

D5431

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§493.1254 Standard: Maintenance and function checks

(a)(2) Function checks as defined by the manufacturer and with at least the

frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

Interpretive Guidelines §493.1254(a)(2)

Function checks refer to those activities performed to evaluate critical operating characteristics (e.g., stray light, zeroing, electrical levels, optical alignment, background counts, counting efficiency) according to the accepted method of operation for each type of device or instrument. Daily quality control activities and function checks are performed prior to patient testing to ensure that an instrument is functioning correctly and is properly calibrated (Checking electrical, mechanical, and operational functions may be independent of the procedure). The performance of daily quality control activities may serve as an additional instrument function check, since analysis of external control samples check the operating characteristics of a test system, including instrument stability and calibration.

The laboratory must follow and document the required functions checks as stated by the laboratory information system (LIS) manufacturer for the LIS computer and devices such as monitors, printers and modems.

For instruments that automatically perform function checks and flag problems, the laboratory is required to document the corrective actions in response to the flagged problems. Use D5793 for deficiencies related to documenting corrective actions in response to the flagged problems.

Flow Cytometry:

A fluorescence standard(s) for each fluorochrome should be used each day of patient testing to ensure:

- Proper alignment of the optical system;
- Standardization of the fluorescence detectors;
- Resolution of dimly-stained particles; and
- Appropriate compensation for spectral overlap of the fluorochromes.

Fluorescence standards should have the same fluorochromes as are used for the test, and with the exception of alignment standards, should have similar fluorescence intensities as found in the test specimens. The laboratory must have an acceptable range of performance for all procedures.

Probes §493.1254(a)(2)

For those methods in which the centrifugation is a critical portion of the test, does the

laboratory check the RPM's and timing periodically (e.g., urine sediments)?

Do the records of a laboratory that moves from testing site to testing site demonstrate the performance of function checks as necessary?

In immunofluorescent test procedures, how does the laboratory ensure that the bulb is emitting ultraviolet light at the correct wavelength?

How does the laboratory ensure that the fluorescent light source has not exceeded the manufacturer's established optimal timeframe?

For procedures or test systems that require pipetting or dilution of patient specimens separately from controls or calibrators, how are autodiluters, microdiluters, and/or pipettors checked for adequate and consistent delivery?

For those systems that perform simultaneous fluid delivery to multi-well plates or tubes, how does the laboratory ensure uniform delivery of reagents or washing solutions to all wells or tubes?

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(b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

Interpretive Guidelines §493.1254(b)

The laboratory must establish and follow procedures for performing maintenance and function checks on each piece of equipment/instrument it uses, including those that are peripherally involved in patient testing (e.g., incubators, centrifuges, safety cabinets, autoclaves and microscopes).

A manufacturer's instructions may not require maintenance and function checks. However, if the laboratory determines that a maintenance and/or function check protocol is necessary in order to ensure accurate and reliable test results, the laboratory must establish a maintenance and/or function check protocol and perform and document the described activities as they are carried out over time.