses risks to patients sensitized to NRL and to users of protective gloves. Previous studies have shown that extractable allergen levels of the gloves vary widely. Since most of the available laboratory methods of NRL allergen measurement lack adequate validation, we wanted to evaluate the performance of a recently developed competitive IgE-ELISA-inhibition, in relation to skin prick test (SPT) and RAST-inhibition, as well as to extractable protein quantification and an immunochemical latex assay (LEAP).

Twenty samples of surgical ( $n=14$ ) and examination gloves ( $n=6$ ), covering >90% of medical glove marketed in Finland in 1994-5, were collected by the Finnish National Research and Development Centre for Welfare and Health, coded, extracted and analyzed by the five methods.

The IgE-ELISA inhibition correlated highly significantly with SPT ( $r = 0.94$ ) and RAST inhibition ( $r=0.96$ ). Likewise, ELISA inhibition and RAST inhibition showed highly significant correlation ( $r=0.96$ ,  $P<0.0001$  in all three instances). Protein quantification by a modified method also correlated highly significantly with SPT ( $r=0.80$ ), RAST inhibition ( $r=0.82$ ), and ELISA inhibition ( $r=0.81$ ,  $P<0.0001$  in all three instances). Clearly weaker correlation, though statistically significant ( $r=0.48$ ,  $P=0.03$ ), was found between SPT and the LEAP assay.

An NRL standard preparation was assigned an arbitrary content of 100 000 allergen units (AU) per ml. In relation to this standard, the NRL allergen level was considered low (<10 AU/ml) in 11, moderate (10 – 100 AU/ml) in two, and high (>100 AU/ml) in seven of 20 glove brands analyzed.

In conclusion, the results of a novel IgE-ELISA-inhibition method of measuring NRL allergen levels in medical gloves correlated highly significantly with those of SPT. The ELISA method was found to be sensitive, reproducible, technically easy, inexpensive, and suitable for the analysis of large number of NRL products. The results of extensive market surveys in 1994 and 1995, communicated to the medical community in Finland, appear to have had a clear effect in moving glove purchasing policies toward the use of low-allergen gloves.