

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0880378	(X3) Date Survey Completed 01/09/2018
Name of Provider or Supplier Green Clinic Pulmonary Lab	Street Address, City, State 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 Recertification Survey was conducted on January 9, 2018 at Green Clinic Pulmonary Lab - CLIA # 19D0880378. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the manual did not include written policy or procedure detailing how the laboratory is to address, document, and handle complaints or problems reported to the laboratory. 2. Interview with Personnel 2 on January 9, 2018 revealed she was unaware of all the policies and procedures that were required. Personnel 2 confirmed the laboratory did not have a complete policy and procedure manual.</p>
D5207	<p>COMMUNICATIONS CFR(s): 493.1234</p> <p>The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. Interview with Personnel 2 on January 9, 2018 revealed she was unaware of all the policies and procedures that were required. Personnel 2 confirmed the laboratory failed to have a complete policy and procedure manual.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Interview with Personnel 2 on January 9, 2018 confirmed the laboratory failed to have a detailed written policy and procedure that included the six (6) mandated items.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies

and procedures for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) what steps to take if corrective action is needed. Quality Control to include: a) What Quality Control material is going to be utilized for testing and reporting of Arterial Blood Gas (ABG). b) How many levels of Quality Control are to be performed. c) What the acceptability Criteria will be for accepting quality control results. d) What corrective action to take when quality control fails to meet the acceptability criteria. Quality Assurance (QA) to include: a) What is being done to ensure quality of testing b) Who is performing quality checks c) Frequency and documentation of quality checks Record Retention 2. Interview with Personnel 2 on January 9, 2018 revealed she was unaware of all the written policies and procedures needed in the laboratory. Personnel 2 confirmed the policy and procedure manual was incomplete.

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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. 2. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5207. 3. The laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Refer to D5209. 4. The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D5401.