Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233527	06/28/2022
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	An announced, on site, routine recertification survey was conducted at Princeton Community Hospital Bluefield Laboratory on June 27 and June 28, 2022, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to attain a satisfactory score of at least 80% for analyte #0555 HCG in one of three College of American Pathologists (CAP) proficiency testing (PT) events in 2021. Findings: 1. Review of CAP records identified a score of 60% for analyte #0555 HCG in the 3rd PT event of 2021. 2. An exit interview with the general supervisor and laboratory director, 6/27/22 at approximately 2:30 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 written policies and procedures (P&P), record review, lack of

	documentation, and interview the laboratory failed to: A) Assess 1 of 9 testing personnel (TP1) competency at the required intervals B) Document the assessment of releasing emergency requested blood bank products to the emergency room of 9 of 9 TP Findings: A) 1. Review of P&P identified a process of assessing TP competency after initial training, at the 6 month testing mark, and annually thereafter for all methodologies and methods utilized in the laboratory. 2. Review of the 9 TP competency assessment records revealed an initial training for TP1 signed and dated 2 /26/21. No other competency assessment documents could be located. B) 1. Review of the 9 TP competency assessment records revealed no documented evaluation of the process for the emergency release of blood bank products for all 9 TP. An exit interview with the general supervisor and laboratory director, 6/27/22 at approximately 2:30 PM, confirmed the findings.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of policies and procedures (P&P), record review, lack of documentation, and interview laboratory testing personnel (TP) failed to follow the established process for documentation of a peripheral scan slide review for 4 of 6 patient results as established in the parameters of result reporting for the hematology analyzer. Findings: 1. Review of P&P identified "HEM-1020.6" which states the WBC parameters that a Peripheral Scan can be performed by TP instead of a manual differential: Basophilia, Eosinophilia, Leukopenia, Lymphopenia, Neutropenia, Monocytosis, Leukocytosis, Lymphocytosis, Neutrophilia. A comment is to be documented on the patient results that a Peripheral Scan was performed and the automated results verified. 2. Review of analyzer printouts and EMR results for 6/24 /22 and 6/25/22 identified 6 hematology results that met the criteria for a Peripheral Scan. 4 of the 6 had no comment a Peripheral Scan was performed. 3. An exit interview with the general supervisor and laboratory director, 6/27/22 at approximately 2:30 PM, confirmed the findings.