## D5783

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## §493.1282 Standard: Corrective actions

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

## Interpretive Guidelines §493.1282(b)(2)

When an internal control fails to fall within the defined limits of acceptability, the laboratory must identify the reason for the failure and correct the problem before resuming testing of patients. The laboratory must evaluate all patients test results since the last acceptable external control.

## Probes §493.1282(b)(2)

When suboptimal staining or improper coverslipping are identified through quality control procedures, what corrective actions does the laboratory take?

What actions does the laboratory take when controls reflect an unusual trend or are outside of the acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem?