Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236987	07/16/2019
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
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 Proficiency Testing (PT) record review and interview with Testing Personnel 1 (TP1), the laboratory failed to verify accuracy 2 times a year for tests that are not included in Subpart I. Findings: 1. A review of PT records from 2018 and 2019 established that the laboratory had not performed commercial PT, or utilized other methods, to verify accuracy on Direct Antiglobulin Testing (DAT) in immunohematology. 2. An interview with TP1, on 07/15/19 at approximately 1135 AM, confirmed that no verification of DAT testing to establish and maintain accuracy had occurred.
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 a review of Quality Control (QC) records, calibration records, and an interview with Testing Personnel 1 (TP1) the laboratory failed to perform and document calibration verification of Chemistry analytes twice a year. Findings: 1. A review of 2018 and 2019 QC and calibration records established that no documentation of the calibration verification of Chemistry analytes occurred twice a year. 2. A review of 2018 and 2019 QC records demonstrated that Chemistry QC was being performed twice a day with 2 levels of QC material, BioRad MultiQual Levels 1 and 2 for general chemistry analytes. 2. An interview with TP1, 7/16/19 at approximately 800 AM, confirmed that no performance of calibration verification occurred twice a year in chemistry.
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 upon a review of Quality Control (QC) records, written laboratory policies and procedures, and an interview with Testing Personnel 2 (TP2) the laboratory failed to follow the written QC procedures for API 20A, HNID, and GP ID test systems. Findings: 1. The written QC procedure for the API 20A states that "both Clostridium perfringens ATCC 13124 and Clostridium histolyticum ATCC 19401 are to be ran with the arrival of each new lot. One of these organisms is to be ran weekly if the lot has been previously QC'd." a. QC (both organisms) was ran for each new lot 6/24/19, 3/14/19, 7/6/18, 4/21/18, and 11/25/17. b. No documentation of weekly QC being performed could be located. c. An interview with TP2, 7/16/19 at approximately 918 AM, confirmed that QC was not being performed on a weekly basis. 2. The written QC procedure for the HNID system states "all 5 organisms are to be ran with the arrival of each new lot. One of these organisms is to be ran weekly if the lot has been previously QC'd." a. QC (all 5 organisms) was ran for each new lot 4/1/19, 4/12/18, and 11/22/17. b. No documentation of weekly QC being performed could be located. c. An interview with TP2, 7/16/19 at approximately 923 AM, confirmed that QC was not being performed on a weekly basis. 3. The written procedure for the GP ID test

	system states that all 5 organisms are to be ran with each new lot opened and one organism is to be ran as QC weekly for the life of the lot. a. QC (all 5 organisms) were ran 7/3/19, 3/20/19, and 1/30/19. b. No documentation of weekly QC being performed could be located. c. An interview with TP2, 7/16/19 at approximately 943 AM, confirmed that QC was not being performed on a weekly basis.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with Testing Personnel 1 (TP1), the laboratory failed to ensure that calculated results from Chemistry Tests were accurate and reliable. Findings: 1. A review of laboratory documents established that no manual verification of calculated Chemistry test results could be located. 2. An interview with TP1, 7/16/19 at approximately 810 AM, confirmed that no electronic Laboratory Information System calculations are verified for accuracy and reliability.