

D3019

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1103 Standard: Requirements for transfusion services

(b) Provision of testing. The facility must provide prompt ABO grouping, D (Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

Interpretive Guidelines §493.1103(b)

Review the agreement and determine if the outside laboratory is CLIA-certified or

equivalent, as determined by CMS. An equivalent laboratory is a Veterans Health Administration (VHA) laboratory, a CLIA-exempt laboratory or a laboratory under the auspices of the Department of Defense (DoD).

Probes §493.1103

For laboratories performing ABO grouping, D typing, unexpected antibody detection or compatibility testing using automated methods, is there a back-up system in place to ensure availability of service on a continuous basis when the automated system is malfunctioning?

Is staff trained and competent in the back-up system?