

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0326986	(X3) Date Survey Completed 06/15/2023
Name of Provider or Supplier Cumberland County Hospital	Street Address, City, State 299 Glasgow Road, Burkesville, 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 06/14/2023 and concluded on 06/15/2023. 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 document review and interview, the laboratory failed to provide evidence of a self-evaluation of 5 proficiency testing (PT) results that were returned as not graded by the PT provider. Findings included: 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 was not graded. Review of the American Proficiency Institute report, titled "Proficiency Testing Performance Evaluation" for the 2022 Microbiology - 1st Event, revealed the gram stain for sample GS-05 was not graded. Review of the American Proficiency Institute report, titled "Proficiency Testing Performance Evaluation" for the 2022 Immunology / Immunohematology - 1st Event, revealed the compatibility for sample SER-05 was not graded. Review of the American Proficiency Institute report, titled "Proficiency Testing Performance Evaluation" for the 2022 Immunology /Immunohematology - 2nd Event, revealed the compatibility for SER-06 was not graded. Review of the American Proficiency Institute report, titled "Proficiency Testing Performance Evaluation" for the 2022 Hematology/Coagulation - 3rd Event, revealed the blood cell identification for sample BCI-14 was not graded. During an</p>

interview on 06/14/2023 at 2:25 PM, General Supervisor #1 confirmed the above findings.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on procedure manual review and interview, the laboratory failed to establish a written procedure for the performance and review of external proficiency testing (PT). Findings included: Review of the laboratory's procedure manual, revealed there was not a procedure that specified the performance and review of PT. During an interview on 06/14/2023 at 2:25 PM, General Supervisor #1 confirmed the laboratory did not have a written PT procedure.