

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2045680	(X3) Date Survey Completed 09/06/2023
Name of Provider or Supplier Mercy Ob/Gyn Pinnacle Hills	Street Address, City, State 3333 Pinnacle Hills Parkway, Suite 600, Rogers, 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 on each day of operation in one of two rooms in which supplies with storage temperature requirements were stored. Findings follow: A) During a tour of the laboratory on 9/6/23 at 2:00 p.m. two separate rooms (main lab, storage room) containing items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the storage room area. C) During a tour of the laboratory on 9/6/23 at 2:00 p.m. two cartons containing 24 urine pregnancy test kits, lot # 0000594726, expiration date 2024-07-03 with a storage temperature requirement of 36 degrees F. to 86 degrees F. were observed in storage room. D) Upon request, the laboratory could not present the temperature records for the storage room in which the supplies identified above were stored. E) In an interview on 9/6/23 at 2:15 p.m., the laboratory staff member (# 1 on the CMS 209) stated " no we don't have temperatures for the storage room".</p>