Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2044214	06/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Low Testosterone Men's Clinic	5604 Colleyville Blvd Suite H, Colleyville, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An entrance conference was held with the laboratory representative. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policy manual, direct observation, patient records, and confirmed in interview, the laboratory failed to follow its own written policy for labeling patient blood collection tubes for 2 of 2 patients in 2021 (June). Findings: 1. Review of the laboratory's policy manual revealed: "TAB 5: Before Performing the

	Test (Pre-Analytic Process) Pre-analytic Policies: Good lab practices include actions such as labeling patient specimens, recording the time and date of testing, having written (opposed to verbal) test orders from the ordering physician, and assigning each patient a unique patient identification number. Proper collection and handling is also an essential component of pre-analytic policies. It is the policy of this lab to adhere to the following procedures, which influence all activities from the time lab tests are ordered through the time that specimens are processed and received by the testing site ... Policies for Collecting, Labeling, Handling, and Storing Specimens Blood specimens are collected, labeled and handled in a manner to optimize patient test results by ensuring that specimens are not mixed-up, mislabeled or deteriorated. Our lab policies for specimen integrity are continuously assessed by our Quality Assessment program. Specimen Collection and Labeling Procedures ... 6. Label collection tubes Label all vacuum tubes with at least the patient's name and your initials as well as the time and date the specimen is drawn." Off to the side of the policy under "6" there was a hand-written note stating: "patient name, unique identifier date & time drawn". 2. During a tour of the laboratory on 06/02/2021 at 9:05 am, the surveyor observed the following blood collection tubes labeled with only a patient first name and no other patient identifiers: 1 serum separator tube (SST), 1 lavender tube (same patient first name) 1 SST, 1 lavender tube, 1 serum heparin tube, 1 transfer tube (same patient first name) The laboratory failed to follow its own written policy for labeling patient blood collection tubes with patient name, unique identifier, date drawn, time drawn, and collector's initials. 3. Review of patient records revealed the above-mentioned patients were identified as patient ID#s 6361 and 8748. 4. During an interview on 06/02/2021 at 9:15 am, Testing Person-3 stated that she labels patient blood collection tubes with the patient name and her initials, confirming the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure blood collection tubes did not exceed their expiration date. Findings: 1. During a tour of the laboratory on 06/02/2021 at 9:05 am, the surveyor observed the following expired blood collection tubes in the cabinet: 3 BD Vacutainer Trace Element Serum tubes; Lot # 9344018; expiration date 12/31/2020 2 BD Vacutainer Trace Element Serum tubes; Lot # 0010762; expiration date 01/31/2021 3 BD Vacutainer Trace Element Serum tubes; Lot # 0133402; expiration date 05/31/2021 2 BD Vacutainer Buff Na Citrate tubes; Lot # 0184336; expiration date 04/30/2021 6 Microtainer tubes; lot #9171923; expiration date 04/30/2021 2. During an interview on 09/15/21 at 9:15 am, Testing Person-3 confirmed the above findings.