

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 21D1007015	<b>(X3) Date Survey Completed</b> 12/19/2018
<b>Name of Provider or Supplier</b> Carroll Arthritis, Pa	<b>Street Address, City, State</b> 412 Malcolm Dr Ste 306, Westminster, MD	
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 the written procedure manual and interview with the testing person, the laboratory did not monitor the incubator temperature for performing tuberculosis (TB) testing. Findings: 1. The laboratory performs TB testing that require incubation between 36-38 Degrees Celsius. 2. The laboratory did not document each day of patient testing the temperature of the incubator. 3. The testing person confirmed that the incubator temperature for performing TB testing was not documented each day of patient testing.</p>
<b>D6050</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing</p>

person, the laboratory director acting as the technical consultant (TC) did not perform observation procedures for competency assessments. Findings: 1. The TC did not perform observation procedures for annual competency checks. 2. The testing person stated he is the only testing person and observation competency procedures were not performed and documented.