Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0324940	05/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Paintsville Arh Hospital	625 James S Trimble Blvd, Paintsville, 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	An Initial Certification Survey was initiated on 05/07/2024 and concluded on 05/08 /2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on facility policy review, document review and confirmed in staff interview; the laboratory failed to provide evidence of corrective action for 2 of 20 proficiency testing (PT) events that were evaluated as unacceptable by the PT provider. Findings included: A facility policy titled, "Proficiency Testing," dated 01/08/2024, revealed, "2. For individual unacceptable proficiency testing results, the laboratory conducts an investigation of all potential causes utilizing a remedial action form (RAF) which provides evidence of the review, and performs corrective action sufficient to address and correct the issues identified in the investigation. These actions are to be documented of the RAF." An American Proficiency Institute (API) report titled, "Proficiency Testing Performance Evaluation" for the "2022 Hematology / Coagulation - 3rd Event," which was not signed or dated by the Laboratory Director or designee, revealed no notation of corrective action for the unacceptable analytes /samples on the performance evaluation page. An API report titled, "Comparative Evaluation" for the "2022 Hematology / Coagulation - 3rd Event," revealed the "Fibrinogen" for samples "COA-11," "COA-12," "COA-13," and "COA-15" were graded as "Unacceptable." An API report titled, "Proficiency Testing Performance Evaluation" for the "2022 Immunology / Immunohematology - 3rd Event," which was not signed or dated by the Laboratory Director or designee, revealed no notation of corrective action for the unacceptable analyte/samples on the performance evaluation

	page. An API report titled, "Comparative Evaluation" for the "2022 Immunology / Immunohematology - 3rd Event," revealed the "C- Reactive Protein" for samples "CRP-05" and "CRP-06" were graded as "Unacceptable." During an interview on 05 /07/2024 at 12:45 PM, Technical Supervisor #2 confirmed the above findings.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on facility policy review, record review, and confirmed in staff interview; the laboratory failed to perform a self-evaluation for proficiency testing (PT) results that were returned as not graded by the PT provider because of a lack of required level of agreement within the test method peer group in 2 of 20 proficiency survey event cycles reviewed. Findings included: A facility policy titled, "Proficiency Testing," effective 01/08/2024, revealed "12. All proficiency testing that is ungraded for reasons of low participants or lack of consensus will be further investigated by repeat analysis if possible and compared to participants results [sic] Assure all QC [quality control] and calibrations, if applicable, are in control. Write the reasons and findings, with regard to why the testing was not graded, on the summary." An American Proficiency Institute (API) report titled, "Proficiency Testing Performance Evaluation" for the "2022 Hematology/Coagulation-3rd Event," which was not signed or dated by the Laboratory Director or designee, revealed no notation of the ungraded analytes /samples on the performance evaluation page or a participant summary sheet. An API report titled, "Comparative Evaluation" for the "2022 Hematology / Coagulation -3rd Event" revealed the "Blood Cell Identification" for sample "BCI-14" as "Not Graded." The report also revealed the "Platelet Estimate" for sample "DIF-03" as "Not Graded." An API report titled, "Proficiency Testing Performance Evaluation" for the "2023 Hematology / Coagulation-3rd Event," signed by the Laboratory Director or designee on 05/03/2024, revealed no notation of the ungraded analyte/sample on the performance evaluation page or a participant summary sheet. An API report titled, "Comparative Evaluation" for the "2023 Hematology / Coagulation-3rd Event" revealed the performance of the "Vaginal Wet Preparation" for sample "VA-03" as "Not Graded." During an interview on 05/07/2024 at 12:45 PM, Technical Supervisor #2 confirmed the above findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on facility policy review, document review, and confirmed in staff interview; the laboratory failed to document the evaluation of proficiency testing performance for 2 of 20 proficiency testing event reports. Findings included: A facility policy titled, "Proficiency Testing," effective 01/08/2024, revealed, "3. The laboratory

	medical director performs a final review of each testing report, even if test events are satisfactory. The review is documented." An American Proficiency Institute (API) report titled, "Proficiency Testing Performance Evaluation" for the "2022 Hematology / Coagulation - 3rd Event" revealed the Laboratory Director or designee did not sign and date the "Performance Review and Corrective Action" section of the form. An API report titled, "Proficiency Testing Performance Evaluation," for the "2022 Immunology/Immunohematology - 3rd Event," revealed the Laboratory Director or designee did not sign and date the "Performance Review and Corrective Action" section of the form. During an interview on 05/07/2024 at 12:45 PM, Technical Supervisor #2 confirmed the above findings.