Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0692885	04/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Marietta Memorial Hospital Of Tyler County Dba	314 South Wells Street, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with testing personnel, the laboratory failed to establish and follow written policies and procedures for monitoring, assessing, and correcting problems identified as required in general laboratory systems. Findings: 1. Review of the binder titled "Policy and Procedure Manual" found no written policy, procedure, or documentation for the monitoring and assessment of general laboratory systems, which includes confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing evaluation. 2. Interview with Testing Personnel #1 (TP1) on 4/25/2019 at approximately 1255 confirmed that there is no written policy for performing quality assessment of the general laboratory systems components.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's procedure manuals and interview with testing personnel, the laboratory failed to establish and follow written policies and procedures for monitoring, assessing, and correcting problems identified in the preanalytic system, as required. Findings: 1. Review of the binder titled "Policy and Procedure Manual" found no written policy, procedure, or documentation for the monitoring and assessment of the preanalytic system, which includes the following: test request and specimen submission, handling, and referral. 2. Interview with Testing Personnel #1 (TP1) on 4/25/2019 at approximately 1255 confirmed that there is no written policy for performing quality assessment of the preanalytic system. 3. Per TP1, preanalytic checks are done on a monthly basis. TP1 was unable to provide documentation of these monthly checks.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with testing personnel, the laboratory failed to establish and follow written policies and procedures for monitoring, assessing, and correcting problems identified in analytic systems, as required. Findings: 1. Review of the binder titled "Policy and Procedure Manual" found no written policy, procedure, or documentation for the monitoring and assessment of the analytic system, which includes the following: procedure manual, test systems/equipment/supplies, establishment and verification of performance specifications, maintenance and function checks, calibration and calibration verification procedures, control procedures, comparison of test results, corrective actions, and test records. 2. Interview with Testing Personnel #1 (TP1) on 4/25/2019 at approximately 1255 confirmed that there is no written policy for performing quality assessment of the analytic system.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with testing personnel, the laboratory failed to establish and follow written policies and procedures for monitoring, assessing, and correcting problems identified in the postanalytic system, as required. Findings: 1. Review of the binder titled "Policy and Procedure Manual" found no written policy, procedure, or documentation for the monitoring and assessment of the postanalytic system, which includes test reports. 2. Interview with Testing Personnel #1 (TP1) on 4/25/2019 at approximately 1255 confirmed that there

	is no written policy for performing quality assessment of the postanalytic system. 3. Per TP1, postanalytic checks are done on a monthly basis. TP1 was unable to provide documentation of these monthly checks.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with testing personnel, the laboratory director failed to ensure the establishment and maintenance of a quality assessment program. Findings: 1. No procedure, policy, or documentation could be found for quality assessment in the laboratory's procedure manuals and records. 2. Interview with testing personnel 1 on 4/25/2019 at approximately 12:55PM confirmed that no formal quality assessment program exists. 3. Refer to citations at D5291, D5391, D5791, and D5891 for more information.