Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0686634	08/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Camc Greenbrier Physicians Ronceverte	1322 Maplewood Avenue, Ronceverte, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based upon a review of Proficiency Testing (PT) records and an interview with Testing Personnel 1 (TP1), the laboratory failed to review and evaluate unsuccessful results for 1 of 3 PT testing events in Hematology and Coagulation for 2018. Findings: 1. A review of PT records for 2018 identified the lack of an investigation for the unsuccessful identification of urine sediment cells in the 1st event of Hematology and Coagulation for 2018. 2. An interview with TP1, on 8/21/19 at approximately 11:00AM, confirmed that no review or investigation of the unsuccessful result could be located.
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 upon a review of of laboratory written policies and procedures and an interview with Testing Personnel 1 (TP1), the laboratory failed to establish a written policy /procedure for Quality Assessment (QA) of the general laboratory systems. Findings: 1. No written policy or procedure for 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. The laboratory is performing QA monitoring of all general laboratory systems, documented on monthly QA forms that are reviewed and signed by the laboratory director. 3. An interview with TP1, on 8/21 /19 at approximately 10:30 Am, confirmed there is no written policy or procedure for the QA of the general laboratory systems.
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 upon a review of of laboratory written policies and procedures and an interview with Testing Personnel 1 (TP1), the laboratory failed to establish a written policy /procedure for Quality Assessment (QA) of preanalytic systems. Findings: 1. No written policy or procedure for QA of preanalytic systems could be located. This includes the following: test request and specimen submission, handling, and referral. 2. The laboratory is performing QA monitoring of all preanalytic systems, documented on monthly QA forms that are reviewed and signed by the laboratory director. 3. An interview with TP1, on 8/21/19 at approximately 10:30 Am, confirmed there is no written policy or procedure for the QA of the preanalytic systems.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with Testing Personnel 1

	(TP1), the laboratory failed to perform calibration verification for testing Chloride, Potassium, and Sodium analytes every 6 months. Findings: 1. A review of quality control and calibration records identified that no calibration verification was being performed and documented for the Chloride, Potassium, and Sodium analytes. The other analytes in Chemistry testing all had a four point calibration performed at least monthly, meeting the requirements for CFR 493.1255. 2. An interview with TP1, on 8 /21/19 at approximately 11:15 AM, confirmed that Chloride, Potassium, and Sodium do not use 3 levels of calibrator and no other calibration verification was performed every 6 months.
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 of laboratory written policies and procedures and an interview with Testing Personnel 1 (TP1), the laboratory failed to establish a written policy /procedure for Quality Assessment (QA) of analytic systems. Findings: 1. No written policy or procedure for QA of analytic systems could be located. This 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. The laboratory is performing QA monitoring of all analytic systems, documented on monthly QA forms that are reviewed and signed by the laboratory director. 3. An interview with TP1, on 8/21/19 at approximately 10:30 AM, confirmed there is no written policy or procedure for the QA of the analytic systems.
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 of laboratory written policies and procedures and an interview with Testing Personnel 1 (TP1), the laboratory failed to establish a written policy /procedure for 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. The laboratory is performing QA monitoring of all postanalytic systems, documented on monthly QA forms that are reviewed and signed by the laboratory director. 3. An interview with TP1, on 8/21/19 at approximately 10: 30 Am, confirmed there is no written policy or procedure for the QA of the postanalytic systems.
D6064	TESTING PERSONNEL QUALIFICATIONS

	CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with Testing Personnel 2 (TP2), TP2 had continued to perform laboratory testing with an expired West Virginia laboratory license. Findings: 1. TP2 had a lapse from 10/17 to 1/11/18 for the West Virginia laboratory license required by WV 64 CSR 57, Clinical Laboratory Technician and Scientist Licensure and Certification Rule. 2. An interview with TP2, on 8/21/19 at approximately 11:15 AM, confirmed that laboratory testing was still being performed during the lapse in licensure.