Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2130154	09/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Global Diagnostic Labs, Llc	4960 Peachtree Industrial Boulevard Suite 220, Norcross, 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) survey was completed on September 9, 2020. The laboratory was found not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records and an interview with the Laboratory Director (LD), the laboratory failed to enroll in a CMS-approved proficiency test (PT) program or peer review as required by Clinical Laboratory Improvement Amendments (CLIA) for the specialty of General Immunology from October 2018 through September 2020. The findings include: 1. Review of laboratory PT records revealed the laboratory was not enrolled in a PT program or peer review for the specialty of General Immunology from October 2018 through September 2020. 2. The laboratory did not have any PT records or peer views for their allergen assay. 3. The Laboratory Director confirmed on 09/09/2020 at 10:30 AM in the conference room, that the facility was not enrolled in a CMS- approved PT program or peer review for the specialty of General Immunology.

D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory supervisor, the laboratory failed to retain quality control, proficiency test, and maintenance records from October 2018 through September 2020. The findings include: 1. The laboratory had no records of their proficiency test or peer review data for their allergen assay. 2. The laboratory was unable to provide quality control data for all test performed in the laboratory.. 3. The laboratory was unable to provide maintenance records for all laboratory equipment. 4. An interview with the Laboratory Director in the conference room on 09/09/2020, at 11:30 AM, confirmed that the laboratory did not maintain quality control, proficiency test, and maintenance records for October 2018 through September 2020.
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: A review of the personnel records and interview with the testing personnel (TP), determined that the laboratory failed to establish a written policy that assess employee competency for their allergen assay performed in the laboratory from their allergen test assay. The findings include: 1. The laboratory failed to have a written policy and procedure to assess competency based on the position responsibilities on an initial, semi-annual, and annual bases. 2. An annual competency assessment was not performed for any of the staff from October 2018 through September 2020 for their allergen assay. 3. An interview with the Laboratory Director in the conference room on September 9, 2020, at 11:30 AM, confirmed that the laboratory did not have a written policy for assessing employee competency for the test performed in the laboratory.
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 surveyor review of laboratory records and interview with the Laboratory Director, the laboratory failed to establish a written quality assessment (QA) to

	monitor, assess, and correct problems in the general laboratory system for quality assessment. The laboratory did not have a written quality assessment policy that encompasses all facets of the laboratory's technical and non-technical functions. 1. The laboratory failed to have a QA that assess patient confidentially, specimen integrity and identification, complaint, corrective actions, proficiency test performance, and personnel competency. 2. The laboratory does not have a written QA policy or any records of QA being performed from October 2018 through September 2020. 3. The Laboratory Director confirmed on September 9, 2020, at 12: 15 PM in the conference room, that the laboratory did not have a written and established QA policy for the laboratory.
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 review of the laboratory procedure manual (SOP), quality assurance (QA) records, and interview with the testing personnel the laboratory failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the laboratory. Th findings include: 1. Review of QA records revealed that the laboratory's current QA policy does not indicate the necessary steps to be taken to identify and correct problems, nor efforts to prevent recurrences and necessary procedures to prevent reoccurrence of problems in the laboratory. Corrective actions are being performed in the laboratory but are not documented. 2. The testing personnel confirmed on 09/09/2020, at 12:30 PM, in the laboratory, that the laboratory is performing corrective actions but not documenting them. TP#1 also confirmed that the QA policy does not adequately assess and identify problems in the laboratory.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on survey review of laboratory records and observation, the laboratory failed to have a written procedure for specimen rejection and the labeling of specimens. The findings include: 1. A review of the laboratory procedure manual and interview with testing personnel, the laboratory failed to have a written procedure for the criteria for specimen rejection for all test performed in the laboratory from October 2018 through September 2020. 2. An interview with the Laboratory Director in the confrence room,

	on 09/09/2020 at 11:30 AM, confirmed that the laboratory did not have a written procedure for specimen rejection or labeling of specimens.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory procedure manual and interview on with General Supervisor, the laboratory failed to establish a client services manual with written instructions to each client that sends specimens/test requests to the facility. The findings include: 1. The laboratory does not have a written policy and procedure manual to instruct their clientele how to send patient specimens and request test from the facility from October 2018 through September 2020. 2. The instructions may contain information on specimen handling (e.g., collection, preservation, storage, transport, testing schedule times and how to obtain additional assistance for unusual circumstances). 3. The Laboratory Director confirmed on 09/09/2020 at 12:30 PM in the conference room, that the laboratory does not have a written policy and procedure manual to instruct their clientele how to send patient specimens and request test from the facility.
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: The laboratory failed to monitor and evaluate the overall quality of the analytic systems in regard to the procedure manual, maintenance and function checks, calibration verification, and control procedures for all instrumentation present in the laboratory. (Refer to D5401 and D5421)
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 surveyor review of the laboratory procedure manual and interview with the

	Laboratory Director, the laboratory failed to establish a written policy for all tests performed in the laboratory. The findings include: 1. Review of the laboratory's policy and procedure manual revealed no evidence of a written procedure for all test performed in the laboratory. 2. The Laboratory Director confirmed on 09/09/2020 at 12:30 PM in the office, that the laboratory does not have a written procedure for all test performed in the laboratory from October 2018 through September 2020.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, it was determined that the laboratory failed to meet analytic system requirements for their allergen assay from September 2018 through September 2020. 1. The laboratory verification process failed to provide a written description that documents all actions required to validate their allergen test assay with CLIA requirements. The laboratory must describe how each test is validated with statistically significant verification for accuracy, precision, analytical specificity, analytical sensitivity, reportable range and reference ranges. 2. The laboratory failed to provide statistically significant data that validated the accuracy, precision, analytical specificity, and analytical sensitivity for their allergen assay. The laboratory had no records for the validation or correlation data for their allergen assay. 3. The laboratory failed to provide validation and linearity records for their own reportable ranges and reference ranges for their allergen assay. 4. The laboratory limits of detection are not supported by the data provided by the laboratory and failed to establish lower and upper limits of detection for all tests performed in the laboratory. 5. An interview with the Laboratory Director on 09/09/2020 at 1:00 PM in the confrence room, confirmed that the laboratory failed to meet specifications for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference interval (normal range) for all tests performed in the laboratory.
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 surveyor record review and interview it was determined the Laboratory Director failed to ensure adequate validation and verification of test methods that were used to establish their allergen assay. The Laboratory Director failed to ensure that the quality control (QC) and quality assessment (QA) programs were maintained appropriately. (Refer to D6082)

D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and an interview with testing personnel (TP), The Laboratory Director (LD) failed to provide statistical data that validated the accuracy, precision, analytical specificity, and analytical sensitivity of their allergen assay. The findings include: 1. The laboratory verification process failed to provide a written description that documents all actions required to validate their allergen test assay with CLIA requirements. The laboratory must describe how each test is validated with statistically significant verification for accuracy, precision, analytical specificity, analytical sensitivity, reportable range and reference ranges. 2. The laboratory failed to provide statistically significant data that validated the accuracy, precision, analytical specificity, and analytical sensitivity for their allergen assay. The laboratory had no records for the validation or correlation data for their allergen assay. 3. The laboratory failed to provide validation and linearity records for their own reportable ranges and reference ranges for their allergen assay. 4. An interview with the Laboratory Director, on 09/09/2020 at 1:00PM in the confrence room, confirmed that the laboratory failed to meet specifications for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference interval (normal range) for all tests performed in the laboratory.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of personnel records and interview with the Laboratory Director (LD), the Technical Supervisor failed to assess the six competency assessment criteria for testing personnel for the specialty of General Immunology. The findings include: 1. A review of testing personnel records revealed that a comprehension assessment was performed for laboratory procedures and skills evaluation, but the assessment did not address the six competency assessment criteria for their allergen assay procedures. 2. An interview with the Laboratory Director in the conference room, on 09/09/20 at 11:30 AM, confirmed that annual competencies did not contain the six competency assessment criteria for testing personnel for the specialty of General Immunology from October 2018 through September 2020.