(E) A working knowledge of reagent stability and storage;
(F) The skills required to implement the quality control policies and procedures of the laboratory;
(G) An awareness of the factors that influence test results; and
(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

§ 493.1425 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual’s education, training or experience, and technical abilities.

(b) Each individual performing moderate complexity testing must—

1) Follow the laboratory’s procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

3) Adhere to the laboratory’s quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

4) Follow the laboratory’s established corrective action policies and procedures whenever test systems are not within the laboratory’s established acceptable levels of performance;

5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and

6) Document all corrective actions taken when test systems deviate from the laboratory’s established performance specifications.