Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0661823	01/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Grafton City Hospital	1 Hospital Plaza, Grafton, 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 Grafton City Hospital on January 9-10, 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.
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 written policies and procedures (P&P), lack of documentation, and interview, the laboratory failed to establish (b)(1) requirements for referral of a

	peripheral smear to a pathologist for specialized review or diagnosis. Findings: 1. Review of P&P for Hematology revealed no process or policy establishing the criteria for determination of when a peripheral smear must be referred to a pathologist for review or diagnosis. 2. Review of P&P for Hematology revealed no process or policy establishing instructions for preparing and submitting a peripheral smear for pathology review. 3. An interview with the technical specialist (TS), 1/10/24 at 10:00 AM, confirmed the lack of a P&P for the referral of a peripheral smear to a pathologist for further evaluation. 4. An exit interview with the laboratory director (LD) and laboratory administration, 1/10/24 at 2:00 PM, confirmed the findings
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review, observation, lack of documentation, and interview the laboratory failed to determine the mean normal patient prothrombin time (MNPT) for one of two new lots (lot 564602) of Innovin prothrombin time (PT) reagent and verify the accuracy of the INR calculation before putting the lot into use for patient testing. Findings: 1. Review of the records for lot 564602 (expiry 7/29/24) of Dade Innovin revealed no documentation of the laboratory determined MNPT and no manual verification of the INR calculation. 2. Observation of the coagulation analyzer (Sysmex CA 600) set up menu, 1/9/24 at 1:30 PM, identified the current ISI in use for lot 564602 to be accurate per Dade Innovin lot specific product insert. 3. An interview with the technical consultant (TC), 1/9/24 at 1:30 PM, confirmed the lack of documentation for the verification of required performance specifications for lot 564602 of Dade Innovin. 4. An exit interview with the laboratory director and laboratory administration, 1/10/24 at 2:00 PM, confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of written policies and procedures (P&P), record review, and interview the laboratory failed to perform external quality control each day of patient testing for Quidel QuickVue serum hCG qualitative testing for 11 of 11 months of 2023. Findings: 1. Review of external QC records (January thru November 2023) for serum hCG testing identified QC documented monthly and with each new lot or shipment of test kits. 2. Review of the hCG testing IQCP stated "For urine testing, controls should be tested with each new lot or shipment of product, with each new operator, monthly as a check on continued storage conditions, or as otherwise

	required.. For serum testing federal, state, and local guidelines should be followed." 3. An interview with the technical consultant (TC), 1/10/24 at 11:00 AM, confirmed the lack of external QC being performed each day of patient testing and that alternate QC frequency for serum hCG had not been established in the IQCP. 4. An exit interview with the laboratory director and laboratory administration, 1/10/24 at 2:00 PM, confirmed the findings.