GOOD LABORATORY PRACTICE
- CLIA NON-WAIVED TESTS MODERATELY COMPLEX

REQUIRED

♦ Obtain Federal CLIA (Clinical Laboratory Improvement Amendments–1988)
♦ Certificate of Compliance or Certificate of Accreditation
  Application at: http://www.cms.hhs.gov/clia
♦ Perform any test categorized by the FDA (Federal Drug Administration) as waived and moderate and high complexity tests listed on your CLIA certificate
  List at: http://www.fda.gov/cdrh/clia/#online, select CLIA Database
♦ Follow manufacturer’s instructions and agency’s requirements
♦ For CLIA compliance regulations: http://www.cms.hhs.gov/clia
♦ For other accredited standards, follow agency requirements

PERSONAL QUALIFICATIONS

See Code of Federal Regulations Title 42, Section 493

♦ Director – Sect. 493.1405 & 493. (duties Sect. 493.1407)
♦ Clinical Consultant – Sect. 493.1417 (duties Sect. 493.1419)
♦ Technical Supervisor – Sect. 493.1411 (duties Sect. 493.1413)
♦ Testing Personnel – Sect. 493.1423 (duties Sect. 493.1425)

OVERSIGHT

♦ Cost – varies by agency and test volume for a two-year cycle
♦ Surveys – every two years
  State agencies schedule visits
  Accrediting agency surveys scheduled or unannounced