

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D0686634	<b>(X3) Date Survey Completed</b> 03/19/2021
<b>Name of Provider or Supplier</b> Camc Greenbrier Physicians Ronceverte	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced, off site, proficiency testing (PT) desk review was conducted at Greenbrier Physicians Inc on March 19, 2021, by the West Virginia Office of Laboratory Services. The laboratory proficiency testing evaluations with the American Proficiency Institute (API) were reviewed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and the CLIA 155D Individual Laboratory Profile for Greenbrier Physicians</p>

	<p>Inc, the laboratory failed to successfully participate in a program approved by CMS for the analytes of FREE TY (# 0545) and TSH (# 0585). The findings include: 1. FREE TY (# 0545) Event 2 (2020) - 60% Event 1 (2021) - 0% 2. TSH (# 0585) Event 2 (2020)- 60% Event 1 (2021)- 0%</p>
<p><b>D2100</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records and the CASPER 155D Individual Laboratory Profile report for Greenbrier Physicians Inc, the laboratory failed to successfully participate in a program approved by CMS for the analytes FREE TY (#0545) and TSH (#0585) for the 1st testing event of 2021. The findings include: 1. FREE TY (#0545) Event 1 (2021)- 0% 2. TSH (#0585) Event 1 (2021)- 0%</p>
<p><b>D2108</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CASPER 155D Individual Laboratory Profile Report and the Failures Summary report from the American Proficiency Institute (API), the laboratory failed to perform satisfactorily in proficiency testing (PT) for the specialty of endocrinology in 2 of 3 consecutive testing events. Findings: 1. Review of CASPER 155D Individual Laboratory Profile Report revealed the following unsatisfactory test event scores for specialty # 0525 ENDOCRINOLOGY: 2nd event 2020 - 73% 1st event 2021 - 0% 2. Review of API Failures Summary report confirmed the following unsatisfactory test event scores for the specialty ENDOCRINOLOGY (#0525): 2nd event 2020 - 73% 1st event 2021- 0%</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p>

This CONDITION is not met as evidenced by:  
Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and the CLIA 155D Individual Laboratory Profile for Greenbrier Physicians Inc, the laboratory director failed to ensure successful participation in a program approved by CMS for the analytes of FREE TY (# 0545) and TSH (# 0585) in 2 of 3 consecutive testing events. The findings include: 1. FREE TY (# 0545) Event 2 (2020) - 60% Event 1 (2021) - 0% 2. TSH (# 0585) Event 2 (2020)- 60% Event 1 (2021)- 0%

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporitions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records and the CASPER 155D report for Greenbrier Physicians Inc, the laboratory director failed to assure compliance with the regulation requiring successful participation in PT testing for the analytes FREE TY (# 0545) and TSH (# 0585) in the specialty of ENDOCRINOLOGY (# 0525). Findings: 1. FREE TY (# 0545) Event 2 (2020)- 60% Event 1 (2021)- 0% 2. TSH (# 0585) Event 2 (2020)- 60% Event 1 (2021)- 0% 3. ENDOCRINOLOGY (# 0525) Event 2 (2020)- 73% Event 1 (2021)- 0%