

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0891080	(X3) Date Survey Completed 11/16/2020
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
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. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Through observation, lack of documentation and interview it was determined that the laboratory failed to document room temperature in two of three rooms surveyed in which supplies with storage temperature requirements were located. Findings follow: A) During a tour of the laboratory on 11/16/20 at approximately 02:30 PM, the surveyor observed two boxes of Quidel Sofia SARS Ag tests, lot # 706189 expiration date 2021-08-12 with a storage temperature requirement of 15 degrees C. to 30 degrees C. in a separate Covid-19 testing room separated from the laboratory by a closable door and 60 boxes of Quidel Sofia SARS Ag tests, lot # 7058987 expiration date 2021-08-12 in a separate storage room separated from the laboratory by a closable door. B) Upon request the laboratory was unable to provide documentation of temperature records for the rooms identified above. C) In an interview on 11/16/20 at approximately 02:30 PM, the laboratory staff member identified as number one on the CMS 209 form confirmed that the laboratory failed to measure and document temperature in the rooms identified above.</p>