

**641—11.19(141) Initial application and certification requirements.**

**11.19(1)** Laboratories desiring to perform HIV testing services shall apply to the department.

**11.19(2)** Laboratories requesting certification to perform HIV testing shall provide to the department:

*a.* A completed “Application to Perform HIV Testing.”

*b.* Proof of current accreditation, certification or licensure by AOA, CAP, CLIA, FDA, JCAHO or Medicare.

*c.* A copy of the documents that describe the interpretive basis for positive, negative and indeterminate screening and confirmatory test results.

NOTE: Recommended guidelines for interpreting test results are those published by the Committee on HIV Testing, Association of State and Territorial Public Health Laboratory Directors, 6728 Old McLean Village Drive, McLean, Virginia 22101, or other guidelines approved by the department.

*d.* Proof of current enrollment in an HIV proficiency testing program. Proficiency testing programs include, but are not limited to, those administered by AAB, AABB, CAP or CDC.

**11.19(3)** Acceptable performance must be maintained during the 12-month certification period in all appropriate areas of HIV proficiency testing. Laboratories shall send copies of their proficiency testing results to the State Hygienic Laboratory on a quarterly basis for the purpose of ongoing monitoring and evaluation of performance. The address is: State Hygienic Laboratory, University of Iowa, Oakdale Hall, Iowa City, Iowa 52242.

**11.19(4)** Acceptable proficiency testing performance is stipulated below:

*a.* For laboratories providing screening tests, four out of five survey specimens must be interpreted accurately with a minimum of five survey specimens analyzed per quarter.

*b.* For laboratories providing confirmatory tests, no unacceptable results are permitted for five out of five survey specimens with a minimum of five survey specimens analyzed per quarter.