

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2068994	(X3) Date Survey Completed 05/01/2023
Name of Provider or Supplier Beckwith Medical Group, Pllc	Street Address, City, State 952 Edwards Ferry Road, Ne, Leesburg, 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 off-site proficiency testing desk review of Beckwith Medical Group, PLLC was conducted on May 1, 2023 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. The laboratory was not in compliance with the following Conditions under 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493.803 (a)(b)(c) Condition- Successful Participation.
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 an off-site desk review of the laboratory's American Proficiency Institutes proficiency testing (PT) records (2022 Third Event and 2023 First Event) and</p>

interview, the laboratory failed to attain a score of at least eighty percent of acceptable responses for White Blood Cell count (WBC), Red Blood Cell count (RBC), Hemoglobin (HGB) Hematocrit (HCT), Platelet count (PLT) and WBC Differential (WBC diff) in two consecutive Hematology testing events resulting in unsuccessful PT performance. See 2130.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on an off-site desk review of the laboratory's proficiency testing (PT) records and interview, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for White Blood Cell count (WBC), Red Blood Cell count (RBC), Hemoglobin (HGB) Hematocrit (HCT), Platelet count (PLT) and WBC Differential (WBC Diff) for two (2) consecutive hematology testing events resulting in unsuccessful PT performance. Findings include: 1. Desk review of the laboratory's American Proficiency Institute (API) PT records revealed WBC, RBC, HCT, HGB, PLT and WBC Diff scores of less than 80% for the following 2 consecutive hematology events: 2022 Event 3 - WBC=60%; RBC=60%; HGB=60%; HCT=60%; PLT=60%; and WBC diff=73%; 2023 Event 1 - WBC, RBC, HGB, HCT, PLT and WBC diff=0%, Unsuccessful, Failure to Participate; resulting in unsuccessful PT performance. 2. In a telephone interview with the Technical Consultant on May 1, 2023, at approximately 12:45 PM, the findings were confirmed.