Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0982961	06/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
East Georgia Diagnostic Services, Inc	333 South Walnut Street, Statesboro, 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 Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on, June 26, 2023. Condition and Standard level Citations were found. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: Condition D6076 493.1441
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the Policy and Procedure AP301APP3 Potential For Biohazard Exposure-Exercise Universal Precautions, the laboratory had no documentation demonstrating that Testing Personnel (TP) 1 and 2 have been monitoring for the Permissible Exposure Levels for Formaldehyde. Findings: 1. Review of the Policy and Procedure AP301APP3 Potential for Biohazard Exposure-Exercise Universal Precautions, page 1, paragraph 3. Definitions, Permissible Exposure Level (PEL), sixth bullet point, states exposure monitoring (every 6 months) Short Term Exposure Level (STEL), sixth bullet point states, Exposure monitoring (annual) Action Level (AL), second bullet point states, exposure monitoring (every 6 months) 2. Interview with TP-1, TP-2, on 06/26/2023 at approximately 4 pm, in the office, confirmed that there was no documentation showing that the monitoring had been performed.
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 the review of the Policy / Procedure, and staff interview, the laboratory failed to follow the policy AP302APP3 Formaldehyde Program Potential for Biohazard Exposure-Exercise Universal Precautions. The laboratory failed to follow the Policy for monitoring the levels for Formaldehyde exposure for the Testing Personnel (TP) for 2022 to 06/26/ 2023. Findings: 1. There were no documents demonstrating the laboratory had performed the Formaldehyde Program to monitor the levels for exposure to Formaldehyde. 2. Interview with the TP-1 and TP-2, on 06 /26/2023, at approximately 4 pm, in the Laboratory Office, confirmed the above aforementioned statement.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Testing Personnel (TP) competency assessments and staff interview the Laboratory Director (LD), filling the Technical Supervisor (TS) job, failed to perform annual competencies on either of the TP-1 and TP-2 for the year 2022. The 2023 competencies were completed. Reference D6079
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the Testing Personnel (TP) competencies, and staff interview, the Laboratory Director(LD) failed to perform competency assessments for 2022. The LD had performed TP competencies in 2023. Findings: 1. Review of the Competency Assessments for the two TP, there was a competency assessment for TP-1 and TP-2 in 2023, but not for either TP-1 or TP-2 for 2021 2. Interview with the TP-1 and TP-2 on June 26, 2023 at approximately 4 pm in the office, confirmed to the aforementioned statement.