

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0226355	(X3) Date Survey Completed 09/04/2020
Name of Provider or Supplier Brandermill Pediatric & Adolescent Medicine	Street Address, City, State 4902 Millridge Pky, Midlothian, VA	
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
D0000	An unannounced CLIA off-site proficiency testing desk review of Brandermill Pediatric & Adolescent Medicine was conducted on September 4, 2020 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. Specific deficiencies cited are as follows:
D2016	<p>SUCCESSFUL PARTICIPATION 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 the review of the hematology proficiency testing (PT) scores for the first and second events in 2020, the CASPER 0153D Unsuccessful PT report and an interview with the lab director at approximately 8:05 AM on September 4, 2020, the</p>

	<p>laboratory failed to achieve satisfactory performance of at least 80% for two consecutive events for the platelet count (PLT) parameter, in which the laboratory received scores of 40% and 0% respectively, resulting in unsuccessful performance (Cross Reference D2130).</p>
<p>D2123</p>	<p>HEMATOLOGY CFR(s): 493.851(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 the review of proficiency testing (PT) records and an interview, the laboratory failed to participate in one (1) of two (2) Complete Blood Count (CBC) events reviewed. Record review included the first 2 testing events in 2020. Findings include: 1. Review of the CASPER 0155D Individual Laboratory Profile Report and the American Proficiency Institute (API) PT records for the second event in 2020 revealed the laboratory received a score of 0%. 2020 Event B- 0%- for the CBC module (Notation by API-failure to participate). 2. An interview with the lab director on September 4, 2020 at approximately 8:05 AM confirmed the findings.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on the review the proficiency testing (PT) scores for the first and second events in 2020, the CASPER 0153D Unsuccessful PT report and an interview, the laboratory failed to achieve satisfactory performance of at least 80% for two consecutive events for the Platelet count (PLT) parameter, resulting in unsuccessful performance. Findings include: 1. Review of the American Proficiency Institute (API) hematology PT scores and the CASPER 0153D Unsuccessful PT report revealed the following scores: 2020 1st event PLT- 40% 2020 2nd event PLT- 0% The laboratory received an unsuccessful API PT score for the above listed analyte. 2. An interview with the lab director on September 4, 2020 at approximately 8:05 AM confirmed the findings.</p>