

## § 26.113

(d) Any specimen of 15 mL or more that the collector suspects has been diluted, substituted, or adulterated, and any specimen of 15 mL or more that has been collected under direct observation under paragraph (c) of this section, must be sent directly to the HHS-certified laboratory for initial and, if required, confirmatory testing, and may not be subject to initial testing at a licensee testing facility.

(e) As much of the suspect specimen as possible must be preserved.

(f) An acceptable specimen is free of any apparent contaminants, meets the required basic quantity of at least 30 mL, and is within the acceptable temperature range.

### § 26.113 Splitting the urine specimen.

(a) Licensees and other entities may, but are not required to, use split-specimen methods of collection.

(b) If the urine specimen is to be split into two specimen bottles, hereinafter referred to as Bottle A and Bottle B, the collector shall take the following steps:

(1) The collector shall instruct the donor to urinate into a specimen container;

(2) The collector, in the presence of the donor and after determining specimen temperature as described in § 26.111(a), shall split the urine specimen. The collector shall pour 30 mL of urine into Bottle A and a minimum of 15 mL of urine into Bottle B. If the quantity of urine available for Bottle B is less than 15 mL, the collector shall pour the remaining urine into Bottle B and forward the specimens in Bottles A and B to the HHS-certified laboratory for drug and validity testing; and

(3) The collector shall ask the donor to observe the splitting of the urine specimen and to maintain visual contact with both specimen bottles until the custody-and-control form(s) for both specimens are completed, the specimens are sealed, and the specimens and form(s) are prepared for secure storage or shipping.

(c) Licensees and other entities may use aliquots of the specimen collected for validity screening and initial validity and drug testing at the licensee testing facility, as permitted under § 26.31(d)(3)(ii), or to test for additional

## 10 CFR Ch. I (1–13 Edition)

drugs, as permitted under § 26.31(d)(1)(i)(A), but only if sufficient urine is available for this testing after the specimen has been split into Bottle A and Bottle B.

### § 26.115 Collecting a urine specimen under direct observation.

(a) Procedures for collecting urine specimens must provide for the donor's privacy unless directed by this subpart or the MRO or FFD program manager determines that a directly observed collection is warranted. The following circumstances constitute the exclusive grounds for performing a directly observed collection:

(1) The donor has presented, at this or a previous collection, a urine specimen that the HHS-certified laboratory reported as being substituted, adulterated, or invalid to the MRO and the MRO reported to the licensee or other entity that there is no adequate medical explanation for the result;

(2) The donor has presented, at this collection, a urine specimen that falls outside the required temperature range;

(3) The collector observes conduct clearly and unequivocally indicating an attempt to dilute, substitute, or adulterate the specimen; and

(4) A directly observed collection is required under § 26.69.

(b) Before collecting a urine specimen under direct observation, the collector shall obtain the agreement of the FFD program manager or MRO to obtain a urine specimen under direct observation. After obtaining agreement, the collector shall ensure that a specimen is collected under direct observation as soon as reasonably practicable.

(c) The collector shall explain to the donor the reason for direct observation of the collection under paragraph (a) of this section.

(d) The collector shall complete a new custody-and-control form for the specimen that is obtained from the directly observed collection. The collector shall record that the collection was observed and the reason(s) for the directly observed collection on the form.

(e) The collector shall ensure that the observer is the same gender as the