Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236132	08/26/2019
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory Proficiency Testing (PT) records and an interview with the General Supervisor (GS), the laboratory director failed to sign the vendor's proficiency testing attestation statement for 2 of 3 Chemistry Core 2018 events and 1 of 3 Hematology/Coagulation 2018 events. Findings: 1. A review of 2018 PT Chemistry Core records identified the laboratory director (LD) did not sign the vendor's proficiency testing attestation statement for 2018 Chemistry Core 2nd testing event and 2018 Chemistry Core 3rd event. 2. A review of 2018 PT Hematology /Coagulation records identified the LD did not sign the vendor's proficiency testing attestation statement for 2018 Hematology/Coagulation 3rd testing event. 3. An interview with GS, on 8/26/19 at approximately 10:30 AM, confirmed the findings.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory Proficiency Testing (PT) records and an interview with Testing Personnel 1 (TP1) the laboratory failed to take and document remedial action for 1 of 2 Hematology/Coagulation testing events of 2019. Findings: 1. Review of the API PT records identified an unacceptable grade for specimen BCI-05 in the Blood Cell Identification part of the 2019 Hematology/Coagulation 1st Testing event. 2. Review of the API PT records identified no documentation of remedial action taken for 2019 Hematology/Coagulation 1st testing event 2019. 3. An interview with TP1, on 8/26/19 at approximately 1030 AM, confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory Quality Control (QC) records, patient testing records, written policies and procedures, and an interview with the General Supervisor (GS) the laboratory failed to perform an external negative and positive control for the serum HCG qualitative test. Findings: 1. Review of the laboratory QC and patient testing records from 2018 and 2019 for serum HCG qualitative testing revealed that patient testing occurred on 7/23/19, 7/26/19, 6/30/19, 3/22/19, and 1/28/19 with no external QC documented. 2. The written policy and procedure for serum HCG qualitative testing states "a positive and negative control is run on each kit each day of testing, every 30 days, and when a new lot is in use." 3. An interview with GS, on 8/27 /19 at approximately 9:00 AM, confirmed that no external QC was documented for the specified dates of testing.