

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2044214	(X3) Date Survey Completed 06/16/2022
Name of Provider or Supplier Low Testosterone Men's Clinic	Street Address, City, State 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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 Southern Operations Branch-Dallas 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.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure expired test kits were not available for use in patient testing for 1 of 1 box of influenza test cassette in 2022 (June). Findings: 1. During a tour of the laboratory on 06/16/2022 at 10:43 am, the surveyor observed the following in a cabinet: 1 box of McKesson Influenza A & B test cassette; lot # 449c11; expiration date 03/31/2021 2. During an interview on 06/16/2022 at 10:43 am, Testing Person-4 confirmed the test kit was expired.</p>

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 2022 (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 06/16/2022 at 10:43 am, the surveyor observed the following blood collection tubes labeled with only a patient last name and no other patient identifiers: 1 serum separator tube (SST), 1 serum heparin tube, 1 lavender tube (same patient last name) Further observations revealed the following blood collection tubes labeled with only the patient's name and date of birth: 1 lavender tube 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. During an interview on 06/16/2022 at 10:43 am, Testing Person-4 stated that she labels patient blood collection tubes with the patient's last name and then those tubes that will be sent out to the reference lab are labeled with the complete patient's name and date of birth. This confirmed the above findings.