Immunodiagnostic Tests for Leprosy; a Need for Standards

TO THE EDITOR:

The immunodiagnosis of leprosy is becoming a realistic possibility with the advent of tests using epitopes specific to *Mycobacterium leprae* ([1-3]). A number of laboratories around the world are evaluating the role of IgM antibody against phenolic glycolipid-I (PGL-I) using the ELISA technique. The results of this assay are very often expressed as optical density at wave lengths ranging from 405–492 (depending on the substrate used). The cut-off points for defining positivity of a given sample are chosen as the mean plus three standard deviations of results obtained from clinically healthy individuals or, in some instances, arbitrarily.

It is not clear from many of the reports whether internal standards (e.g., dilutions of pooled leprosy serum) were included in the assay. It is well known that the ELISA technique is sensitive to even slight variations in the assay conditions. The results in the twilight zone between negative and positive are most susceptible to this variation and can be pushed either way.

To minimize and eventually eliminate variability and to make this assay comparable when performed in various parts of the world, a standard ought to be included as an essential part of the assay. This could be prepared from pooled leprosy sera containing high titers of anti-PGL-I antibody. The synthetic disaccharide conjugated to

bovine serum albumin (D-BSA) can be used as the antigen to isolate and purify this antibody on an affinity column. Inclusion of such a standard would enable the results to be expressed in mass units (mg/ml).

Similarly, the results of the two other specific, quantitative diagnostic tests ([2, 3]) can also be expressed in mass units by using known quantities of the respective monoclonal antibodies. Since each of these methods looks at one epitope, the use of such standards is logical since both the test and the standard would follow the same kinetics in the assay.

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