Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0235176	06/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
St Mary's Medical Center Himg Campus	5170 U S Route 60 East, Huntington, 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 St Mary's Medical Center HIMG Campus on June 13, 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.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on written policies and procedures (P&P). record review, lack of documentation, and interview the laboratory failed to retain the documentation of the Quality Assurance (QA) checklists developed to monitor the QA program of the laboratory for 2022 thru the date of survey. Findings: 1. Review of P&P identified "Quality Assurance Program" that states a QA checklist was developed to monitor the program and the completion of the checklists will be performed by the general supervisor and laboratory director. 2. No completed QA Checklists from January 2022 thru the date of survey could be located. 3. An interview with the general supervisor, 6 /13/23 at approximately 11:41 AM, confirmed the lack of completed QA checklists. 4. An exit interview with the administration and general supervisor, 6/13/23 at approximately 3:00 PM, confirmed the findings.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of

	collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on written policies and procedures (P&P), a tour of the laboratory, and interview the laboratory failed to ensure that positive patient identification is maintained throughout the testing process in Hematology for 7 of 11 manual differential slides reviewed. Findings: 1. Review of P&P identified "Preparation of a Blood Smear" that states each slide prepared for a manual differential or slide review must be labeled with patient's name, date of birth, and date the slide is made. 2. During a laboratory tour at approximately 1:15 PM, 11 recent blood smear slides were examined: 5 slides had only the patient's name and date of birth, 2 slides had only the patient name. 3. An interview with the general supervisor, on 6/13/23 at approximately 1:20 PM, confirmed the lack of proper identification on the blood smear slides. 4. An exit interview with the administration and general supervisor, 6/13 /23 at approximately 3:00 PM, confirmed the findings.
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, lack of documentation, and interview the laboratory failed to (d)(2) perform external quality control (QC) for the Cepheid GeneXpert CT/NG testing system as established by the current Individualized Quality Control Plan (IQCP) for 5 of 5 months in 2023. Findings: 1. Review of P&P identified an IQCP for performance of external quality control on the Cepheid GeneXpert stating the established frequency as once a month and each new lot or shipment. 2. Review of QC records for January 2023 thru May 2023 revealed no documentation of the external QC being performed in the 5 months of GeneXpert CT/NG testing. 3. An interview with the general supervisor, on 6/13/23 at approximately 2:00 PM, confirmed the lack of external QC for the CT/NG testing system. 4. An exit interview with the administration and the general supervisor, 6/13/23 at approximately 3:00 PM, confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)

	(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on written policies and procedures (P&P), record review, and interview the laboratory failed to document the corrective action taken when the Sysmex XN-1000 analyzer printouts had flags in 7 of 9 patient CBC results. Findings: 1. Review of P&P identified "Guidelines for Manual Differentials" which states to perform a scan of the peripheral blood smear to evaluate all instrument flags and document DIFF SCANNED in EMR unless one of 6 criteria are present and a manual differential is performed. 2. 9 randomly reviewed Sysmex XN-1000 analyzer printouts for June 2023 CBCs demonstrated "platelet clumps" or "scan slide" flags. No documentation of the slide scan could be located in the EMR for 7 of 9 flagged patient results. 3. An interview with the general supervisor, 6/13/23 at approximately 12:45 PM, confirmed the lack of corrective action documentation for the 7 patient results. 4. An exit interview with the administration and general supervisor, 6/13/23 at approximately 3: 00 PM, confirmed the findings.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on record review, written policies and procedures (P&P), and interview the laboratory failed to (4) document the annual testing personnel (TP) competency for 4 of 4 staff in the Coagulation testing methodology of the ACL Elite for 2022. Findings: 1. Review of TP competency records for 2022 revealed no documented competency in the Coagulation testing on the ACL Elite for all 4 of the staff that release patient results. 2. Review of P&P identified the delegation of the responsibility of documentation and performance of the annual TP competency to the general supervisor. 3. An interview with the general supervisor, 6/13/23 at approximately 8:00 AM, confirmed that no annual competency in 2022 had been performed on the 4 TP for Coagulation testing on the ACL Elite. 4. An exit interview with the administration and the general supervisor, 6/13/23 at approximately 3:00 PM, confirmed the findings.