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Performance of a Rapid, On-Site Human Immunodeficiency Virus Antibody Assay in Public Health Settings

The utility of the Single Use Diagnostic System (SUDS) human immunodeficiency virus type 1 (HIV-1) (Murex) assay in the STD Clinic and Counseling and Testing Clinic in Dallas County was evaluated from March to July 1993 (4). For 1,923 specimens drawn for HIV testing, SUDs sensitivity was 100% with 99.5% specificity in comparison with enzyme-linked immunosorbent assays with Western immunoblot confirmation. Inadequate centrifugation and elevated ambient laboratory temperatures led to a 7.7-fold increase in false-positive results (4). The concern about elevated laboratory temperatures affecting the otherwise outstanding performance of SUDS is indeed very legitimate and needs to be addressed immediately. Elevated ambient temperatures can no longer be considered confined only to developing countries. During the 1995 heat wave in Chicago, the maximum temperature reached was 40°C. The heat index, an estimate of heat and humidity on evaporative and radiative transfer of heat from the atmosphere, had peaked 48.3°C (3). Furthermore, similar events are expected to be the rule rather than the exception in the future both in industrialized and developing countries. The likely impact of the impending global climatic change of up to a 4°C rise in temperature by the end of the next century (2) would indeed be tremendous.

The impact of global climatic changes on the otherwise outstanding 100% sensitivity and 99.5% specificity of SUDS (4) could be minimized through appropriate technological modifications in different kit components to enable its robust performance in high ambient temperatures and humidity. Last but not least, it would be imperative to monitor SUDS performance at low ambient temperatures as well. In many countries, the ambient temperatures are below 10°C, and facilities for the maintenance of such temperatures around 20°C are not available (1). A hot- and cold-adapted SUDS would be able to maintain its sensitivity and specificity right through the next century universally.

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Authors' Reply

Dr. Arya correctly notes that temperatures in the laboratory in excess of 25°C may result in an increased false-positive rate for the SUDS HIV-1 assay. These conditions can occur in a variety of settings, and are more frequently in resource-poor settings such as laboratories which lack air conditioning and in the tropical climates of many developing countries. Arya also suggests that the performance of the test be monitored at temperatures lower than the manufacturer's recommended range of 20 to 25°C, a condition that we did not encounter in our field trial. Users of the SUDS HIV-1 assay need to be aware of the temperature in the laboratory. If the assay must be used in conditions that fall outside of the manufacturer's recommended temperature range, users should know that these conditions will affect the test's performance. Good laboratory practice obliges users to employ tests appropriate for local conditions, considering such factors as storage requirements, laboratory environment, and technical skills as well as cost.

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