

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0982971	(X3) Date Survey Completed 04/19/2018
Name of Provider or Supplier Louisiana Gastroenterology Associates, Llc	Street Address, City, State 1211 Coolidge Blvd, Suite 303, Lafayette, 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	AN INITIAL CERTIFICATION SURVEY was performed at Gastroenterology Clinic of Acadiana - CLIA # 19D0982971 on April 19, 2018. Gastroenterology Clinic of Acadiana was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1487 CONDITION: Testing Personnel performing high complexity testing.
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 laboratory failed to have written policies and procedure for addressing complaints and problems reported to the laboratory. The policy should include a detailed procedure on how to address, document and handle complaints or problems reported to the laboratory. 2. Interview with the Laboratory Director on April 19, 2018 confirmed the laboratory failed to 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 problems associated with a breakdown in communication between the laboratory and authorized persons. 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 the Laboratory Director on April 19, 2018 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 testing personnel 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 the Laboratory Director on April 19, 2018 confirmed the laboratory failed to have a detailed written policy and procedure that included the six (6) mandated items for personnel competency.

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 ensure the laboratory policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory

	<p>policy and procedure manual revealed the laboratory failed to have policies and procedures for: Test Requisitions: what mandated information needs to be on the test requisition: a) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. b) The patient's name or unique patient identifier. c) The sex and age or date of birth of the patient. d) The test(s) to be performed. e) The source of the specimen, when appropriate. f) The date and, if appropriate, time of specimen collection. g) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. Description of the course of action to take if a test system becomes inoperable. Record Retention policies 2. Interview with the Laboratory Director on April 19, 2018 confirmed the policy and procedure manual was incomplete</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that a complete approved policy and procedure manual is available to all personnel responsible for any aspect of the testing process. Refer to D5205, D5207, D5209 and D5401.</p>
<p>D6168</p>	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to ensure testing personnel met the qualifications of education and licensure to perform high complexity testing. Findings: 1. The laboratory failed to have a current license issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow testing personnel to perform high complexity testing for one (1) of one (1) testing persons performing high complexity testing. Refer to D6170. 2. Interview with the Laboratory Director and Testing Personnel confirmed the above findings.</p>
<p>D6170</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a)</p> <p>Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the laboratory failed to have a current license issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow testing personnel to perform high complexity testing for one (1) of one (1) testing persons performing high complexity testing. Findings: 1. Review of the Laboratory's Test Menu revealed testing personnel performed gross examination of tissue which is categorized as high complexity. 2. Review of Testing Personnel records revealed no documentation of a State License to perform gross examinations. 3. Interviews with the Laboratory Director and Testing Personnel on April 19, 2018 revealed they were unaware that individual performing gross examinations needed to have a State License from the Louisiana State Board of Medical Examiners (LSBME). Both the Laboratory Director and Testing Personnel confirmed that the Testing Personnel did not have a State License for performing gross examinations.