

42 C.F.R. § 493.57

Requirements for a registration certificate.

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by HHS.

- (a) HHS will issue a registration certificate if the laboratory—
- (1) Complies with the requirements of § 493.55;
- (2) Agrees to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only);
- (3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and
- (4) Remits the fee for the registration certificate specified in subpart F of this part.

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