
42 C.F.R. § 493.49

Requirements for a certificate of compliance.

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in § 493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

- (a) HHS will issue a certificate of compliance to a laboratory only if the laboratory—
 - (1) Meets the requirements of §§ 493.43 and 493.45;
 - (2) Remits the certificate fee specified in subpart F of this part; and
 - (3) Meets the applicable requirements of this subpart and subparts H, J, K, M, and Q of this part.
- (b) Laboratories issued a certificate of compliance—
 - (1) Are subject to the notification requirements of § 493.51; and
 - (2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part—
- (i) To determine compliance with the applicable requirements of this part;

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