Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233778	03/18/2020
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	An announced, on-site, recertification survey was conducted at Pocahontas Memorial Hospital on March 17, 2020, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D3015	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103 A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities. This STANDARD is not met as evidenced by: Based on a review of the blood bank patient logs, gel and tube method quality control (QC) logs, and an interview with the general supervisor (GS), the laboratory failed to document QC for immunohematology testing performed. Findings: 1. Review of the immunohematology patient testing log for January and February 2020, identified a total of 15 days of patient testing or retyping of received units (1/2/20, 1/9/20, 1/12 /20, 1/17/20, 1/23/20, 1/24/20, 1/26/20, 1/29/20, 1/30/20, 2/4/20, 2/6/20, 2/8/20, 2/13 /20, 2/17/20, 2/28/20). 2. Comparison of patient testing to QC records, for both gel and tube testing, in immunohematology identified 7 of the 15 days patient testing or retyping of units was performed that no QC was documented (1/2/20, 1/12/20, 1/17 /20, 1/23/20, 1/29/20, 2/6/20, 2/28/20). 3. During an interview with the GS, on 3/17 /2020 at approximately 2:00 PM, the GS stated that no documentation of QC for the 7 days could be located.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the

	laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of laboratory written policies and procedures (P&P) and an interview with the technical supervisor (TS), the laboratory failed to establish a system that ensures all testing personnel (TP) are aware of and follow the written P&P for laboratory processes. Findings: 1. A review of written P&Ps identified an effective date of 4/24/2018, signed into use by the laboratory director (LD). The written P&P manual had a LD review date of 8/31/2019. 2. A review of written P&P manual identified no documentation of TP having read the current P&Ps for the laboratory that were put into use 4/24/2018. 3. During an interview with the TS, on 3/18/2020 at approximately 10:30 AM, the TS stated that there was no documentation of TP having read the written P&P and no other system to ensure TP are aware of, and following, the laboratory written P&P.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, a review of maintenance logs, a review of manufacturer instructions, and an interview with the technical supervisor (TS), the laboratory failed to monitor and document (1) water quality. Findings: 1. A tour of the laboratory identified the Millipore H2O water system that is used as a source for microbiology and coagulation testing. 2. A review of 2019 and 2020 maintenance logs for the Millipore H2O system identified a column labeled "Bacteria Count" that had not been documented as performed for 14 of the 14 months reviewed. 3. A review of the Millipore H2O manufacturer instructions identified a recommended "periodic testing for bacteria count" of the water quality. 4. During an interview with the TS, on 3/18/2020 at approximately 8:00 AM, the TS stated that no bacteria count was currently being performed or documented on the maintenance logs and that a written policy and procedure for determining the criteria for performing the bacteria count would be created for the water system.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on a review of laboratory maintenance logs for the Sysmex hematology analyzer, the manufacturue instructions, and an interview with the technical supervisor (TS), the laboratory failed to document the daily background check for the analyzer. Findings: 1. A review of the January 2020 and February 2020 maintenance logs for the Sysmex hematology analyzer revealed no documentation for the daily background check performed on the Sysmex in 2 of 2 monthly maintenance logs. 2. A review of the manufacturer instructions for the Sysmex hematology analyzer states a passing background check is to be performed daily before running quality control and patient testing. 3. During an interview with TS, on 3/18/2020 at approximately 8:00 AM, the TS stated that there was no place to document the Sysmex background check on the current maintenance log and corrected the form on site.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a tour of the laboratory and an interview with the technical supervisor (TS), the laboratory failed to calibrate the MLA pipettes used in Immunohematology as required by the manufacturer. Findings: 1. A tour of the Immunohematology laboratory identified 7 MLA pipettes and 1 Fisherbrand Elite Adjustable Volume Pipette. 3 of the 8 pipettes had documentation of calibration performed on 4/23/2018. There was no documentation on the other 5. a. 25 ul MLA (2) b. 10 ul MLA c. 100 ul MLA calibration done 4/23/18 due 10/2018 d. 400 ul MLA calibration done 4/23/18 due 10/2018 e. 300 ul MLA f. 50 ul MLA calibration done 4/23/18 due 10/2018 g. Fisherbrand Elite 0.5-5 ml 2. The manufacturer instructions state calibrations should be performed every 6-12 months depending on frequency of use. 3. During an interview with the TS, on 3/18/2020 at approximately 9:30 AM, the TS stated that no calibration of the laboratory pipettes had occurred in 2019 and that the pipettes would be calibrated and a system established to ensure the calibration of the pipettes occurs on the required basis.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration

	for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of laboratory quality control (QC) records and an interview with the technical supervisor (TS), the laboratory failed to document the lot number and shipment of antimicrobial agents before use. Findings: 1. A review of microbiology QC records, from January 2019 thru February 2020, identified no documentation of specific lot numbers and shipments for Catalase, Coagulase, Oxidase, Bacitracin, Optochin agents in 14 of the 14 QC documentation records. 2. During an interview with the TS, on 3/17/2020 at approximately 1:30 pm, the TS stated there was no documentation of the lot numbers and shipments for QC records and that a new form will be created and put into use with documentation of the lot numbers and shipments. This was corrected on site.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 a review of written policies and procedures (P&P), a review of temperature charts and maintenance logs for Immunohematology, and an interview with the general supervisor (GS), the laboratory failed to follow established P&P regarding blood bank unit inspection while in storage. Findings: 1. A review of written P&P identified a Blood Bank Lab policy effective 4/24/2018, that states "Unit Inspection Each day all units of blood in the blood bank will be examined for the following: Hemolysis, Turbidity, Broken bags/leaks, Expiration dates". 2. A review of 2019 and 2020 temperature charts and maintenance logs for Immunohematology identified no documentation of this daily unit check. 3. During an interview with the GS, on 3/18 /2020 at approximately 10:00 AM, the GS stated that there was no documentation of the daily checks of units in blood bank and a form will be created to document the criteria and completion of daily checks on blood bank units stored in the laboratory.