D5403
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1251 Standard: Procedure manual

(b) The procedure manual must include the following when applicable to the test procedure:

(b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242.

Interpretive Guidelines §493.1251(b)(1)

If testing is delayed or not performed daily, specimens must be preserved or stored in accordance with the laboratory's procedures to ensure specimen integrity.

Determine if the laboratory has a procedure for handling and identifying aliquotted specimens; e.g., sputum sent for Mycobacteriology and Cytology examinations; stool specimens for occult blood, routine culture, parasitology and C. difficile toxin assay; and cerebrospinal fluids for cell count, culture, glucose and protein.

(b)(2) Microscopic examination, including the detection of inadequately prepared slides.

(b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

(b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.

(b)(5) Calibration and calibration verification procedures.

Interpretive Guidelines §493.1251(b)(5)

Calibration and calibration verification procedures must be established in accordance with §493.1255.

(b)(6) The reportable range for test results for the test system as established or verified in §493.1253.

(b)(7) Control procedures.

Interpretive Guidelines §493.1251(b)(7)

Determine if the laboratory's quality control procedures include the following:

- Type of control (e.g., manufacturer or in-house, electronic);
- Identity (e.g., normal, abnormal, level I, II, patient or a control);
- Number and frequency of testing controls;
- Control limits established in accordance with §§493.1253 and 493.1256; and
- Criteria to determine acceptable control results.

(b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.

Interpretive Guidelines §493.1251(b)(8)

Ensure that corrective action procedures are established in accordance with §493.1282(b)(2).

(b)(9) Limitations in the test methodology, including interfering substances.

(b)(10) Reference intervals (normal values).

(b)(11) Imminently life-threatening test results, or panic or alert values.

(b)(12) Pertinent literature references.

(b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.

Interpretive Guidelines §493.1251(b)(13)

Ensure the procedure manual provides instructions for reporting the patient's test results

in the appropriate units or terminology. Use D5805.

Probes §493.1251(b)(13)

Do laboratory procedures address the process for reporting (oral and written) results on patients with multiple laboratory encounters to ensure that the exact name, date, time and identification of specimen is conveyed to the authorized person?

(b)(14) Description of the course of action to take if a test system becomes inoperable.

Interpretive Guidelines §493.1251(b)(14)

Laboratory information systems (LIS) procedures must be available to operators. Instructions should identify the individual(s), either by name or position, to notify if the LIS goes down or if a system error occurs.

Probes §493.1251(b)(14)

When the primary testing system is inoperable, what procedure does the laboratory use to bring the backup system on line?