D5413
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§493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following:

(b)(1) Water quality.

(b)(2) Temperature.

(b)(3) Humidity.

(b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

Interpretive Guidelines §493.1252(b)

Water quality is classified by several different organizations into different reagent grades dependent on microbial content, resistivity, silicate content, and particulate matter. Each laboratory is expected to use the appropriate water quality as required for each instrument, kit, or test system. Laboratories producing water should consider parameters such as pH, silicate content, particulate matter, and bacterial and organic content in assessing water quality. These parameters vary by test system and should be assessed by the laboratory for appropriateness and monitoring. Laboratories purchasing water that has already been classified are not expected to evaluate the above parameters unless specified by the manufacturer or by the laboratory in its procedure manual.

Temperature-controlled spaces, equipment, and instruments must be monitored and results documented for acceptable temperature ranges. Corrective action is needed when acceptable temperature ranges are exceeded. Use D5781 when corrective action not documented.

Continuous monitoring of temperatures by a recording thermograph is acceptable provided the data and time of use are annotated. The charts must be retained to document that temperatures were within the limits established by the laboratory.

In lieu of manual temperature recording, it is acceptable for temperatures to be maintained and monitored internally by the instrument, provided either test results are flagged or not generated when the temperature range for test performance is exceeded.

Probes §493.1252(b)(1)-(b)(4)

How does the laboratory provide special conditions when required for specimen or reagent storage?

How is room temperature and humidity monitored when necessary for test performance, proper operation of reagents, instruments, equipment, or laboratory computer systems? When temperatures and/or humidity are outside acceptable limits, how does the laboratory rectify the problem?

How does the laboratory that moves from testing site to testing site demonstrate that the conditions necessary for quality testing are maintained?

When mobile laboratory or temporary testing site equipment is not in use (weekends, overnight) how are instruments, reagents, stains, and other solutions protected from extreme temperature fluctuations?