Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2068994	07/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Beckwith Medical Group, Pllc	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 announced CLIA recertification survey was conducted at Beckwith Medical Group on July 18, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
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 on a review of the proficiency testing (PT) records, policy and procedure manual, and an interview with Testing Personnel A (TP A), the laboratory lacked a written policy to assess and address unacceptable analyte scores of less than one-hundred (100) percent (%) for four (4) of seven (7) American Proficiency Institute (API) events reviewed from November 2017 to July 2019. Findings include: 1. Review of the laboratory's API PT events revealed the following: 2018 Chemistry Core Event 1-Free Thyroxine=80%; 2018 Hematology/Coagulation Event 2-Erythrocyte Count=80%; 2018 Hematology/Coagulation Event 3-Erythrocyte Count, Hematocrit, MCH, MCHC, Platelet Count=80%; 2019 Hematology/Coagulation Event 1-Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, MCH, MCHC=80%. A total of 4 events. The surveyor requested documentation of the assessment and remedial action taken for the PT events listed above. 2. Review of the laboratory's policy and procedure manual revealed a lack of a written policy for assessing and documenting remedial action taken for unacceptable analyte scores of less than 100 %. 3. In an exit interview with TP A at approximately 1:45 PM, TP A confirmed the findings.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, Hematology Quality Control (QC) records, and an interview with Testing Personnel A (TP A), the laboratory failed to follow their corrective action policy and document corrective actions for Hematology QC that was "out of range" for thirteen (13) of sixty-five (65) days reviewed from April 1, 2019 to June 29, 2019. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "How to Interpret Control Runs", that included "8. The appropriate documentation of problems and their solutions should be shown on the QC evaluation worksheet and initialed by personnel who solved the problem. It should be brought to the attention of the Laboratory Director as well." 2. Review of the laboratory's QC records from April 1, 2019 to June 29, 2019 revealed the following days when the Horiba Micros 60+ Minotrol 16 QC was "out-of-range": 4/3/19 Minotrol 16 lot MX416 normal exp 5/5/19 Red Blood Cell (RBC) low. Repeated and QC in range; 4/3/19 Minotrol 16 lot MX416 high exp 5/5 /19 Red Blood Cell (RBC) low. Repeated and QC in range; 4/8/19 Minotrol 16 lot MX416 low exp 5/5/19 Platelet (PLT) low. Repeated times two (2). QC in range; 4/8 /19 Minotrol 16 lot MX416 high exp 5/5/19 Red Blood Cell (RBC) low. Repeated and QC in range; 4/9/19 Minotrol 16 lot MX416 high exp 5/5/19 Red Blood Cell (RBC) low. Repeated times 2 and QC in range; 4/15/19 Minotrol 16 lot MX416 low exp 5/5/19 White Blood Cell (WBC) low. Repeated times two (2) and QC in range; 4 /17/19 Minotrol 16 lot MX416 high exp 5/5/19 Red Blood Cell (RBC) low. Repeated and QC in range; 4/18/19 Minotrol 16 lot MX416 low exp 5/5/19 WBC low. Repeated and QC in range; 4/18/19 Minotrol 16 lot MX416 normal exp 5/5/19 RBC low. Repeated and QC in range; 4/23/19 Minotrol 16 lot MX416 high exp 5/5/19 Red Blood Cell (RBC) low. Repeated and QC in range; 4/26/19 Minotrol 16 lot MX416 normal exp 5/5/19 RBC low. Repeated and QC in range; 5/13/19 Minotrol 16 lot MX417 high exp 7/5/19 RBC low. Repeated and QC in range; 5/21/19 Minotrol 16 lot MX417 high exp 7/5/19 WBC low. Repeated and QC in range; 5/28/19 Minotrol 16 lot MX417 high exp 7/5/19 WBC low. Repeated and QC in range; 6/10/19 Minotrol 16 lot MX417 normal exp 7/5/19 WBC low. Repeated and QC in range; 6/17/19 Minotrol 16 lot MX417 high exp 7/5/19 WBC, RBC, Hemoglobin (HGB), Hematocrit (HCT) high. Repeated and QC in range; A total of 13 days with "out-of-range" QC. 3. Review of the laboratory's QC records from April 1, 2019 until June 29, 2019 revealed no "QC evaluation worksheet" documentation of "problems and their solutions" for the above listed dates when the Hematology QC was "out-of-range". The surveyor requested to review the "problems and their solutions" documentation for the "out of range" QC for the dates listed above. The laboratory provided no documentation of the "problems and their solutions" taken. 4. In an exit interview with TP A at approximately 1:45 PM, TP A confirmed the findings.

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: Based on a review of the laboratory's policy and procedure manual, proficiency testing (PT) records, Hematology Quality Control (QC) records and interviews, the laboratory director failed: to ensure the testing personnel followed the established QC corrective action policy and document corrective actions for Hematology QC that was "out of range" (Cross Reference D6020); to ensure a written Quality Assessment policy was established (REPEAT DEFICIENCY-Cross Reference D6021 A); and to ensure a written policy was established to address and correct unacceptable analyte scores of less than one-hundred (100) percent (%) (Cross Reference D6021 B).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, Hematology Quality Control (QC) records, and an interview with Testing Personnel A (TP A), the Laboratory Director (LD) failed to ensure the testing personnel followed the established QC corrective action policy and document corrective actions for Hematology QC that was "out of range" for sixteen (16) of sixty-five (65) days reviewed from April 1, 2019 to June 29, 2019 (Cross Reference D5781).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's policy and procedure manual and an interview with Testing Personnel A (TP A), the Laboratory Director (LD) failed to ensure a written Quality Assessment policy was established during the twenty months reviewed from November 2017 until July 2019. REPEAT DEFICIENCY Findings

	include: 1. Review of the laboratory's policy and procedure manual revealed no policy for the quality assessment of the analytic system. The surveyor requested to review the laboratory's Quality Assessment policy. No policy was provided by the laboratory. 2. In an exit interview with TP A at approximately 1:45 PM, TP A confirmed the findings. B. Based on a review of the proficiency testing (PT) records, policy and procedure manual, and an interview with Testing Personnel A (TP A), the Laboratory Director failed to ensure a written policy was established to assess and address unacceptable analyte scores of less than one-hundred (100) percent (%) for four (4) of seven (7) American Proficiency Institute (API) events reviewed from November 2017 to July 2019 (Cross reference D5291).