

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0323967	(X3) Date Survey Completed 09/20/2023
Name of Provider or Supplier Pineville Community Health Center	Street Address, City, State 850 Riverview Avenue, Pineville, 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 conducted on 09/20/2023. 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 policy review, document review and interview, the laboratory failed to provide evidence of a self-evaluation for eleven (11) of twenty-six (26) proficiency testing (PT) samples scored as "not graded" by the Proficiency Testing Provider. The Findings include: Review of the laboratory policy titled, "External Proficiency Testing," revised 12/01/2022, revealed "PT results that are not evaluated (for example - due to lack of consensus, incorrect method reporting or results reported after the cutoff date) will be reviewed and evaluated by the manager by comparison with the reported peer results." Review of the American Proficiency Institute Comparative Evaluation," for the "2021 Chemistry Core - 2nd Event", revealed the troponin T for samples CM-07 and CM-10 and the folate for sample IA-07 were not graded. Review of the "American Proficiency Institute Comparative Evaluation", for the "2021 Hematology/Coagulation - 2nd Event", revealed the blood cell identification for sample BCI-07 was not graded. Review of the "American Proficiency Institute Comparative Evaluation," for the "2021 Hematology/Coagulation - 3rd Event", revealed the nucleated red blood cells for sample COU-12 and the vaginal wet preparation for sample VKP-03 were not graded. Review of the "American</p>

Proficiency Institute Comparative Evaluation," for the "2021 Immunology /Immunoematology - 3rd Event", revealed the direct antigen test - polyspecific for sample DAT-06 was not graded. Review of the "American Proficiency Institute Comparative Evaluation," for the "2022 Hematology/Coagulation - 1st Event", revealed the nucleated red blood cells for samples COU-01 and COU-02 were not graded. Review of the "American Proficiency Institute Comparative Evaluation," for the "2022 Immunology/Immunoematology - 1st Event" revealed the compatibility for sample SER-05 was not graded. Review of the "American Proficiency Institute Comparative Evaluation," for the "2022 Immunology/Immunoematology - 2nd Event", revealed the compatibility for sample SER-06 was not graded. No documentation of self-evaluation by the laboratory for any of the ungraded PT samples above was available for review. During an interview on 09/19/2023 at 2:00 PM, Technical Supervisor #1 and General Supervisor #2 confirmed that a self-evaluation of the ungraded PT samples was not performed.