Auria: What is CLIA?

What is CLIA and how is it different from FDA?

The Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing and require clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing. Laboratories can obtain multiple types of CLIA certificates, based on the kinds of diagnostic tests they conduct. The FDA, CMS, and CDC are all responsible for elements of CLIA. The main responsibilities of each agency are listed below.

Table 1: CLIA Responsibilities of FDA, CMS, & CDC

FDA	CMS	CDC
• Categorizes test based on complexity either low, medium, or high complexity • Reviews applications companies submit for their product to be CLIA waived • Develops rules/guidelines for CLIA complexity categorization	• Collects user fees • Issues laboratory certificates • Conducts inspections and enforces regulatory compliance • Approves private accreditation organizations for performing inspections, and approves state exemptions • Monitors laboratory performance on Proficiency Testing (PT) and approves PT programs • Publishes CLIA rules and regulations	• Provides analysis, research, and technical assistance • Develops technical standards and laboratory practice guidelines, including standards and guidelines for cytology • Conducts laboratory quality improvement studies • Monitors proficiency testing practices • Develops and distributes professional information and educational resources • Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC)

Reference: https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia

Namida is monitored periodically by CMS through proficiency testing (PT). Since our test utilizes a “non-regulated” analyte, we designed our proficiency testing protocol using Federal (CLIA) Regulations CFR Part 493 Subpart H and 493.1236, which requires us to establish accuracy and reliability through PT two times each year.

Table 2: Explanation of Terms

Explanation of Terms	
LDT	An LDT or Lab Developed test is a designed, developed, and performed within a single laboratory, regulated by the Centers for Medicare and Medicaid Services (CMS), through the Clinical laboratory Improvements Amendments.
Accuracy	The accuracy of a clinical test refers to the “closeness of agreement” between the test results and the true values from an established reference method. For qualitative methods, this means establishing that the method will identify the presence/absence of the analyte.
Precision	The precision of a clinical test refers to the closeness of agreement between a series of test measurements obtained from multiple samplings of the same specimen(s) on the same day/same run, on different days/different runs, and with different employees and different instrumentation (if applicable).
Sensitivity	The sensitivity of a clinical test refers to the ability of the test to correctly identify those patients with the disease; the lowest concentration or amount of the analyte that can be measured or distinguished from a blank.
Specificity	The specificity of a clinical test refers to the ability of the test to correctly identify those patients without the disease; the ability to measure the analyte in the presence of other components expected to be present. The lab must document information regarding interfering substances form product information, references, or its own testing.
Linearity	The linearity of a clinical test refers to the ability of a test to give results that are directly proportional to the concentration of analyte.