641—11.81(126) Definitions. For the purpose of these rules, the following definitions shall apply:

"CLIA" means the Clinical Laboratories Improvement Act as administered by the Health Care Financing Administration.

"FDA" means the U.S. Food and Drug Administration.

"HIV" means the human immunodeficiency virus identified as the causative agent of AIDS.

"HIV home collection kit" means a product for human immunodeficiency virus testing that provides for the specimen to be collected by an individual and then submitted to a laboratory, for determination of test results.

"HIV home testing kit" means a product for human immunodeficiency virus testing that provides for specimen collection and determination of test results by an individual without the utilization of a laboratory.

"Laboratory" means a laboratory meeting the CLIA requirements for HIV testing.

"Specimen" means a human body fluid or tissue sample.