

Advancing Laboratory Quality Through Continuous Improvement

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A Better World Through Accreditation



Topic

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- Top 10 CLIA Deficiencies
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About A2LA

A2LA is an independent non-profit, non-governmental, third-party accreditation body, offering internationally recognized accreditation services to testing and calibration laboratories, sampling organizations, inspection bodies, proficiency testing providers, reference material producers, biobanking facilities, and product certifiers.

- Founded in 1978
- Largest U.S. multi-discipline Conformity Assessment Body (CAB) Accreditation system
 - 3,600+ CABs currently accredited
 - 4,200+ certificates
- Fifth largest system in the world
- Extensive experience working with US Regulators – CPSC, FCC, DoD, DoE, FDA, EPA, CMS, etc.



Top 10 CLIA Deficiencies

1. 493.1235: Personnel Competency Assessment Policies
2. 493.1242 (a): Specimen Submission, Handling, and Referral Policies and Procedures
3. 493.1251 (a): Procedure Manual
4. 493.1251 (b)(8): Corrective Actions within the Procedure Manual
5. 493.1445 (b): Laboratory Director Oversight of Reappointions Performance of Responsibilities
6. 493.1252 (b)(2): Environmental Conditions for Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies- Temperature
7. 493.1252 (b)(3): Environmental Conditions for Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies- Humidity
8. 493.1252 (d): Components of Reagent Kits
9. 493.1254 (a)(2): Function Checks
10. 493.1256: Control Procedures



Solution: Cause Analysis and Continual Improvement

At A2LA, we expect all laboratories to provide complete corrective action responses, including:

- Cause analysis,
- Corrective action, and
- Objective evidence of implementation.

We also follow-up on all deficiencies during subsequent assessments.

We provide an additional optional accreditation program in which focus on continual improvement.





As a patient, wouldn't you be more confident in your test results coming from a laboratory that is focused on continuous improvement?





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