D5667
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1274 Standard: Cytology

(h) Documentation. The laboratory must document all control procedures performed, as specified in this section.

Interpretive Guidelines §493.1274(h)

QC records should include lot numbers, date prepared/opened, expiration dates, the actual measurements, reactions, and/or observations and demonstrate that controls were tested when shipments of reagents, stains, or kits were opened or when the laboratory prepared these materials.

The actual measurements(s) taken, reactions and/or observations must be recorded. However, do not dictate the acceptable format for documentation.

The laboratory must maintain documentation to demonstrate that ten percent of the negative cases were rescreened.

All QC records must be maintained for two years, for example: five year retrospective review, 10 percent rescreens, cytology/histology correlations, cytotechnologist's performance evaluations, individual's and laboratory's statistics (use D3031). Use D3043 for retention of glass slides and D3041 for retention of patient test reports.

The laboratory must document the evaluation of quality control data and ensure that corrective actions are effective. Use D5793.

NOTE: Please refer to D2064 and D6116 for laboratories performing Human Papillomavirus (HPV) testing.

Probes §493.1274(h)

What information is documented on the quality control records?

What records does the laboratory maintain to document that stains are filtered or changed when necessary?