

D5505

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§493.1261 Standard: Bacteriology

(a)(3) When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every 6 months thereafter.

Interpretive Guidelines §493.1261(a)(3)

In addition to Salmonella and Shigella antisera, antisera used for serotyping of homologous isolates, (i.e., streptococcal serotyping systems) must be checked for positive and negative reactivity. Polyvalent antisera should be tested with at least one organism from each polyvalent group.

Requirements for antisera QC apply to testing that has a direct impact on patient care.

