

§493.1254 Standard: Maintenance and function checks

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

Interpretive Guidelines §493.1254(b)(2)(i)-(b)(2)(ii)

The laboratory must establish and follow procedures for performing 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).

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 serves as an additional instrument function check. Analysis of external control samples check the operating characteristics of a test system, including instrument stability and calibration.

When function checks are critical to test performance, the laboratory must have a mechanism in place to monitor such items as:

- Rotator speed and circumference;
- Timers;
- Anaerobic chambers;
- Cell washers;
- Radioactive particle counters;
- Blood cell counters; and
- Nucleic acid amplification equipment.

Flow Cytometry:

A fluorescence standard(s) for each fluorochrome must 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 must have the same fluorochromes incorporated into them as are used for the test, and with the exception of alignment standards, must have similar fluorescence intensities as found in the test specimens. The laboratory must have an acceptable range of performance for all procedures.

For flow cytometers with air-cooled lasers, the laser should be tested each day patients are tested by peaking the laser signal and monitoring the current input (amps) to laser

light output (milliwatts) to determine whether the brewster windows are in need of cleaning.

Probes §493.1254(b)(2)

For those methods in which the centrifugation is a critical portion of the test, how has the laboratory checked the established RPM's and timing as necessary?

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

If function checks are not required or recommended by the manufacturer, how does the laboratory establish the performance criteria of its equipment and instruments?

For RIA testing, are backgrounds or baselines measured for each setting? For example, if the laboratory uses more than one type of isotope, at what window setting are background counts performed and recorded?

When performing flow cytometry analysis using two or more fluorochromes simultaneously, how does the laboratory identify and adjust for "spill over" into the other fluorescence detectors?

§493.1255 Standard: Calibration and calibration verification procedures

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system. Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following:

Interpretive Guidelines §493.1255

For definitions of calibration and calibration verification, refer to §493.2.

For calibration and calibration verification of blood gas analysis, see §493.1267(a) through (d).

In many instances, the performance of method calibration serves to satisfy the requirement for instrument calibration. Calibration procedures are not to be confused with instrument/equipment function checks at §493.1254.