Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0910926	09/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Minnie Hamilton Health Care Center Inc	186 Hospital Hill, Grantsville, 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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based upon a review of the laboratory Proficiency Testing (PT) records, current test menu, and interview with the General Supervisor (GS), the laboratory failed to verify accuracy at least twice per year for the Direct Antiglobulin Test (DAT), an analyte that is not included in Subpart I. Findings: 1. A review of PT records from 2018 and 2019 established that the laboratory had not performed commercial PT, or utilized other methods, to verify accuracy on the DAT testing in Immunohematology twice a year. 2. An interview with the GS, on 9/3/19 at approximately 1:30 PM, confirmed the findings.
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 written laboratory policies and procedures and an interview with the General Supervisor (GS), the laboratory failed to establish and follow a written policy and procedure for monitoring, assessing, and correcting problems of the

	general laboratory systems. Findings: 1. No written policy or procedure for the Quality Assessment (QA) of the general laboratory systems could be located. This includes the monitoring and assessment of confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing evaluation. 2. An interview with GS, on 9/4/19 at approximately 12:30 PM, confirmed the findings.
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 a review of laboratory written policies and procedures and an interview with the General Supervisor (GS), the laboratory failed to establish and follow a written policy/ procedure for the Quality Assessment (QA) of preanalytic systems. Findings: 1. No written policy or procedure for the QA of preanalytic could be located. This includes the following: test request and specimen submission, handling, and referral. 2. An interview with the GS. on 9/4/19 at approximately 12:30 PM, the findings.
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 upon a review of the laboratory written policies and procedures and an interview with the General Supervisor (GS), the laboratory failed to establish a written policy/procedure for the Quality Assessment (QA) of analytic systems. Findings: 1. No written policy or procedure for the QA of analytic systems could be located. This included 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. An interview with the GS, on 9/4/19 at approximately 12:30 PM, confirmed the findings.
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 upon a review of the written laboratory policies and procedures and an

	interview with the General Supervisor (GS), the laboratory failed to establish a written policy/procedure for the Quality Assessment (QA) of postanalytic systems. Findings: 1. No written policy or procedure for QA of postanalytic systems could be located, which includes test reports. 2. An interview with the GS, on 9/4/19 at approximately 12:30 PM, confirmed the findings.