

## **D3000**

**(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)**

### **§493.1100 Condition: Facility administration**

**Each laboratory that performs nonwaived testing must meet the applicable requirements under §§493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).**

#### **Interpretive Guidelines §493.1100**

To determine which tests are categorized as waived or nonwaived (i.e. moderate or high complexity tests), refer to the following web link for the FDA categorization database (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm?sAN=0>). Test systems, assays, and examinations not yet classified are considered high complexity.

Significant deficiencies cited under this condition may also indicate deficiencies under personnel responsibilities.