Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236132	09/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Marietta Memorial Hospital Of Tyler County Inc Dba	314 S Wells St, Sistersville, 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 conducted at Marietta Memorial Hospital of Tyler County on August 31 and September 1, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review, a lack of documentation, and interview the laboratory failed to retain all required documentation for 4 of 9 American Proficiency Institute (API) 2021 proficiency testing (PT) events. Findings: 1. Review of API Hematology /Coagulation 2021 PT records revealed a lack of documentation for the examination and testing of PT specimens in 2 of 2 events. a. 1st event 2021 Hematology /Coagulation- no original test data of testing performed for any PT specimens, no signed attestation statement by the laboratory director b. 2nd event 2021 Hematology /Coagulation- no original test data of testing performed for following specimens:

	ISED CAD-03, ISED CAD-04, FOB-03, WST-03, WST-04, BCI-06, BCI-07, BCI-08, BCI-09, BCI-10, DIF-02, VA-02, VKP-02. 2. Review of API Microbiology 2021 PT records revealed a lack of documentation for the examination and testing of PT specimens in 1 of 2 events. a. 1st event 2021 Microbiology- no original test data of testing performed for following specimens: CDF-01, CDF-02, CDF-03, CDF-04, CDF-05. 3. Review of API Immunology/Immunohematology 2021 PT records revealed a lack of documentation for the examination and testing of PT specimens in 1 of 2 events. a. 1st event 2021 Immunohematology- no original test data of testing performed for DAT-01, DAT-02 b. 1st event 2021 Immunology- no original test data of testing performed for HPY-01, HPY-02, HS-01, HS-02, RF-01, RF-02, RF-03, RF-04, RF-05 4. An interview with the general supervisor, 8/31/21 at approximately 2:30 PM, confirmed the findings.
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to attain a satisfactory score for 1 of 3 2020 proficiency testing (PT) events in Compatibility Testing for the American Proficiency Institute (API) commercial PT program. Findings: 1. Review of the API PT records for 2020 identified an unsatisfactory performance of 80% for Immunohematology Compatibility Testing 1st event 2020. Sample SER-01 reported as Compatible Sample SER-01 expected result Not Compatible 2. An interview with the general supervisor, 8/31/21 at approximately 1:00 PM, confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to document the performance of monthly maintenance and verify the accurate ISI and Reference time on the Stago Compact Max analyzer maintenance logs. Findings: 1. Review of Stago Compact Max maintenance logs (January 2020 thru August 2021) identified no monthly maintenance (replacement of O Ring and syringe tip) for 15 of 20 months reviewed. a. January 2020 thru December 2020- no documented monthly maintenance January, February, March, April, May, July, August, September, October b. January 2021 thru August 2021- no documented monthly maintenance January, February, April, May, June, August 2. Review of Stago Compact Max maintenance logs for June 2021 thru August 2021 revealed the daily check of ISI and Reference time had not been changed to reflect the current lot of reagent in use for 3 of 3 months reviewed. a. Lot 257658 was put into use 6-16-21. The manufacturer product insert (PI) specified an ISI of 1.25 and a mean reference time of 12.8. b. June, July, and

	August maintenance logs had the daily ISI and reference time checked as verified. The data for the ISI and reference time on the maintenance logs were not reflective of the PI information.
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 perform and document quality control (QC) procedures for DDimer testing as established by the laboratory in the policy and procedure (P&P) for Coagulation testing. Findings: 1. Review of P&P 110866.3219 Stago Readiness Performed identified that 2 levels of QC are to be ran every 8 hours for DDimer testing. 2. Review of QC records for April 2021 identified 26 of 30 days DDimer QC was not documented as performed every 8 hours. 3. An interview with the laboratory supervisor, 9/1/21 at approximately 10:00 AM, confirmed the findings.
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, lack of documentation, and interview the laboratory failed to (c)(2) perform and document temperature alarm checks for the storage of blood products from January 2020 thru the date of survey. Findings: 1. Review of temperature logs and inventory checks for the blood bank refrigerator identified no documentation of the performance of temperature alarm checks for the storage of blood products from January 2020 thru the date of survey. 2. An interview with the blood bank supervisor, 9/1/21 at approximately 1:00 PM, confirmed the findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review the laboratory director failed to (e)(3)(ii) sign the method validation data summary of the Stago Compact Max analyzer. Findings: 1. Review of the method validation data for the Stago Compact Max revealed the laboratory implemented the methodology in October 2017. 2. Review of the method validation summary identified no laboratory director signature.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory testing personnel failed to document and perform quality control (QC) and maintenance as specified in written policies and procedures. Findings: 1. Review of maintenance records for the Stago Compact Max from January 2020 thru the date of survey identified a lack of documentation for the required monthly maintenance. Refer to D5429 2. Review of maintenance records for the Stago Compact Max for June 2021 thru the date of survey identified a failure to verify the correct ISI and mean reference time for the specific lot of reagent in use. Refer to D5429 3. Review of QC records for April 2021 identified a failure to perform and document DDimer QC every 8 hours as stated in the policy and procedure for DDimer testing. Refer to D5445 4. Reiew of blood product storage logs revealed no documentation of routine storage alarm verification. Refer to D5555