Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0661760	05/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Summers County Arh Hospital Laboratory	115 Summers Hospital Road, Hinton, 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
D0000	A routine recertification survey was performed at Summers County ARH Hospital Laboratory, April 30 and May 1, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to return proficiency testing (PT) results to the American Proficiency Institute (API) program by the submission date for one of three routine chemistry events in 2023. Findings: 1. Review of API records revealed unsatisfactory scores for the Routine Chemistry 2nd event of 2023: 0% pH Blood Gas (#0315) 0% PO2 Blood gas (#0325) 0% PCO2 Blood Gas (#0335) 2. Review of the laboratory corrective action for the unsatisfactory performance revealed the results for the blood gas portion of the 2nd routine chemistry event were not submitted to API before the date due. 3. An interview with the technical consultant, 4/30/24 at 10:00 AM, confirmed the failure to submit results within the timeline specified by API for the 2nd event of 2023.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of policies and procedures (P&P), patient test records, and interview the laboratory failed to update the (10) reference ranges (RR) for Hematology to reflect the Sysmex XN-1000 performance specifications. Findings: 1. Review of P&P identified a list of reference ranges for the Sysmex XN-1000 hematology analyzer based on gender. 2. Review of a CBC test report for a female identified RR for hemoglobin and hematocrit that differed from the P&P. 3. Review of a CBC test report for a male identified RR for hemoglobin and hematocrit that differed from the P&P. 4. An interview with the technical supervisor, 5/1/24 at 11:15 AM, confirmed the RRs on the patient test report did not match the RRs in the P&P for the Sysmex XN-1000.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on policies and procedures (P&P), observation, record review, and interview the laboratory failed to ensure the correct ISI for Dade Innovin lot 564642 (expiry 1/5 /26) was programmed into the CA-660 coagulation analyzer for performance of prothrombin time (PT/INR) testing in accordance with the manufacturer's instructions. Findings: 1. Review of coagulation P&P identified a process to place new lots of reagents into use stating the INR calculations performed in PT testing utilizes the manufacturer defined ISI for the lot of Dade Innovin reagent in use. 2. Observation of the laboratory CA-660 coagulation analyzer, 4/30/24 at 3:00 PM, identified the current ISI in use for Dade Innovin lot 564642 (expiry 1/5/26) as 1.05. 3. Record review of the manufacturer instructions for Dade Innovin lot 564642 (expiry 1/5/26) identified the ISI for the CA-660 as 1.06. 4. An interview with the technical consultant, 4/30/24 at 3:10 PM, confirmed the ISI programmed into the CA-660 coagulation analyzer did not match the manufacturer defined ISI for lot 564642 (expiry 1/5/26) of Dade Innovin reagent used in PT/INR testing.

D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to perform and document two levels of quality control (QC) for DDimer testing within the 8 hour timeframe before test results were released for 7 of 43 patient test records reviewed. Findings: 1. Review of P&P "CA 660 Innovance DDimer" identified that 2 levels of QC are to be tested every 8 hours of patient testing. 2. Review of patient DDimer test records for March and April 2024 (3 /3 thru 4/28) identified 43 DDimer tests completed for patients. 3. Review of DDimer QC records for March and April 2024 (3/3/24 thru 4/28) identified 7 of the 43 test results released without documentation of two levels of QC performed within the previous 8 hours. 4. An interview with the technical consultant, 4/30/24 at 4:50 PM, confirmed that no documentation could be located of two levels of QC being performed within the required 8 hour timeframe for the 7 DDimer patient test results.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to establish acceptability criteria for evaluating the instrument comparison studies between the I-Stat and GEM 4000 instruments used for blood gas testing. Findings: 1. Review of P&P identified that "instrument comparisons are to be performed every 6 months". No P&P could be located in the chemistry, respiratory therapy, or general laboratory procedure manuals that defined acceptability criteria for the evaluation of the I-Stat and GEM 4000 instrument comparisons. 2. Review of 2023 instrument comparison records revealed comparisons were being performed between the I-Stat and GEM 4000 instruments. No evaluation of the acceptability of the instrument comparison data could be located. 3. An interview with the technical consultant, 4/30/24 at 1:40 PM, confirmed no P&P could be located that defined the acceptability criteria for the evaluation of the I-Stat and GEM 4000 instrument comparisons.