

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1007969	(X3) Date Survey Completed 12/13/2019
Name of Provider or Supplier Cornerstone Medical Clinic PLLC	Street Address, City, State 825 North Main Street, Suite 1, Harrison, 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 the laboratory failed to monitor room temperature in one of two rooms in which supplies with storage temperature requirement were stored. Findings follow: A) During a tour of the laboratory on 12/13/19 at approximately 09:30 AM, two boxes of Precision Multi-Use Drug Cups, lot # 0904259, with an expiration date of 2021-05-10 with a storage temperature requirement of 2 degrees C. to 30 degrees C. were observed stored in a storage room separate from the laboratory . B) Upon request, the laboratory was unable to provide records of room temperature in the separate storage room. C) In an interview on 12/13/19 at approximately 10:30 AM, the laboratory staff member, identified as number three on the CMS 209 form, stated that the laboratory did not monitor the room temperature in the storage room identified above.</p>