

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D0393469	<b>(X3) Date Survey Completed</b> 04/12/2023
<b>Name of Provider or Supplier</b> Associated Physicians, Llp	<b>Street Address, City, State</b> 4410 Regent St 1st Flr, Madison, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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: Based on surveyor observation of the laboratory supervisor's office, review of the manufacturer's requirements and temperature logs, and interview with the laboratory supervisor, staff A, the laboratory did not define an acceptable temperature range that was consistent with the manufacturer's acceptable range for the Cepheid 4-plex Xpress and Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) reagents stored in the laboratory office. Findings include: 1. Observation of the laboratory supervisor's office April 12, 2023, at 9:32 AM showed Cepheid Gene Xpert 4-plex and CT/NG cartridges were being stored in the office. Further observation showed the manufacturer's required storage at 2-28 degrees Celsius (C). 2. Review of temperature logs showed a no established room temperature range or documentation of temperatures for the laboratory supervisor's office. 3. Interview with the staff A on April 12, 2023, at 11:55 AM confirmed the laboratory had not defined an acceptable range for the laboratory office and did not document temperatures in the area the reagents were stored.</p>
<b>D5781</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p>

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on surveyor review of temperature logs and interview with the general supervisor, the laboratory did not document corrective action when readings were outside the defined acceptable range for humidity for two hundred and four days of three hundred and four days in 2022. Findings include: 1. Review of humidity temperature logs revealed no documentation of corrective action on humidity readings outside the defined acceptable range of 30-80 percent (%) for the following in 2022: January 24 of 24 days February 23 of 23 days March 26 of 27 days April 25 of 26 days May 16 of 25 days June 9 of 26 days July 3 of 25 days August 2 of 27 days September 7 of 25 days October 23 of 26 days November 21 of 25 days December 25 of 25 days 2. Interview with staff A on April 12, 2023, at 11:55 AM confirmed the laboratory did not document corrective action when the humidity readings were outside the defined acceptable range for two hundred and four days of three hundred and four days in 2022.