

§493.1282 Standard: Corrective Actions

(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

Interpretive Guidelines §493.1282(a)

Corrective action must be taken when unacceptable differences in test values occur with testing performed using different methodologies or instruments or with the same test performed at multiple testing sites.

Probes §493.1282(a)

When test results do not correlate with patient information (e.g., age, sex, submitted diagnosis) what actions are taken by the laboratory to confirm test results or patient information?