NHANES 1999–2000 Public Data Release File (June 2002)

Laboratory 7 – Latex and Latex class

Description

Latex allergy

The emergence of latex allergy now represents a significant public health problem. Serologic screening for latex-specific IgE in NHANES will provide an estimate of the prevalence of latex sensitization, enable determination of secular trends in the emergence of this problem and help delineate demographic factors (e.g., age, occupation) for the development of latex sensitization. NHANES data will be used to identify other at-risk groups and to formulate strategies/guidelines for the prevention of latex sensitization and, ultimately, life-threatening hypersensitivity reactions.

Laboratory

Blood and urine specimens are collected on participants aged one year and older

Eligible Sample

Participants aged 12 to 59 years who do not meet any of the venipuncture exclusion criteria.

Data Collection Methods

Blood specimens are processed, frozen, and shipped to the Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention for analysis.

Examination Protocol

Detailed specimen collection and processing instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Vials were stored under appropriate frozen (minus 20 degrees Centigrade) conditions until they were shipped to Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention for testing. The analytical methods are described in the Analytic methodology section.

Analytic Methodology

Latex

Many allergies are mediated by immunoglobulins of the IgE class. In sensitized individuals suffering from this immediate (atopic or anaphylactic) type of allergy, IgE molecules act as points of contact between the allergen and specialized cells that release histamine and other agents upon exposure to the allergen; this initiates the events which we recognize as allergic reactions.[1, 2] When evaluated in the light of other clinical and laboratory findings, in vitro allergen-

specific IgE tests can help the physician identify the allergen (or allergens) to which an individual is sensitive.

The AlaSTAT Microplate Allergen-Specific IgE system is an enzyme-labeled immunometric assay, based on liquid allergen complexes, monoclonal antibodies, and separation by ligand-coated wells. It represents a significant advance over conventional methods relying on allergens attached to a solid-phase support, such as a paper disk. Allergens, in a liquid format, are covalently bound to a soluble polymer/copolymer matrix, which in turn is labeled with a ligand – the same ligand used for coating the reaction wells. The use of an amino acid copolymer amplifies the amount of allergen that the matrix can support.

AlaSTAT Microplate assays use a patented technology (U.S. Patent No. 4,778,751) exploiting liquid-phase kinetics in a microplate format. Ligand-labeled allergen complexes and a patient sample are pipetted into ligand-coated wells and then incubated for 1 hour. During this time, any endogenous IgE specific for the test allergen binds to it. Addition of a multivalent anti-ligand creates a bridge between the allergen/IgE complexes and the ligand-coated wells during the second 1-hour incubation. Separation of bound from free is then a simple matter of decanting and washing. The allergen/IgE complexes thus linked to the microplate wells are reacted with horseradish peroxidase-labeled monoclonal anti-IgE during a third 1-hour incubation, after which excess enzyme label is washed away. A chromogenic indicator (3, 3′,5,5′-tetramethylbenzidine) in a buffered hydrogen peroxide solution, reactive with the enzyme label, is then added, and the rate of color development is ascertained by monitoring the product using a kinetic microplate analyzer during a 5-minute read at 650 nm. Reaction rates, measured in milliOptical Density units per minute (mOD/min), are directly related to allergen-specific IgE concentrations. The reader makes the OD readings available to the WINMAX Windows software, which calculates the mOD/min, plots the calibration curve derived from 6 IgE calibrators, and calculates results for control and participant samples. The AlaSTAT system yields results both in familiar Class numbers and in a continuous concentration scale.

Analytic notes

Results are automatically reported by the instrument in IU/ml and in Class numbers. A negative result (LBXLACL=0) indicates the absence of detectable latex-specific IgE. A positive result ((LBXLACL=I or greater) indicates that antibodies to the latex allergen are present in the participant's sample. LBXAL is the level of IgE in IU/ml.

Latex testing will be dropped from the NHANES laboratory protocol beginning in 2002.

References

1. Halpern GM. Markers of human allergic disease. J Clin Immunoassay 1983;6:131-138.

2. Wide L, Bennich H, Johansson SGO. Diagnosis of allergy by an *in vitro* test for allergen antibodies. Lancet 1967;2:1105-1107.