

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2068994	<b>(X3) Date Survey Completed</b> 10/07/2021
<b>Name of Provider or Supplier</b> Beckwith Medical Group, Pllc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Beckwith Medical Group, PLLC on October 7, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Beckwith Medical Group, PLLC is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements. The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems; D6000 - 42 C.F.R. 493.1403 Condition: Moderate complexity laboratory director. The specific deficiencies are as follows:
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, lack of documentation, and an interview, the Laboratory Director (LD) and testing personnel (TP) failed to sign two (2) of seven (7) PT attestation statements from July 2019 to October 2021. Findings include: 1. Review of the American Proficiency Institute (API) PT records from July 2019 until October 2021 revealed the following PT event attestation statements were not signed by the Laboratory Director (LD) and Testing Personnel (TP): API 2019 Event 2 and API 2019 Event 3. Two (2) of 7 attestation statements were not signed by Laboratory Director and TP. The surveyor requested to review the signed attestation statements for the PT events listed above. The laboratory provided no documentation for review. 2. In an exit interview with the director of operations on October 7, 2021 at approximately 11:45 AM, the findings were confirmed</p>

**D2121**

**HEMATOLOGY**

CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on a review of Centers for Medicare and Medicaid Services CASPER 0096D report form (CMS CASPER 96), proficiency testing (PT) records, and an interview, the laboratory failed to attain an overall score of at least eighty (80) percent (%) of acceptable responses for Hematology in two (2) of seven (7) PT testing events from July 2019 until October 2021. Findings include: 1. Review of the CMS CASPER 96 report included an overall unsatisfactory PT score for the speciality of Hematology for 2020 Event 1 with a score 75% and an unsatisfactory analyte score for Cell Identification for 2021 Event 1 of 67%. 2. Review of the laboratory's American Proficiency Institute (API) PT records from July 2019 until October 2021 revealed the following unsatisfactory scores: 2020 Event 1 Hematology/Coagulation scored as 75% with individual scores of Red Blood Cell count 60% and Hematocrit 60%; 2021 Event 2 Hematology/Coagulation scored as Cell Identification 67%. 3. In an exit interview with the director of operations on October 7, 2021 at approximately 11:45 AM, the findings were confirmed.

**D2128**

**HEMATOLOGY**

CFR(s): 493.851(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policy and procedure manual, proficiency testing (PT) records, and interviews, the laboratory failed to follow their established policy and investigate three (3) unsatisfactory results in two (2) of seven (7) Hematology PT events from July 2019 until October 2021. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT records from July 2019 to October 2021, a total of 7 events, revealed a lack of evidence of the investigation for the following 3 unsatisfactory Hematology PT results: API 2020 - Event 1 Red Blood Cell Count (RBC) scored as 60% and Hematocrit (HCT) scored as 60%; API 2021 - Event 1 Cell Identification scored as 67%. The surveyor requested documentation of the investigation of API 2020 Event 1 RBC, HCT and API 2021 Event 1 Cell ID. The laboratory provided no documentation for review. 2. Review of the laboratory's policy and procedure manual revealed a "Monthly QA Checklist" with a statement, "PT failures were investigated and remedial action was documented." The surveyor requested to review the "Monthly QA Checklists" and corrective actions taken from calendar years 2020 and 2021. The laboratory provided no documentation

	<p>of the "Monthly QA Checklists" and corrective actions taken. 3. In an exit interview with the director of operations on October 7, 2021 at approximately 11:45 AM, the findings were confirmed.</p>
<p><b>D5211</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director failed to review and sign seven (7) of seven (7) PT result evaluations from July 2019 until October 2021. Findings include: 1. Review of the laboratory's American Proficiency Testing (API) PT records from July 2019 until October 2021 (a total of 7 events) revealed a lack of documentation of the signature of laboratory director for the following PT events: API 2019 Hematology/Coagulation Event 2 and 3; API 2020 Hematology/Coagulation Events 1, 2 and 3; and API 2021 Hematology/Coagulation Events 1 and 2. A total of 7 events. The surveyor requested documentation of the above listed PT evaluations signed by the laboratory director. The laboratory provided no documentation for review. 2. In an exit interview with the director of operations on October 7, 2021 at approximately 11:45 AM, the findings were confirmed.</p>
<p><b>D5400</b></p>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies and procedures, manufacturer's operators guide, instrument calibration records, instrument maintenance logs, quality assessment (QA) documents, lack of documentation and interviews, the laboratory failed to: 1. provide documentation of the weekly maintenance performed on the Horiba ABX Micros 60 hematology analyzer 24 weeks (Cross Reference D5429); 2. follow their established policy and manufacturer's requirement for performing Horiba ABX Micros 60 calibration procedures at least once every six months in 2020 and 2021 (Cross Reference D5437); 3. follow their QA plan and document a "Monthly QA Checklist" and corrective actions taken from July 2019 and October 2021 (Cross Reference D5791).</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on the review of laboratory's monthly maintenance logs, manufacturer's operator guide, lack of documentation and interview, the laboratory failed to provide documentation of the weekly maintenance performed on the Horiba ABX Micros 60 hematology analyzer for twenty-four (24) of one hundred twelve (112) weeks from July 2019 until October 2021. Findings include: 1. The laboratory utilizes the Horiba ABX Micros 60 analyzer to perform Complete Blood Counts (CBC). Review of the Horiba Micros 60 operator's guide revealed the following statements, "Instrument Maintenance-Weekly Maintenance: Concentrated Cleaning Cycle - once weekly, perform a concentrated cleaning cycle using MINOCLAIR solution." 2. Review of monthly maintenance logs from July 2019 up to date of survey on October 7, 2021 revealed lack of documentation of the weekly maintenance for the following: June 2020 - 2 weeks; October 2020 - 2 weeks; December 2020 - 2 weeks; January 2021 - 1 week; February 2021 - 4 weeks; April 2021 - 1 week; May 2021 - 4 weeks; June 2021 - 4 weeks; and August 2021 - 4 weeks. A total of 24 weeks. The surveyor requested to review documentation for the weekly maintenance for the above listed weeks. The laboratory provided no documentation for review. 3. In an exit interview with the director of operations on October 7, 2021 at approximately 11:45 AM, the findings were confirmed.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policies and procedures, Horiba ABX Micros 60 operator's guide, instrument calibration records, and interview, the laboratory failed to follow their established policy and manufacturer's requirement for performing Horiba ABX Micros 60 Hematology analyzer calibration procedures at least once every six (6) months in 2020 and 2021. Findings include: 1. Review of the laboratory's policy and procedures revealed a statement, "Calibration is performed per the manufacturer's specifications. See each instrument's specific manual for specific instructions." 2. Review of the Horiba Micros 60 operator's guide revealed a statement, "Calibration Procedures-When to Calibrate - Requirements specify that hematology instruments be calibrated at least once every six months, and whenever major components are replaced, major maintenance is performed or when advised to do so by a Horiba Medical technical support representative." 3. Review of the Horiba ABX Micros 60 calibration records revealed calibration procedures were performed on 11/27/2019, 6/25/2020, and 12/8/2020. The surveyor requested to review

documentation of the six month Horiba ABX Micros 60 calibration procedures for 11/27/2019 to 6/25/2020, and 12/8/2020 to 10/7/2021. The laboratory provided no documentation to review. 4. In an exit interview with the director of operations on October 7, 2021 at approximately 11:45 AM, the findings were confirmed

**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 on review of the laboratory's policies and procedures, Quality Assessment (QA) documentation, lack of documentation and interview, the laboratory failed to follow their QA plan and document a "Monthly QA Checklist" and corrective actions taken from July 2019 until October 2021. Findings include: 1. Review of the laboratory's policies and procedures revealed a written and approved QA policy that included a "Monthly QA Checklist" and monitors for compliance to be performed by the laboratory director. The "Monthly QA Checklist" included a section "Analytic Systems" with the following statements, "Our analytic testing policies were followed: ...Check Instrument Maintenance log. All non-routine instrument maintenance was performed and documented...Check calibration-Calibration was performed and documented at least every 6 months or after major instrument maintenance." and "Attach any pertinent reports to this checklist (complaints, incidents, PT failures, etc). If you answered "No" to any item, explain the problem and how you resolved it. Also, explain any changes made to laboratory policies and procedures as a result of the Quality Assessment program. Describe corrective actions taken and how changes have improved quality of the testing process..." 2. Review of the laboratory's QA documents revealed a lack of documentation of the "Monthly QA Checklist" from July 2019 until October 2021 and corrective actions taken for the lack of documentation of the Horiba Micros 60 maintenance and calibration (Cross Reference D5429 and D5437). The surveyor requested to review the "Monthly QA Checklist" from July 2019 until October 2021 and corrective action documentation for the missing Horiba maintenance and calibration documents. The laboratory provided no documentation for review. 3. In an exit interview with the director of operations on October 7, 2021 at approximately 11:45 AM, the findings were confirmed.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:

**\*\*REPEAT DEFICIENCY\*\*** Based on review of laboratory policies and procedures, proficiency testing (PT) records, Quality Assurance (QA) plan, calibration records, maintenance records, lack of documentation, and interviews, the laboratory director (LD) failed to: 1. Sign PT attestation statements and result evaluations from July 2019

	<p>until October 2021 (Cross Reference D6018); 2. Ensure a corrective action plan was followed and remedial actions documented for three (3) unsatisfactory PT results from July 2019 until October 2021 (Cross reference D6019); 3. Ensure the laboratory QA policies were maintained and corrective actions taken when needed from July 2019 until October 2021(Cross reference D6020).**REPEAT DEFICIENCY**</p>
<p><b>D6018</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</p> <p>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. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director failed to: 1. Sign attestation statements for two (2) of seven (7) American Proficiency Institute events from July 2019 to October 2021 (Cross reference D2009); 2. Review and sign seven (7) of seven (7) PT result evaluations from July 2019 until October 2021 (Cross reference D5211).</p>
<p><b>D6019</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iv)</p> <p>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. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, available corrective action records, interview and lack of documentation, the laboratory director (LD) failed to ensure a corrective action plan was followed and remedial actions documented for three (3) unsatisfactory results in two (2) of seven (7) Hematology PT events reviewed from July 2019 until October 2021 (Cross reference D2128).</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:

**\*\*REPEAT DEFICIENCY\*\*** Based on a review of laboratory policies and procedures, quality assurance (QA) records, calibration records, maintenance records, and an interviews, the laboratory director (LD) failed to ensure the laboratory's QA policies were maintained and corrective actions were taken when needed from July 2019 until October 2021 (Cross reference D5791).