Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 04D2173838	**(X3) Date Survey Completed** 05/02/2023
Name of Provider or Supplier Salem Family Clinic P A	**Street Address, City, State** 507 N Main St, Salem, 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Through review of laboratory policy and procedure, laboratory temperature/humidity records, lack of documentation and interview with laboratory staff members it was determined that in one of twelve months reviewed the laboratory failed to monitor temperatures and humidity in areas with supplies and/or equipment with environmental requirements for storage or utilization . Findings follow: A) Review of the laboratory's policy and procedure for quality assurance revealed that the laboratory records temperatures and/or humidity on each day of operation in areas, incuding rooms, refrigerators and freezers, that contain supplies or equipment with environmental requirements and the environmental monitors are reviewed monthly by the technical consultant. B) Review of the laboratory's records of temperature and humidity for the 2022 calendar year revealed that no records were presented for July 2022, or 6/24/22 and 6/27/22. C) Upon request, the laboratory was unable to provide environmental monitor records for July 2022 or 6/24/22 and 6/27/22. D) In an interview of 5/2/23 at 3:43 p.m., the laboratory staff (# 2 on the CMS 209 form), confirmed that the laboratory was in operation on the dates identified above and records of temperatures and humidity are not recorded.