Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233778	05/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pocahontas Memorial Hospital	150 Duncan Road, Buckeye, 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 conducted at Pocahontas Memorial Hospital on May 21 and 22, 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 cited are explained below.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to verify the accuracy of c-reactive protein (CRP) and direct antiglobin testing (DAT) not included in subpart I twice annually in 2023. Findings: 1. Review of 2022, 2023, and 2024 proficiency testing (PT) records revealed no commercial PT documented for CRP and DAT testing in 2023. 2. No documentation of the twice annual verification of CRP and DAT testing could be located for 2023. 3. An interview with the general supervisor, 5/21/24 at 12:15 PM, confirmed the lack of alternate verification of CRP and DAT testing twice annually in 2023 and that the two tests were not enrolled in commercial PT for 2023.
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 record review, observation, lack of documentation, and interview the laboratory failed to determine the mean normal patient prothrombin time (MNPT) for one of two new lots (lot 564643) of Innovin prothrombin time (PT) reagent and verify the accuracy of the INR calculation before putting the lot into use for patient testing. Findings: 1. Review of Sysmex CA-660 coagulation analyzer records for the verification of new Dade Innovin reagent lot 564643 (expiry 1/12/26) revealed no documentation of the manual verification of the INR calculation or the determined MNPT. 2. Observation of the coagulation analyzer set up menu, 5/22/24 at 9:45 AM, identified the current ISI in use for lot 564643 to be accurate per Dade Innovin lot specific product insert. 3. An interview with the technical consultant (TC), 5/22/24 at 9:55 AM, confirmed the lack of documentation for the verification of required performance specifications for lot 564643 of Dade Innovin.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, observation, and interview the laboratory failed to ensure that the Vitros 7600 chemistry analyzer or the HMS Medhost laboratory information system (LIS), had set detection limits to identify patient results falling outside the verified analytical measuring ranges (AMRs) for 60 of 60 chemistry analytes. Findings: 1. Review of the Vitros 7600 chemistry analyzer validation records (analyzer put into use 9/25/23) revealed established upper and lower AMRs for 60 of 60 analytes tested. 2. During an observation in the laboratory, 5/22/24 at 4:00 PM, the state surveyor and general supervisor (GS) chose 4 chemistry analytes to review and identified no programmed AMRs in the VItros 7600 analyzer or the LIS for 4 of 4 analytes (Lactate, AST, ALT, CK). 3. During an interview on 5/22/24 at 4:03 PM, the GS confirmed the findings, stating the instrument installer/service representative did not program the AMRs into the Vitros 7600 and the facility information technology (IT) staff did not program the AMRs into the LIS before the Vitros 7600 was put into use on 9/25/23. 4. An interview with the IT staff of the hospital, 5/22/24 at 4:15 PM, confirmed the IT staff had not programmed the upper and lower AMRs in the LIS system for 60 of 60 analytes.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for

	example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to verify the (ii) manufacturer stated reference range, mean, and standard deviation for lot 02222 (expiry 9/10/25) external quality control (QC) used for the Innovance DDimer assay before putting into use for patient testing on the CA-660 coagulation analyzer. Findings: 1. Review of 2023 and 2024 external QC records for DDimer testing identified lot 02222 (expiry 9/10/25) contained level 1 575511 and level 2 575611 as the current lot of external QC in use. 2. No documentation of the verification of the reference range, mean, and standard deviation values stated by the manufacturer for DDimer testing on the CA-660 could be located for lot 02222 (level 1 575511 and level 2 575611). 3. An interview with the general supervisor, 5/22/24 at 10:00 AM, confirmed the lack of verification for the lot of DDimer QC currently in use for patient testing.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. 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 director (LD) failed to ensure the complete testing procedure and investigation were performed for two of two transfusion reactions identified by the facility between January 2023 thru date of survey (DOS). Findings: 1. Review of Immunohematology P&P identified facility policies stating the criteria for identification of transfusion reactions by nursing staff and to immediately stop the transfusion and notify the laboratory. Laboratory Immunohematology P&P state the testing to be performed for a suspected transfusion reaction and the responsibility of LD to review the transfusion reaction workup. 2. Review of laboratory transfusion records (January 2023 thru DOS) identified two transfusion reactions (Patient A on 9 /24/23 and Patient B on 10/20/23). 3. Review of the 9/24/23 transfusion reaction records for patient A revealed documentation for transfusions of packed red blood cells (PRBCs) and platelets as follows: PRBC, unit# W202323253983, transfusion

	complete on 9/24 at 1710 PRBC, unit# W203523735903, transfusion complete on 9 /24 at 1930 Platelets, unit# W203523854913, transfusion complete on 9/25 at 0013 The laboratory was notified on 9/25 at 0130 that a possible transfusion reaction had occurred and a transfusion reaction workup was initiated. The laboratory collected post transfusion specimens on 9/25 at 0200. The empty bags from the two transfused PRBCs were returned to the laboratory for testing. No documentation that the platelet unit bag was returned to the laboratory for testing in accordance with the P&P could be located. 4. Review of the 10/20/23 transfusion reaction records for patient B revealed documentation for transfusions of PRBCs as follows: PRBC, unit# W202723570636, transfusion complete 10/20 at 1435 PRBC, unit # W203523744666, transfusion complete 10/20 at 1700 The laboratory was notified on 10/20 at 1800 that a possible transfusion reaction had occurred and a transfusion reaction workup was initiated. The laboratory collected post transfusion specimens on 10/20 at 1815. No documentation that the laboratory director had reviewed the transfusion reaction workup or confirmed whether a transfusion reaction occurred could be located. 5. An interview with the general supervisor, 5/22/24 at 10:45 AM, confirmed the lack of documentation in the performance, review, and assessment of two of two possible transfusion reactions.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on observation, policies and procedures (P&P), review of patient records, and interview the laboratory failed to establish an adequate system to ensure that (a)(1) the absolute number and percentage of white blood cells (WBCs) calculated when performing a manual differential are accurately transcribed and resulted into the patient final CBC test report. Findings: 1. On 5/22/24 at 1:15 PM, the state surveyor observed testing personnel (TP1) perform a manual differential on patient A. TP1 entered the WBC values from the manual differential into a spreadsheet for calculating the absolute number and percentages of WBCs. TP1 stated that the LIS does not calculate absolute values or percentages of WBCs when a manual differential is performed and that TP must use the spreadsheet to calculate these values and manually enter the results in the HMS Medhost LIS. 2. No P&P for calculating the absolute number and percentage of WBCs and entering the results of a manual differential cell count into the EMR could be located. 3.. Review of 5 patient manual differential CBC results (November 2023 thru date of survey) identified 5 of the 5 records listed percentages and absolute numbers of each type of WBC that did not correlate to the manual differential cell count. 4. An interview with the general supervisor, 5/22/24 at 1:30 PM, confirmed the inaccurate WBC percentages and absolute numbers for the 5 patient CBC manual differential results in the electronic health record and the lack of a P&P to establish the process of data entry.

D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory director (LD) failed to ensure that 1 of 7 laboratory testing personnel (TP) were assessed for annual competency in Immunohematology testing in 2023. Findings: 1. Review of 2023 CA for TP revealed no documentation of a completed Immunohematology competency assessment for TP4 in 2023. 2. An interview with the LD, 5/21/24 at 1:00 PM, confirmed the lack of a documented CA for TP4 in 2023 for Immunohematology.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory director (LD) failed to evaluate and review the proficiency testing (PT) performance of the laboratory for 3 of 3 events in 2023 for Immunohematology testing from the American Proficiency Institute (API). Findings: 1. Review of Immunohematology 2023 API PT records revealed no LD signature for the evaluation and review of the laboratory performance for 3 of 3 events. 2. An interview with the general supervisor, 5/21/24 at 11:00 AM, confirmed the lack of LD review and signature for the 3 PT Immunohematology events in 2023.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of policies and procedures (P&P), individualized quality control plans (IQCP), lack of documentation, and interview the laboratory director (LD) failed to annually evaluate the effectiveness of 4 of 4 IQCPs (SureVue Mono,

	MedTox UDS, SureVue serum hCG, Microscan Autoscan4) testing for 2023 and one of 4 IQCPs (MedTox UDS) for 2022. Findings: 1. Review of quality assessment P&P identified that IQCPs are to be reviewed for effectiveness by the LD annually. 2. Review of IQCP records revealed the following LD review dates: SureVue Mono 5/25 /2022, MedTox UDS 7/9/21, SureVue serum hCG 4/4/2022, and Microscan 2/16 /2022. 3. No documentation of the LD review for 2022 could be located for the MedTox UDS IQCP. 4. No documentation of the LD review for 2023 could be located for 4 of 4 IQCPs. 5. An interview with the general supervisor, 5/22/24 at 9:00 AM, confirmed the lack of LD review for the IQCPs.