Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0880378	03/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Green Clinic Pulmonary Lab	1200 South Farmerville, Ruston, LA	

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	A Certification Survey was performed at Green Clinic Pulmonary Laboratory - CLIA # 19D0880378 on March 21, 2022. Green Clinic Pulmonary Laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and procedure, quality control and patient records as well as interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 2. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Arterial Blood Gas testing. Refer to D5445.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory's policy and procedure manual and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not have detailed, written policies and procedures for the following: a) Detailed, written instructions for an Individualized Quality Control Plan (IQCP) to include a Risk Assessment (RA), Quality Control Plan (QCP) and Quality Assessment Plan (QAP) as well as the data to support the IQCP and how that data will be retained. Also to include the acceptability criteria of quality controls, who will review and sign off on the IQCP and when the IQCP will be implemented for testing. b) Performance Specification and Verification procedures to include written, detailed instructions for accuracy, complete precision (day to day, run to run, within run and operator variance) reportable range and reference range as well as the acceptability criteria for each. 2. In interview on March 21, 2022 at 3:13 pm, Personnel 2 stated that she was unaware the identified policies were required for the policy manual. Personnel 2 confirmed the identified policies were not included in the laboratory policy and procedure manual.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and procedure, quality control documentation, patient records and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Arterial Blood Gas testing.

	Findings: 1. Direct observation by surveyor during the laboratory tour on March 21, 2022 at 2:18 pm revealed the laboratory utilizes the EPOC Arterial Blood Gas (ABG) analyzer for blood gas testing (pH, pCO2, and pO2). 2. In interview on March 21, 2022 at 2:25 pm, Personnel 2 stated two (2) levels of external QC is performed every thirty (30) days and with new lot change of ABG cassettes. 3. In further interview on March 21, 2022 at 3:13 pm, Personnel 2 stated the manufacturer for the EPOC system informed the facility that QC was only required every thirty (30) days. 4. Review of the laboratory's policy manual revealed the laboratory did not have the documentation for an IQCP to include a Risk Assessment (RA), Quality Control Plan (QCP) and Quality Assessment Plan (QAP) along with the in-house quality control data to support the reduction of external controls to every thirty (30) days. 5. Review of patient records from June 1, 2021 through January 10, 2022 revealed the laboratory did not have acceptable QC for the following twenty three (23) of twenty five (25) patients reviewed: a) Patient ID# 16626: ABG performed on June 28. 2021 at 12:49 pm (last QC performed on June 1, 2021) b) Patient ID# 635858: ABG performed on June 29, 2021 at 10:11 am (last QC performed on June 1, 2021) c) Patient ID# 9973: ABG performed on August 5, 2021 at 11:20 am (last QC performed on August 3, 2021) d) Patient ID# 70657: ABG performed on August 9, 2021 at 10:18 am (last QC performed on August 3, 2021) e) Patient ID# 689483: ABG performed on August 10, 2021 at 10:48 am (last QC performed on August 3, 2021) f) Patient ID# 610354: ABG performed on August 17, 2021 at 10:59 am (last QC performed on August 3, 2021) g) Patient ID# 26643: ABG performed on August24, 2021 at 10:07 am (last QC performed on August 3, 2021) h) Patient ID# 15818: ABG performed on August 24, 2021 at 14:44 pm (last QC performed on August 3, 2021) i) Patient ID# 49657: ABG performed on August 30, 2021 at 11:30 am (last QC performed on August 3, 2021) j) Patient ID# 565261: ABG performed on September 7, 2021 at 10:33 am (last QC performed on September 3, 2021) k) Patient ID# 660884: ABG performed on September 28, 2021 at 10:06 am (last QC performed on September 3, 2021) l) Patient ID# 552730: ABG performed on October 18, 2021 at 13:29 pm (last QC performed on October 8, 2021) m) Patient ID# 39498: ABG performed on October 25, 2021 at 12: 37 pm (last QC performed on October 8, 2021) n) Patient ID# 48703: ABG performed on October 28, 2021 at 11:23 am (last QC performed on October 8, 2021) o) Patient ID# 23319: ABG performed on December 2, 2021 at 9:36 am (last QC performed on December 1, 2021) p) Patient ID# 645933: ABG performed on December 14, 2021 at 11:26 am (last QC performed on December 1, 2021) q) Patient ID# 109452: ABG performed on December 20, 2021 at 12:47 pm (last QC performed on December 1, 2021) r) Patient ID# 40135: ABG performed on December 28, 2021 at 12:00 pm (last QC performed on December 1, 2021) s) Patient ID# 20086: ABG performed on December 29, 2021 at 11:34 am (last QC performed on December 1, 2021) t) Patient ID# 701783: ABG performed on January 11, 2022 at 11:24 am (last QC performed on January 10, 2022) u) Patient ID# 555561: ABG performed on January 11, 2022 at 14: 55 pm (last QC performed on January 10, 2022) v) Patient ID# 34452: ABG performed on January 18, 2022 at 11:09 am (last QC performed on January 10, 2022) w) Patient ID# 29308: ABG performed on January 25, 2022 at 11:30 am (last QC performed on January 10, 2022) 6. In interview on March 21, 2022 at 3:54 pm, Personnel 2 stated she understood that since the laboratory did not have a complete IQCP that the identified patients were performed without QC . 7. In further interview on March 21, 2022 at 3:54 pm, Personnel 2 confirmed the laboratory did not have a complete IQCP to support the reduction of external controls to every thirty (30) days. 8. Review of the task 1&3 form provided to surveyor revealed the laboratory performs 150 ABG tests annually.
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 observation by surveyor, review of laboratory records, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that a quality control program was established to assure quality laboratory services were provided. Refer to D6020. 2. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to 6031.
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 review of laboratory policy and procedure, quality control records and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure quality laboratory services were provided. Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for Arterial Blood Gas testing. Refer to D5445.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5403.