

42 C.F.R. § 493.1254

Standard: Maintenance and function checks.

(a) *Unmodified manufacturer's equipment, instruments, or test systems.* The laboratory must perform and document the following:

- (1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.
- (2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

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