D5311

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§493.1242 Standard: Specimen submission, handling, and referral

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable:

(a)(1) Patient preparation.

Probes §493.1242(a)(1)

How does the laboratory ensure that all staff, including phlebotomists, gives appropriate instructions for patient preparation when needed?

Does the laboratory provide instructions directly to patients or to the client when proper patient preparation is required for optimal specimen collection? For example:

- Proper preservation (temperature) and transportation time of semen specimens;
- Fasting instructions for lipid profile testing;
- Dietary restrictions prior to occult blood testing;
- Twenty-four hour urine collection for specific tests; and
- Fasting and two hour post-prandial glucose collections.

If a patient has special communication needs (hearing impaired, not fluent in English etc.), are resources available to the client or to the patient, as appropriate, to ensure that instructions for specimen collection, preservation, and transportation to the laboratory, are properly understood?

Has the laboratory provided to its staff and/or individuals external to the laboratory who collect specimens, written procedures to ensure that patient preparation requirements have been followed?

(a)(2) Specimen collection.

Interpretive Guidelines §493.1242(a)(2)

Verify that procedures are available to the appropriate staff responsible for collecting the correct specimen, that personnel are using the appropriate collection technique (order and site of draw) and proper containers (e.g., acceptable anti-coagulant, sterile containers for culture specimens, dacron swabs vs. cotton swabs).

(a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.

Interpretive Guidelines §493.1242(a)(3)

If the laboratory receives two specimens simultaneously with the same first and last name or birth date, the laboratory must have a system in place to process these specimens using

distinct identifying indicators in order to distinguish between the specimens. This also pertains to personnel collecting and labeling specimens. This may include a system that involves labeling the specimen container and request slip (or the patient's medical record or chart) with a unique patient identification number, but does not preclude the use of other mechanisms to assist in patient identification and tracking of specimens throughout the collection, accessioning, testing, and reporting processes.

(a)(4) Specimen storage and preservation.

Interpretive Guidelines §493.1242(a)(4)

Review manufacturer's instructions for performance of each test method to ensure that specimens are properly stored (e.g., maintained at room temperature, kept refrigerated after separation, separated and frozen).

Probes §493.1242(a)(4)

What instructions are provided for specimen preservation and transportation, when applicable? For example:

- Sputum for Cytology;
- Specimens for parathyroid hormone;
- Specimens for blood gas analysis;
- Specimens for urine culture and colony count; and
- Specimens for 24-hour urine collections requiring preservatives.

(a)(5) Conditions for specimen transportation.

Probes §493.1242(a)(5)

Does the laboratory follow the manufacturer's or the referral laboratory's instructions, as appropriate, for transport of specimens?

(a)(6) Specimen processing.

Interpretive Guidelines §493.1242(a)(6)

Specimen processing may include receiving the specimen, accessioning the specimen, preparing the specimen for in-house analysis, preparation to send to a reference laboratory, preparing slides, and inoculating primary culture media, etc. Specimen processing also includes: Parasitology: the fixation and concentration of specimens; Virology: the pretreatment of specimens with antibiotics, the manipulation of cell culture

tubes and inoculation of the cell cultures prior to incubation; Mycobacteriology: performing digestion-decontamination and concentration procedures on clinical specimens; and Histopathology: specimen accession with or without fixation, embedding the paraffin block, cutting the paraffin block, mounting the embedded cut tissue to a slide, preparing the slide for staining, staining and cover slipping the slide, or any other slide preparation procedures that do not involve examination resulting in diagnostic interpretation.

Note: for histopathology specimens, specimen processing does not constitute a CLIA test. Only gross examinations (including weighing, measuring, describing color, specific orientation for diagnostic interpretation, and other characteristics of the tissue, or performing other mechanical procedures including dissection, inking, and marking) require a CLIA certificate. Microscopic examinations of tissue with diagnostic interpretation and reporting is a Histopathology test and requires CLIA certification.

Probes §493.1242(a)(6)

What policies or systems does the laboratory have in place to differentiate specimens that have similar names or identification information?

How does the laboratory recognize and process timed patient specimens (e.g., peaks and troughs)?

(a)(7) Specimen acceptability and rejection.

Interpretive Guidelines §493.1242(a)(7)

Criteria for specimen acceptability and rejection must include the disposition of the rejected specimen(s). Use D5805. The laboratory should promptly notify the authorized person when a specimen meets its rejection criteria and is unsuitable for testing.

(a)(8) Specimen referral.

Interpretive Guidelines §493.1242(a)(8)

Ensure that the laboratory has a current service manual available for each reference laboratory that it uses that contains the reference laboratory's specimen requirements for the test to be performed.

Probes §493.1242(a)(8)

Are laboratory personnel familiar with procedures to prepare and/or submit specimens to the appropriate reference laboratory?

How does the laboratory ensure the security and preservation of specimens submitted to their reference laboratory (e.g., if the office closes before the arrival of the reference

laboratory's courier)? How does the laboratory ensure a timely pick-up of specimens to be performed at the referral laboratory?