

D3007

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

§493.1101 Standard: Facilities

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

Interpretive Guidelines §493.1101(b)

Base deficiencies related to inappropriate or insufficient equipment on a determination that patient results are or may be adversely affected. Ensure that the laboratory has the appropriate equipment to prepare reagents, stains, solutions, controls, and calibration materials (e.g., pipettes, hydrometers, graduated cylinders, autoclaves, balances, centrifuges, distilled/deionized water). If the equipment or instrumentation is found to be inappropriate or insufficient, document the reasons for this finding.

Ensure that the laboratory has test systems, equipment and/or instruments capable of producing results within the laboratory's stated test performance specifications.

Ensure that the laboratory has test systems, equipment and/or instruments necessary to perform the laboratory's volume of testing (preanalytic, analytic, postanalytic) within established turnaround times.

Data capacity in the laboratory's information system should be sufficient for current data entry. If capacity is maintained by deletion of data, it should be scheduled and documented.

For Cytology, laboratories should use coverslips that cover the entire surface of the specimen.