

Federal Agency	Responsibilities	Website
CMS	<ul style="list-style-type: none"> <li>• Approves private accreditation organizations that perform inspections; approves state exemptions</li> <li>• Collects user fees</li> <li>• Conducts inspections</li> <li>• Enforces regulatory compliance</li> <li>• Issues laboratory certificates</li> <li>• Monitors laboratory performance on PT and approves PT programs</li> <li>• Publishes CLIA rules and regulations</li> </ul>	<a href="https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/">https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/</a>
FDA	<ul style="list-style-type: none"> <li>• Categorizes tests based on complexity</li> <li>• Develops rules and guidance for CLIA complexity categorization</li> <li>• Reviews requests for Waiver by Application</li> </ul>	<a href="https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm">https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm</a>
CDC	<ul style="list-style-type: none"> <li>• Conducts laboratory quality improvement studies</li> <li>• Develops and distributes professional information and educational resources</li> <li>• Develops technical standards and laboratory practice guidelines</li> <li>• Manages the CLIA Advisory Committee</li> <li>• Monitors PT practices</li> <li>• Provides analysis, research, and technical assistance</li> </ul>	<a href="https://wwwn.cdc.gov/clia/">https://wwwn.cdc.gov/clia/</a>

CMS, Centers for Medicare and Medicaid Services; FDA, Food and Drug Administration; CDC, Centers for Disease Control and Prevention; PT, proficiency testing

Source: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CLIABrochure.pdf>