

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0904608	<b>(X3) Date Survey Completed</b>  05/28/2024
<b>Name of Provider or Supplier</b>  Conway Womens Health Center Pa	<b>Street Address, City, State</b>  2519 College Avenue, Conway, AR	
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 review of policy and procedure manuals, temperature logs, and interview with staff, the laboratory failed to follow instructions for operational environment policies for temperature and relative humidity. Findings follow: A) Review of the "The Lab Area: Safety and Environment Monitoring", section "Procedures for Monitoring Temperature; Record the temperature of the room and the laboratory refrigerator, along with the humidity, at the beginning of each day. Use the Temperature/Humidity Chart (behind FORMS Tab) to document these readings. Adjust temperature and humidity readings that are out of range, then recheck to verify that readings have returned to the acceptable range", and section "What to Do if Temperatures Are Out of Range; Document all remedial action taken on the reverse side of the Temperature/Humidity Chart". B) Review of the normal operating condition for Affirm VPIII test system must be operated at 22-28C (71.6-82.4F) and 10-85% humidity. C) Review of the Temperature/Humidity Chart January 2024 revealed 9 days out of 21 days temperature below 71.6F. February 2024, 2 days out of 21 days temperature below 71.6F. December 2023, 5 days out of 19 days temperature below 71.6F. November 2023, 4 days out of 20 days temperature below 71.6F. September 2023, 6 days out of 19 days temperature below 71.6F. June 2023, 2 days out of 22 days temperature below 71.6F. D) During an interview on 5/28/2024 at 12:</p>

47 p.m. the Testing Personnel (TP) #1, listed on the CMS-209 form, confirmed the 29 days temperature below 71.6F. No corrective action taken on any of the 29 days temperature below 71.6F.

**D6024**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(7)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Through review of policy and procedure manuals, quality control results, lack of documentation, and interview it was determined that the director failed to ensure that remedial actions are taken when deviations of performance characteristics are identified as cited at: D5413 - The director failed to ensure corrective action policies were written or that remedial action was documented when temperatures did not meet the laboratory's criteria for acceptability.