

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0891080	(X3) Date Survey Completed 10/18/2022
Name of Provider or Supplier Community Clinic Springdale Medical	Street Address, City, State 614 E Emma Ave, Ste 300, Springdale, AR	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Through review of laboratory policy and procedure, observation and interview it was determined that the laboratory failed to label two of twelve specimen collection containers with patient name or unique patient identifier. Findings follow: A) During a tour of the laboratory on 10/18/22 at 1:00 pm twelve urine specimen containers were observed in the laboratory testing area; two labeled on the specimen lid only. B) Review of the laboratory policy and procedure revealed that "patient specimen containers must be labeled with the patient's name and unique identifier". . C) In an interview on 10/18/22 at 3:23 pm , the laboratory staff member (#1 on the CMS 209 form) confirmed that the specimens identified above had been analyzed and lacked proper patient identification on the containers as required by policy and procedure.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.</p>

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature in one of three rooms in which supplies with storage temperature requirements were stored on each day of operation. Findings follow: A) During a tour of the laboratory on 10/18/22 at 01:00 p.m. three rooms containing items with a temperature storage requirement (the main laboratory, a storage room and separate area for microscopy) all separated by a closable door, were observed. B) During a review of the laboratory's temperature records it was noted that temperature records for only the main laboratory and storage room were presented. C) During a tour of the laboratory on 10/18/22 at 03:03 p.m. one container of KOH 10% solution (lot # 3004-00 expiration date 2024-01-31) with a storage temperature requirement of 15 degrees C. to 35 degrees C was observed in the microscopy area. D) Upon request, the laboratory could not present the temperature records for the microscopy area in which the supplies identified above were stored,. E) In an interview on 10/18/22 at 03:23 p.m. the laboratory staff member (# 1 on the CMS 209 form) stated that the daily temperature of the microscopy room in which the supplies identified above were stored had not been monitored and recorded..

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:

. Through observations made during a tour of the laboratory and interviews with staff, it was determined the laboratory had supplies available for use when they had exceeded their expiration date. Survey findings follow: A) During a tour of the laboratory on 10/18/22 at 03:00 p.m., the surveyor observed three BD 6.0 ml Red Top blood collection tubes (lot# 1132882, expiration date 2022-9-30) in a plastic bin located in Phlebotomy drawing room. B) In an interview on 10/18/22 at 03.03 p.m., the laboratory staff member (#1 on the CMS 209 Form) confirmed the supplies were available for use when they had exceeded their expiration date.