ACT 165

H.B. NO. 3151

A Bill for an Act Relating to HIV Antibody Testing.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. Purpose. The legislature finds that in light of the Congressional Office of Technology Assessment's October 1987 report discussing the lack

of enforced quality assurance standards in laboratories performing HIV Antibody testing and the consequent high number of false positive test results from such laboratories, it is the policy of the State that nationally accepted standards be followed at all HIV antibody testing facilities in the State of Hawaii.

SECTION 2. Section 325, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"§325- Quality assurance standards for HIV antibody testing. (a) All laboratories performing screening and diagnostic tests for the presence of the antibody to HIV (Human Immunodeficiency Virus) shall follow the recommended protocols as set forth below. Any initially reactive ELISA (Enzyme-linked Immunosorbant Assay) test must be confirmed by a second ELISA. Any sera yielding reactive results to both ELISA tests must have a supplemental test performed such as a Western Blot, an IFA (Immunofluorescence Assay), or an antigen detection assay; provided that these standards may be superseded by rules adopted by the department pursuant to chapter 91.

(b) Any laboratory performing tests for the presence of HIV may be required by the department of health to refer a sample from any specimen yielding a reactive result to the department for the purpose of supplemental testing of some or all samples for quality assurance purposes. The department may specify the information which shall accompany the specimen for epidemiological purposes; provided that

the information shall not include any personal identifiers.

(c) The penalty for any violation of this section shall be as specified in section 325-14."

SECTION 3. New statutory material is underscored.¹

SECTION 4. This Act shall take effect upon its approval.

(Approved June 1, 1988.)

Note

1. Edited pursuant to HRS §23G-16.5.