Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233527	06/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Wvu Med Princeton Community Hospital Bluefield	500 Cherry St, Bluefield, 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 WVU Med Princeton Community Hospital Bluefield on June 4-5, 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.
D2025	BACTERIOLOGY CFR(s): 493.823(c) 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 submit the Group A Strep (GAS) proficiency testing (PT) results to College of American Pathologists (CAP) before the deadline for one of 3 events in 2023. Findings: 1. Review of CASPER 155D Report revealed an unsatisfactory score of 0% for bacteriology in PT event 2 of 2023. 2. Review of 2023 CAP PT records revealed the bacteriology 0% unsatisfactory score for event 2 2023 was due to the PT results for GAS testing not being submitted to the program within the specified timeframe. 3. An interview with the general supervisor, 6/4/24 at 10:50 AM, confirmed the findings.
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 submit the CK Isoenzyme (CK-MB) proficiency testing (PT) results to College of American Pathologists (CAP) before the deadline for one of 3 events in 2023. Findings: 1. Review of CASPER 155D Report revealed an unsatisfactory score of 0% for analyte #0395 CK Isoenzyme (CK-MB) in PT event 2 of 2023. 2. Review of 2023 CAP PT records revealed the 0% unsatisfactory score for event 2 2023 was due to the PT results for analyte #0395 not being submitted to the program within the specified timeframe. 3. An interview with the general supervisor, 6/4/24 at 10:50 AM, 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 policies and procedures (P&P), personnel record review, and interview the laboratory failed to ensure one of 9 testing personnel (TP) had a documented competency assessment (CA) evaluation for all test methodologies employed by the laboratory for patient testing in 2023. This is a repeat deficiency. Findings: 1. Review of laboratory general P&P revealed a process for assessing TP competency for all test methodologies at prescribed intervals. 2. Review of 2022 and 2023 TP competency assessment records identified the last retained annual CA for TP9 dated 1/7/2022. No documentation of an annual CA for TP9 in 2023 could be located. 3. An interview with the general supervisor, 6/4/24 at 9:15AM, confirmed the lack of CA for TP9 in 2023.
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 record review, lack of documentation, and interview the laboratory failed to evaluate two of two educational challenge events for College of American Pathologists (CAP) hematology proficiency testing (PT) in 2023. Findings: 1. Review of CAP hematology PT records identified two educational challenge events for virtual peripheral blood smear (VPBS-A and VPBS-B) in 2023. 2. Review of the 2023 CAP PT evaluation reports for VPBS-A and VPBS-B revealed laboratory testing personnel (TP) participated in the educational challenge events. No documentation that the results were reviewed or evaluated could be located for the two (VPBS-A and VPBS-B) events. 3. An interview with the general supervisor, 6/4/24 at 10:00 AM, confirmed the lack of documented evaluation of performance and review by the laboratory for VPBS-A and VPBS-B in 2023.
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 semiannually verify the accuracy of troponin and wet prep testing in 2023. Findings: 1. Review of 2022, 2023, and 2024 proficiency testing (PT) records revealed no commercial PT documented for troponin and wet prep testing in 2023. 2. No documentation of the alternative twice annual verification of troponin and wet prep testing could be located for 2023. 3. An interview with the general supervisor, 6/4/24 at 10:50 AM, confirmed the lack of alternate verification of troponin and wet prep testing twice annually in 2023 and that the two tests were not enrolled in commercial PT in 2023.
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 review of written policies and procedures (P&P), quality assurance (QA) records, and interview the laboratory failed to establish a process for the step by step performance that evaluates and defines the correlation of test results between the Hematology automatic differential and manual differential testing methodologies twice a year. Findings: 1. Review of hematology and QA P&P revealed no procedure for completing intra-lab comparison studies of testing personnel (TP) performance of manual differentials. No documentation that comparison studies were performed in 2022 or 2023 could be located. 2. Review of hematology and QA P&P revealed no procedure for completing comparison studies between the Beckman Coulter DxH560 automated differential and a manual differential. No documentation that comparison studies were performed between the two methodologies in 2022 or 2023 could be located. 3. An interview with the general supervisor, 6/5/24 at 9:30 AM, confirmed the lack of P&P and that no intra-lab TP comparison studies or comparison studies between the DxH650 and a manual differential were performed in 2022 and 2023.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on primary source verification, record review, and interview, 8 of 8 respiratory therapy laboratory testing personnel (TP) did not possess a current WV Clinical

	Laboratory Practitioner License and performed moderate complex patient testing (lactate) in 2024 (January thru date of survey). Findings: 1. WV State rule Clinical Laboratory Practitioner Licensure and Certification 64 CSR 57 states that a current license is required for any individual performing moderately complex testing. 2. Review of WV licensure primary source verification for the respiratory therapy TP listed on the current CMS 209, identified 8 of 8 TP had no current WV license in 2024. 3. Review of two patient test results (DOS) released by respiratory therapy testing personnel from the ABL90 analyzer identified blood lactate results released. 4. An interview with respiratory therapy testing personnel (TP1 and TP2), 6/5/24 at 1:00 PM, confirmed that lactate was on the current test menu for the ABL90 in the respiratory therapy department and lactate testing testing was performed and released by respiratory therapy TP.