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## 42 C.F.R. § 493.61

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### Requirements for a certificate of accreditation.

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(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory—

- (1) Meets the requirements of § 493.57 or, if applicable, § 493.49 of subpart C of this part; and
- (2) Remits the certificate of accreditation fee specified in subpart F of this part.

(b) Laboratories issued a certificate of accreditation must—

- (1) Treat proficiency testing samples in the same manner as patient samples;
- (2) Meet the requirements of § 493.63;
- (3) Comply with the requirements of the approved accreditation program;
- (4) Permit random sample validation and complaint inspections as required in subpart Q of this part;
- (5) Permit HHS to monitor the correction of any deficiencies found through the inspections specified in paragraph (b)(4) of this section;
- (6) Authorize the accreditation program to release to HHS the laboratory's inspection findings whenever HHS conducts random sample or complaint inspections; and

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