Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0233677	04/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Welch Community Hospital	454 Mcdowell Street, Welch, 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 Welch Community Hospital, completed on April 16, 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.
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 5 of 9 testing personnel (TP) had a documented competency evaluation for the performance of manual differential testing in 2023. 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 hematology competency assessment records for 2023 revealed documented evaluations of manual differential testing for 4 of 9 TP (TP6, TP7, TP8, TP9) in 2023. No documentation for the evaluation of manual differential testing in 2023 for 5 of 9 TP (TP1, TP2, TP3, TP4, TP5) could be located. 3. An interview with the general supervisor, 4/15/24 at 11:00 AM, confirmed that no documented competency for the performance of manual differentials could be located for 5 of 9 TP in 2023.
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 record review and interview, the laboratory failed to perform external quality control (QC) each day of patient testing for moderate complexity Alere Triage Tox Drug Screen and Alere Triage BNP testing for 12 of 12 months in 2023. Findings: 1. Review of QC records (January thru December 2023) for Alere Triage Tox Drug Screen testing identified external QC documented monthly and with each new lot or shipment of test kits. 2. Review of QC records (January thru December 2023) for Alere Triage BNP testing identified external QC documented monthly and with each new lot or shipment of test kits. 3. No Individualized Quality Control Plan (IQCP) for Alere Triage Tox Drug Screen or Alere Triage BNP testing could be located. 4. An interview with testing personnel (TP1), 4/16/24 at 12:15 PM, confirmed no IQCP could be located and external QC was not being run each day of patient testing for Alere Triage Tox Drug Screen or BNP testing.
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 policies and procedures (P&P), record review, and interview, the laboratory failed to establish a system for performing and evaluating comparison studies for test results between the two Coulter DxH 690T analyzers in hematology and between the two Siemens Dimension EXL 200 analyzers in chemistry. Findings: 1. Review of 2022 and 2023 records revealed comparisons were being performed monthly between the hematology analyzers and between the chemistry analyzers.. 2. No P&P could be located in the hematology, chemistry, or general laboratory procedure manuals that defined the process used to compare test results, criteria for evaluating the data, and the frequency of performance. 3. An interview with the testing personnel and general supervisor, 4/16/24 at 10:30 AM, confirmed that no P&P defining the frequency of the comparison between analyzers and the criteria for evaluation of the test results could be located.