

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0325173	(X3) Date Survey Completed 11/30/2023
Name of Provider or Supplier Highlands Arh Regional Medical Center	Street Address, City, State 5000 Ky Rt 321, Prestonsburg, KY	
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	A Recertification Survey was initiated on 11/29/2023 and concluded on 11/30/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on facility policy and document review and interview, the laboratory failed to provide evidence of self-evaluation for five (5) of thirty (30) proficiency testing (PT) results that were returned as not graded by the PT provider. The findings include: Review of the laboratory policy titled, "Proficiency Testing," last reviewed 08/25 /2020, revealed "12. Testing ungraded for reasons of low participants or lack of census on grading will be further investigated by repeat analysis if possible and compared to participants results and percentages of correct participants. Assure all QC [quality control] and calibrations, if applicable, are in and in control. Write the reason and findings on why testing was not graded on summary." Review of the American Proficiency Institute report titled, "Proficiency Testing Performance Evaluation" for the 2021 Hematology/Coagulation - 3rd Event revealed the vaginal wet preparation for sample "VKP-03" noted as not graded. Review of the American Proficiency Institute report titled, "Proficiency Testing Performance Evaluation" for the 2021 Immunology/Immunohematology - 3rd Event revealed the DAT (direct antiglobulin test) Polyspecific for sample "DAT-06" noted as not graded. Review of the American Proficiency Institute report titled, "Proficiency Testing Performance Evaluation" for</p>

the 2022 Immunology / Immunochemistry - 1st Event revealed the compatibility for sample "SE-05" noted as not graded. Review of the American Proficiency Institute report titled, "Proficiency Testing Performance Evaluation" for the 2022 Immunology / Immunochemistry - 2nd Event revealed the compatibility (auto) for sample "AUT-08" noted as not graded. Review of the American Proficiency Institute report titled, "Proficiency Testing Performance Evaluation" for the 2023 Chemistry Core - 1st Event revealed the ALT (alanine transaminase)/ SGPT (serum glutamic pyruvic aminotransferase) for sample "CH-01" noted as not graded. During an interview on 11/30/2023 at 8:30 AM, the Laboratory Manager confirmed the above findings.