

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2102641	(X3) Date Survey Completed 06/16/2021
Name of Provider or Supplier Pathology And Laboratory Medicine Research	Street Address, City, State Robert C Byrd Hsc, Pathology, Rooms 2122, 2128, Morgantown, WV	
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
D0000	<p>An announced, on site, recertification survey was conducted at Pathology & Laboratory Medicine Research on June 16, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.</p>
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: Based on record review, policies and procedures (P&P), and interview the laboratory failed to define the acceptable criteria for the (2) temperature and (3) humidity for the environmental conditions of the testing equipment and proper reagent storage for 12 of 12 months in 2020 and 6 of 6 months in 2021. Findings: 1. Review of P&P (Histology Quality Control) identified a procedure for the daily temperature documentation of ovens, freezers, tissue flotation baths, embedding centers, and refrigerators and acceptable specified ranges as follows: Refrigerators -8 to -4 C Freezers -20 to -5 C Embedding centers 56 to 64 C Tissue Flotation Baths 40 to 46 C Cryostat -20 to -5 C Oven #4 37 to 42 C Oven #5 35 to 40 C Oven #6 60 to 65 C Oven #7 56 to 65 C 2. A review of P&P (SOP #67) identified a procedure for the daily temperature documentation of ovens, freezers, tissue flotation baths, embedding</p>

centers, and refrigerators and defined "acceptable temperature range is listed on each equipment specific recording sheet, as appropriate for that piece of equipment" or as necessary for a particular research study. 3. No P&P for the documentation and defined criteria for the room temperatures and humidity could be located. 4. Review of temperature logs for January 2020 thru December 2020 identified daily temperatures and humidity logs for 12 pieces of laboratory equipment and 3 room temperature/humidity logs. 4 of 12 equipment temperature logs had no acceptable criteria range specified for January 2020 thru December 2020 8 of 12 equipment temperature logs had a different criteria range specified than stated in the P&P for January 2020 thru December 2020 5. Review of 2021 room temperature and humidity logs for 3 areas of the lab identified no acceptable criteria for the temperature or the humidity for all 3. 6. The findings were confirmed during the exit interview with the general supervisor on 6/16/2021 at approximately 11:30 AM.