
42 C.F.R. § 493.959

Immunoematology.

(a) *Types of services offered by laboratories.* In immunoematology, there are four types of laboratories for proficiency testing purposes—

- (1) Those that perform ABO group and/or D (Rho) typing;
- (2) Those that perform ABO group and/or D (Rho) typing, and unexpected antibody detection;
- (3) Those that in addition to paragraph (a)(2) of this section perform compatibility testing; and
- (4) Those that perform in addition to paragraph (a)(3) of this section antibody identification.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunoematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

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