Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2197452	02/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Emergent Testing Lab Dba Lux Enterprise	13 Corporate Boulevard, Ne, Suite 100, Brookhaven, GA	

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 CLIA complaint investigation and an initial inspection was performed on February 22, 2022. The complaint findings were not substaniated. Based on the CLIA initial survey this facility was found not to be in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.
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 review of the laboratory procedure manual (SOP), quality assurance (QA) policy and interviews with staff and laboratory director, the laboratory failed to have an adequate (QA) policy to assess, evaluate, monitor and correct problems in the laboratory as required by CLIA. The findings include: 1. Review of QA records revealed that the laboratory's current QA policy does not indicate the necessary steps to identify and correct problems. Corrective actions and QA activities were not documented in the laboratory to reflect all phases of testing (Pre analytic, Analytic and Post Analytic phases) in 2021 and 2022. 2. An interview with the laboratory director and lab manager on 02/22/2022 at approximately 3:00 PM in the review room confirmed that the laboratory had no adequate QA in policy 2021 and 2022.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the

	effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA documents review revealed the lack of a QA checklist and documentation in 2021 and 2022. 2. During interviews with the Laboratory Director and lab manager on 02/22/2022 at 3:15 PM in the conference room confirmed the lack of an adequate QA checklist and documentation in 2021 and 2022.
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: Based on laboratory review and interview with the laboratory director(LD), the LD failed to document and oversee the overall quality assessment process as required for a high complexity laboratory. Findings include: 1. Documents review of the overall quality assessment revealed the lab director did not implement a robust quality assessment procedure or process in 2021 and 2022. 2. Interviews with LD and lab manager on 02/22/2022 at approximately 03:20 PM in a conference room confirmed the lack of a robust quality assessment process thus far by the lab director.