Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233778	05/25/2022
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, routine recertification survey was conducted at Pocahontas Memorial Hospital on May 24 and May 25 2022, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to receive a satisfactory score of at least 80% in Bacteriology for 1 of 1 American Association of Bioanalyst (AAB) proficiency testing (PT) events in 2022. Findings: 1. Review of 2022 PT records revealed an unsatisfactory score of 64% for CMS analyte #0005 Bacteriology for the following incorrect results: Specimen #2 904-Streptococcus salivarius 0% Specimen #4 819-Micrococcus sp.; NOS 0% 2. An exit interview with the laboratory director and administration team, 5/25/22 at approximately 5:00 PM, confirmed the findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to document the competencies of 4 of 4 laboratory testing personnel (TP) in 2021 for each testing methodology used in the laboratory. Findings: 1. Review of TP records revealed 4 of 4 2021 competencies had only Immunohematology methodologies completed. 2. An interview with the laboratory director, 5/25/22 at approximately 1: 00 PM, confirmed the findings.
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) and interview the laboratory failed to establish (b)(3) the criteria for interpretation and positive identification of organisms from the Microscan analyzer for 2 of 2 panels (NUC84 and PC34). Findings: 1. Review of P&P identified the manufacturer instructions being used as the standard operating procedure for the Microscan. 2. No instructions for evaluation and acceptance of identification results from the NUC84 and PC34 Microscan panels could be located. 3. An exit interview with the laboratory director and administration team, 5/25/22 at approximately 5:00 PM, confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of policies and procedures, quality control (QC) records, lack of documentation, and interview the laboratory failed to perform and document external quality control (QC) at the required interval for the following: Findings: Microscan PC34 Panel (29 weeks reviewed) 1. Review of P&P identified an Individualized Quality Control Plan (IQCP) for the Microscan that states 6 organisms (29212, 29213, 51299, 35218, 43300, and BAA-977) are to be ran weekly for the PC34 Panel. 2. Review of Microscan PC34 Panel QC records (November 2021 thru date of survey) revealed 18 of 29 weeks without acceptable QC for all 6 organisms: 12/1/21, 12/22 /21, 12/29/21, 1/5/22, 1/12/22, 1/26/22, 2/9/22, 2/16/22, 2/23/22, 3/2/22, 3/9/22, 3/16 /22, 3/23/22, 3/30/22, 4/6/22, 4/13/22, 4/20/22, 5/4/22 Serum Rapid Mono (reviewed 10/12/21 thru date of survey) 1. Review of P&P identified no IQCP for serum Mono testing. 2.Review of the Rapid Mono Log (10/12/21 thru date of survey) revealed 5 of 8 patient testing days for mono had no documented external QC (10/12/21, 11/27/21, 12/16/21, 1/2/22, 2/1/22) AimTab Ketone Tablets 1. Review of P&P identified a policy stating external QC is to be performed each day of patient testing. 2. Review of AimTab Ketone Tablet Log (2/14/22 thru date of survey) revealed 12 of 14 patient testing days for ketones had no documented external QC (2/14/22,3/14/22, 3/30/22,4/2 /22, 4/5/22, 4/12/22, 4/16/22, 4/22/22, 4/23/22, 5/1/22, 5/15/22, 5/16/22). MedTox Drug Screen 1. Review of P&P identified no IQCP for the MedTox Drug Screen. 2. Review of the MedTox Drug Screen Log (12/20/21 thru date of survey) revealed 46 of 68 patient testing days had no documented external QC (12/23/21, 12/26/21, 12/29/21, 1/5/22, 1/11/22, 1/13/22, 1/20/22, 1/21/22, 1/23/22, 1/25/22, 1/26/22, 2/1/22, 2/2/22, 2 /4/22, 2/6/22, 2/10/22, 2/13/22, 2/16/22, 2/20/22, 2/23/22, 3/1/22, 3/2/22, 3/8/22, 3/11 /22, 3/12/22, 3/13/22, 3/15/22, 3/22/22, 3/30/22, 4/9/22, 4/12/22, 4/21/22, 4/22/22, 4 /24/22, 4/26/22, 4/27/22, 4/28/22, 5/1/22, 5/3/22, 5/4/22, 5/5/22, 5/11/22, 5/12/22, 5/15 /22, 5/20/22, 5/22/22). An exit interview with the laboratory director and administration team, 5/25/22 at approximately 5:00 PM, confirmed the findings.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of policies and procedures (P&P), review of quality control (QC) records, lack of documentation, and interview the laboratory failed to (e)(4)(ii) check each lot of microbiology media for the ability to support or inhibit growth, as applicable, from 7/14/21 thru date of survey. Findings: 1. Review of P&P identified no Individualized Quality Control Plan (IQCP) for the QC of eligible microbiology media (SBA, TSA, and blood culture bottles). 2. Review of Media QC Log Sheet (7 /14/21 thru date of survey) identified no documentation of supporting growth or inhibition checks for the following: BIPLATE 4 of 4 lots, CNA 2 of 2 lots, CHOC 7 of 9 lots, TSA 10 of 10 lots, MAC 10 of 10 lots, BLD 6 of 6 lots 3. No documentation

	of QC for blood culture bottles could be located. 4. An exit interview with the laboratory director and administration team, 5/25/22 at approximately 5:00 PM, confirmed the findings.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to maintain (a)(4) the record and dates of all manual testing performed for each specimen, the testing personnel who performed each test, the specimen source site, and the specific media inoculated for 80 of 112 specimen culture worksheets reviewed in Microbiology. Findings: 1. Review of patient testing records for Microbiology specimen cultures (April 2022 and May 2022) identified 80 of 112 worksheets that lacked complete documentation of each manual test performed, the date each test was performed, the testing personnel who performed the test, the specimen source, and the specific media inoculated. 2. An exit interview with the laboratory director and administration team, 5/25/22 at approximately 5:00 PM, confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of policies and procedures, quality control (QC) records, lack of documentation, and interview the laboratory failed to ensure an ongoing review process to identify and correct the following: 1) Lack of external QC for testing. Refer to D5445 2) Lack of ability to support or inhibit growth QC, as applicable, for microbiology media. Refer to D5477 3) Lack of documentation for each manual test performed, date of test, who performed each test, specimen source site, and specific media inoculated for microbiology culture specimen workups. Refer to D5787. 4) Lack of documentation for ongoing QC review of Chemistry, Hematology, and Microbiology test methods. An interview with the laboratory director and administration team, 5/25/22 at approximately 5:00 PM, confirmed the findings.