Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236987	07/30/2025
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	A routine recertification survey was completed at Grant Memorial Hospital on July 30, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of three analyzer verification records, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to (b)(1)(ii) verify the appropriateness of reference intervals (RI) for the laboratory population during the verification of the Sysmex XN-450, Sysmex XN-550, and Alinity i analyzers in 2024 and 2025. Findings: 1. Review of the hematology Sysmex XN-450 analyzer verification records (go live 9/24/2024) revealed no documentation that published or laboratory established RI for the complete blood count with differential (CBC/DIFF) parameters had been evaluated for suitability to the laboratory population. 2. Review of the hematology Sysmex XN-550 analyzer verification records (go live 9/24/2024) revealed no documentation that published or laboratory established RI for the CBC /DIFF parameters had been evaluated for suitability to the laboratory population. 3. Review of the chemistry Abbott Alinity i analyzer verification records (go live 7/22 /2025) revealed no documentation that published or laboratory established RI for 12

	of 12 analytes had been evaluated for suitability to the laboratory population. 4. During an interview, 7/29/25 at 11:15 AM, the TS stated no documentation could be located for the verification of the RI for the two Sysmex analyzers put into use in September 2024. 5. During an interview, 7/30/25 at 10:19 AM, the TS stated no documentation could be located for the verification of the RI for analytes on the Alinity i analyzer put into use in July 2025.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, microbiology policies and procedures, quality assurance (QA) records, lack of documentation, and an interview with the technical supervisor (TS), the laboratory failed to (b) establish the number, type, and frequency of external quality control testing for the moderate complexity BioFire Respiratory Panel (RP 2.1) and the high complexity MicroScan Gram Positive Panel (PM38). Findings: A. 1. The manufacturer instructions for the BioFire RP 2.1 directs users to perform external quality controls in accordance with the laboratory's protocol and any accreditation requirements. 2. The "Biofire Panels Quality Assessment and Quality Control Plan" microbiology policy directs personnel to perform two levels of external QC (positive and negative) when a new test kit is opened, when new personnel are trained, laboratory temperatures fall outside of established ranges, or if a patient results are questionable. 3. Review of QA records identified current, approved Individual Quality Control Plan (IQCP) for the BioFire blood culture identification and gastrointestinal panels. No IQCP or policy validating external QC performance that is less stringent than the regulatory requirements for the RP 2.1 panel could be located. B. 4. Review of QA records identified documentation that the MicroScan PM38 panel was validated and put into use 2/19/2025. 5. Review of microbiology policies and procedures identified the MicroScan Positive panel PM38 manufacturer instructions as the procedure for performing patient testing, stating that external quality control (QC) should be performed per the laboratory's established policy. 6. No IQCP or policy establishing the laboratory's performance of external QC (number, type, and frequency requirements) for the PM38 could be located. 7. During an interview, 7/29/25 at 3:30 PM, the TS agreed that no IQCP, plan, or policy establishing the number, type, and frequency of external QC for the BioFire RP2.1 and MicroScan PM38 panels could be located.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for

	its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of microbiology media quality control (QC) records, lack of documentation, and an interview with the technical supervisor (TS), the laboratory failed to document the performance of sterility checks and the ability to support growth for one of one batch of Cary Blair media in 2025. Findings: 1. During a tour of the laboratory, 7/29/25 at approximately 4:00 PM, the surveyor identified lot number 263564 (expiry 10/19/26) of Cary Blair transport media in use for testing stool specimens with the Biofire FilmArray Torch Gastrointestinal (GI) panel. 2. Review of microbiology media QC records (January 2024 thru date of survey) revealed no documentation of sterility checks or the ability of the Cary Blair media (lot #263564) to support growth. 3. During an interview with the TS, 7/29/25 at approximately 4:00 PM, the TS agreed no QC for the lot of Cary Blair media currently in use could be located.
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. This STANDARD is not met as evidenced by: Based on review of quality control (QC) log sheets for manual fluid cell counts, lack of documentation, and interview with the technical supervisor (TS), the laboratory failed to (a)(2) perform and document the duplicate testing of external quality control (QC) for two of 9 manual fluid cell counts performed from January 2025 thru date of survey (DOS). This is a repeat deficiency. Findings: 1. Review of "Log Sheets for Cell Counts" (January 2025 thru DOS) identified 9 manual fluid cell counts performed in the time period reviewed. 2. Review of QC documentation for the manual fluid cell counts revealed no documentation of the QC performed in duplicate for two of the nine fluid specimens (E929602 and E2706211). 3. During an interview with the TS, 7/30/25 at 7:30 AM, the TS agreed the QC had not been documented as performed in duplicate for two of the nine fluid specimens.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of policies and procedures, Sysmex hematology analyzer verification records, EPIC laboratory information system (LIS) patient reports, and interview with the technical supervisor (TS), the laboratory failed to ensure accurate reference

	intervals (RI) are provided to clients for all 27 parameters in a complete blood count with differential (CBC/DIFF). Findings: 1. Review of the hematology "Sysmex 550" and "Sysmex 450" procedures identified stated reference intervals in "X. Reporting Results" for 27 of 27 parameters tested and stated reference intervals in "XVI. Appendix A Reference Ranges" for 23 of 27 parameters tested with a CBC/DIFF. 2. Review of the Sysmex XN-450 and Sysmex XN-550 analyzer verification records (go live 9/24/2024) revealed no documentation of the verification of the appropriateness, for the laboratory population, of the 27 reference intervals tested with a CBC/DIFF. Refer to D5421. 3. Review of four EPIC patient CBC/DIFF reports (E4217336, E516887, E2161184, E4208859) from the Sysmex XN-550 identified 4 parameters lacking a stated reference interval: Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil % 4. Review of EPIC patient CBC/DIFF report (E2161184, 11 yo male) identified a reference interval of 10.7-20.0 g/dL for Hemoglobin (HGB). Review of the "Sysmex 550" procedure stated reference intervals (RI) identified a RI of 10.7-13.4 g/dL for HGB on an 11 yo male. 5. During an interview 7/29/25 at 12:10 PM, the TS agreed the 4 CBC/DIFF parameters lacked a stated reference interval on the final report and stated the EPIC reference interval for HGB on an 11 yo male was discrepant from the procedure.