

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2160356	(X3) Date Survey Completed 11/19/2019
Name of Provider or Supplier Appalachian Labs Of Wv	Street Address, City, State 708 Bigley Ave, Charleston, 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
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 a tour of the laboratory and an interview with Testing Personnel 1 (TP1), the laboratory failed to accurately monitor the conditions (2) temperature and (3) humidity essential for proper storage of reagents and test system operation. Findings: 1. The room temperature and humidity of the laboratory were being monitored and documented from a thermometer/hydrometer that had an expired NIST calibration. The NIST certified calibration of the Control Company 4095 thermometer/hydrometer (SN 140202060) expired 3/21/2016. 2. The temperature of the freezer, used to store patient specimens, was being monitored and documented from a thermometer that had an expired NIST calibration. The NIST certified calibration of the Control Company 4227 thermometer (SN 140090585) expired 2/3/2016. 3. The temperature of the two refrigerators, used to store reagents and quality control materials, were being monitored and documented from thermometers that had expired NIST calibrations. The NIST certified calibrations of the Control Company 4227 thermometers (SN 140524828 and SN 140571239) expired 8/4/2016 and 8/26/2016. 4. An interview with TP1, on 11/19/19 at approximately 11:45 AM, confirmed the findings.</p>