Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236987	06/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Grant Memorial Hospital	117 Hospital Drive, Petersburg, 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 performed at Grant Memorial Hospital on June 27 and 28, 2023, 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 cited are explained below.
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to perform and document the biannual accuracy evaluation for testing procedures not included in Subpart I for 2022 and 2023. Findings: 1. Review of proficiency testing (PT) records (January 22 thru date of survey) revealed no commercial enrollment for semen analysis and the GI panel and Blood Culture panel testing on the Biofire Torch test system. 2. No documentation of alternate testing to maintain the accuracy of semen analysis and the GI panel and Blood Culture panel testing on the Biofire could be located. 3. An interview with the general supervisor, on 6/27/23 at approximately 9:30 AM, confirmed the lack of enrollment and/or biannual verification of accuracy for semen analysis and the GI panel and Blood Culture panel testing on the Biofire Torch.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

	This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to test proficiency testing (PT) specimens only the same number of times as patient samples are tested for all three specimens in the CM-A 1st testing event 2023. Findings: 1. Review of PT records revealed two analyzer printouts for each PT specimen (CM-01, CM-02, and CM-03) from the 1st event of 2023. Documentation on the printouts by the testing personnel state "these samples were ran 5 minutes apart w/ slight variations in results." 2. An interview with testing personnel 1 (TP1), on 6/27/23 at approximately 10:30 AM, established that patient specimens are only tested one time for a routine urinalysis. 3. An interview with the general supervisor (GS), on 6/27/23 at approximately 10:35 AM, confirmed the PT specimens had been analyzed twice and that the standard practice for the laboratory was to perform one urinalysis per patient specimen. 4. An exit interview with the GS, TP1, and laboratory administration, 6/28 /23 at approximately 3:30, confirmed the findings.
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 return proficiency testing (PT) results within the required timeframe for the 1st Bacteriology testing event of 2023. Findings: 1. Review of American Proficiency Institute (API) PT evaluations revealed a score of 0% failure to participate for the 1st event of 2023 in Bacteriology. 2. Review of the laboratory self evaluation identified a failure to submit the PT results for the 1st event within the timeframe required. 3. An interview with the general supervisor, 6/27/23 at approximately 9:00 AM, confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of written policies and procedures (P&P), quality control (QC) records, calibration records, patient test records, observation, and interview the laboratory failed to ensure the overall quality of the analytic systems and correct identified problems. Findings: 1. P&P lacked required elements. See D5403 2. Results released outside established performance specifications. See D5411. 3. No process to track and ensure quality of reagents and control materials. See D5417. 4. No calibration verification of the chemistry analytes on the Alinity analyzer. See D5439.

	5. No external QC performed for manual cell counts and semen analysis. See D5543. 6. No documented alarm checks for the storage of blood and blood products. See D5555.
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) and interview the laboratory failed to: (a) specify the calibration verification procedure for the Alinity chemistry analyzer and (b) include the process and reagents required for external quality control (QC) for manual cell counts, semen analysis,blood type and Rh, antibody screens, and crossmatches. Findings: a. Review of P&P revealed no process for performing the calibration verification procedures for the 40 analytes tested on the Alinity chemistry analyzer. b. Review of P&P for manual cell counts, semen analysis, blood type and Rh, antibody screens, and crossmatches revealed no written process specifying the reagents, frequency, and the procedure to perform and document external QC for the testing. An interview with the general supervisor, on 6/27/23 at approximately 3:00 PM, confirmed the lack of required elements in the P&P. An exit interview with the general supervisor and administration, 6/28/23 at approximately 3: 00 PM, confirmed the fidings.
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, and interview the laboratory failed to perform Acetaminophen testing in a manner consistent with the established performance

	specifications on the Alinity chemistry analyzer for two of 112 patient results. Findings: 1. Review of the 2021 validation data and assay manufacturer instructions for the Alinity chemistry analyzer identified the established reference range (RR) of Acetaminophen to be 17-30 ug/mL. 2. Observation of the Alinity analyzer programmed reference range for Acetaminophen revealed a lower limit of 10 ug/mL. 3. Review of statistic report for patient Acetaminophen results (112 patient results January 2022 thru date of survey) identified two numerical results released outside the established RR lower limit of 17 ug/mL- 12.96 ug/mL and 16.16 ug/mL. 4. An interview with the general supervisor, 6/28/23 at approximately 10:00 AM, confirmed the two patient results had numerical values outside the established RR for Acetaminophen testing.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to establish a process to track reagents and control materials for manual cell counts, semen analysis, and fibrin degradation products (FDP) testing to ensure quality. Findings: 1. Review of quality control (QC) records and manual testing logs (January 22 thru date of survey) revealed no documentation of the lot numbers and expiration dates of reagents and control materials utilized in manual cell counts, semen analysis, and FDP testing. 2. An interview with the general supervisor, 6/28/23 at approximately 8:00 AM, confirmed the lack of system to ensure quality of reagents and control materials for manual testing. 3. An exit interview with the general supervisor and administration, 6 /28/23 at approximately 3:00 PM, confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent

	calibration verification. This STANDARD is not met as evidenced by: Based on record review, written policies and procedures (P&P), and interview the laboratory failed to perform and document the calibration verification of the 40 analytes on the Alinity chemistry analyzer in 2022. Findings: 1. Review of 2022 calibration records revealed no documented calibration verification for the 40 analytes on the Alinity chemistry analyzer. 2. No P&P for the calibration verification process for the Alinity analytes could be located. See D5403. 3. An interview with the general supervisor, on 6/28/23 at approximately 1:00 PM, confirmed the findings.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review, written policies and procedures (P&P) and interview, the laboratory failed to perform and document the testing of external quality control (QC) for 4 of 4 manual cell counts and 6 of 6 semen analysis performed from January 2023 thru date of survey. Findings: 1. Review of laboratory statistic report for January 2023 thru date of survey identified 4 manual cell counts performed for patient testing. 2. No documentation of an external QC being performed could be located for the 4 manual cell counts. 3. Review of statistic report for January 2023 thru date of survey identified 6 semen analysis performed for patient testing. 4. No documentation of an external QC being performed could be located for the 6 semen analysis. 5. An interview with the general supervisor, on 6/27/23 at approximately 2:30 PM, confirmed the lack of external QC being performed for manual cell counts and semen analysis.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to document the inspection of the alarm system used to monitor the storage of blood and blood products in 2022 and 2023. Findings: 1. Review of quality assurance and quality control records (January 2022 thru date of survey) revealed a lack of documentation for the routine alarm checks performed on the refrigerator and freezer used to store blood and blood products in the laboratory. 2. An interview with the general supervisor, 6/28/23 at

	approximately 2:30 PM, confirmed no record or documentation could be located for the alarm checks in 2022 and 2023.
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 (P&P), record review, and interview the laboratory failed to establish an adequate system is in place to ensure continous improvement and quality of services in the analytic system. Specifically: a) P&P lacked required elements. See D5403 b) Results released outside established performance specifications. See D5411. c) No process to track and ensure quality of reagents and control materials. See D5417. d) No calibration verification of the chemistry analytes on the Alinity analyzer. See D5439. e) No external QC performed for manual cell counts and semen analysis. See D5543. f) No documented alarm checks for the storage of blood and blood products. See D5555. An exit interview with the general supervisor and administration, on 6/28/23 at approximately 3:00 PM, confirmed the findings.