

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0904608	<b>(X3) Date Survey Completed</b> 02/05/2020
<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>D0000</b>	This is the CLIA recertification survey of the laboratory conducted on 2/5/2020. At the time of the survey the laboratory was not in compliance with the following Condition of Participation: 493.1421 Laboratory Testing Personnel
<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: Through a review of the BD (Becton Dickinson) MAX manufacturer's instructions, TEMPERATURE/HUMIDITY CHARTS for February 2019 through January 2020 (12 months), and interviews with staff, it was determined the laboratory failed to define acceptable humidity requirements which were consistent with the manufacturer's instructions. Survey findings include: A. The manufacturer's instructions for the BD MAX state that the acceptable operating humidity for the instrument is 20% to 80%. B. The humidity range in use on the TEMPERATURE /HUMIDITY CHARTS for February 2019 through January 2020 is 10% to 85%. C. Due to the incorrect humidity range being used the laboratory failed to identify that humidity was unacceptable on 40 of 251 days during the 12 months reviewed. D. During an interview on 2/5/2020 at 11:34, laboratory employee #2 confirmed the incorrect range was in use and that temperatures were outside of the manufacturer's acceptable range.</p>

**D6063**

**LABORATORY TESTING PERSONNEL**

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Through a review of personnel files for eleven of eleven laboratory testing personnel listed on the form CMS-209, through a lack of documentation, and through interviews with staff, it was determined that two of eleven laboratory testing personnel failed to meet qualification requirements as testing personnel as evidenced by: D6065 - two of eleven laboratory testing personnel lacked documentation of appropriate education to qualify as a testing personnel

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Through a review of personnel files for eleven of eleven laboratory testing personnel listed on the form CMS-209, through a lack of documentation, and through interviews with staff, it was determined that two of eleven laboratory testing personnel lacked documentation of appropriate education to qualify as a testing personnel. Survey findings follow: A. Documentation of appropriate education was not available for laboratory employees #7, and #11 (listed as testing personnel) as listed on the form CMS-209. B. In an interview at 11:37 on 2/5/2020, laboratory employee #2 (as listed on CMS-209) confirmed the lack of documentation of appropriate education for two of eleven testing personnel.