

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468992	(X3) Date Survey Completed 05/24/2023
Name of Provider or Supplier Pathology Services Laboratory Pa	Street Address, City, State 1430 West C Street, Russellville, 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, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature in three of five rooms in which supplies with storage temperature requirements were stored on each day of operation. Findings follow: A) During the laboratory tour on 5/23/23 at 10:04 a.m. five rooms were noted with supplies that required temperature monitoring. B) During a review of the laboratory's temperature records it was noted the main laboratory and Panther instrument room were the only rooms with temperature documented. No temperature records were presented for the grossing room and two storage rooms. C) Upon request, the laboratory could not present the temperature records for the grossing room and two storage room areas in which the supplies identified above were stored. D) During a tour of the laboratory on 5/24/23 at 12:47 p.m. ThinPrep PreservCyt Solutions lot number 3103AA (2 trays of 25 each in flammable storage room), ThinPrep PreservCyt Solutions lot number 3336BA (5 trays of 25 each in flammable storage room), and ThinPrep PreservCyt Solutions lot number 2215AB (2 trays of 25 each in grossing room) with a storage temperature requirement 15C - 30C. Aptima Urine Specimen Collection Kit (1 box of 50 each in second storage room) with a storage temperature requirement 15C - 30C. E) In an interview on 5/24/23 at 1:20 p.m. the laboratory staff stated that the daily temperature</p>

of the grossing and two storage room areas in which the supplies identified above were stored had not been monitored and recorded.