

personnel responsibilities. Use D5300 when deficiencies are identified that have the potential to, or are adversely affecting patient testing, or when they are systemic and pervasive throughout the laboratory, and are not limited to any one specialty or subspecialty.

To determine which tests are categorized as waived or nonwaived testing (i.e., moderate and 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 included in this listing (i.e., not yet categorized) are considered high complexity.