Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2218021	08/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lablinq Diagnostics	874 West Lanier, Suite 250-Lab, Fayetteville, 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	The Georgia State Department of Community Health performed a complaint investigation at the LabLINQ laboratory located at 874 West Lanier, suite 250; Fayetteville, Ga. 30214 on August 24, 2021. The complaint was substantiated. The laboratory was not in compliance with applicable CLIA regulations. The following condition level deficiencies were found : D2000, D5010, D5014, D5200, D5300, D5400, D5800, and D6076.
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 the lack of proficiency testing (PT) documentation and video conference interview with a compliance officer for Lablinq , the laboratory failed to enroll in a proficiency testing (PT) program. Findings include: 1. The lab was unable to produce PT documentation at the time of the survey. 2. Video conference interview with the compliance officer assigned to the survey team, on 8/24/21, at approximately 11:15 AM, confirmed the lab was not enrolled in a PT program at the time of the survey.
D5010	VIROLOGY CFR(s): 493.1205

	If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the lack of a standard operating procedure (SOP) manual and video conference interview with a compliance officer for Lablinq, the laboratory failed to have procedures for the subspecialty of virology. Findings include: 1. The lab was unable to produce procedures for the subspecialty of virology at the time of the survey. 2. Video conference interview with the compliance officer assigned to the survey team, on 8/24/21, at approximately 11:22 AM, confirmed the lab did not have procedures for the subspecialty of virology at the time of the survey.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the lack of a standard operating procedure (SOP) manual and video conference interview with a compliance officer for Lablinq, the laboratory failed to have procedures for the subspecialty of general immunology . Findings include: 1. The lab was unable to produce procedures for the subspecialty of general immunology at the time of the survey. 2. Video conference interview with the compliance officer assigned to the survey team on 8/24/2, at approximately 11:15 AM, confirmed the lab did not have procedures for the subspecialty of general immunology at the time of the survey.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on lack of documents and subsequent staff interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems for each specialty and subspecialty of testing performed as required. Findings include: For details refer to D5291
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 Center for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvements Amendments (CLIA) Application for Certification form (CMS 116), lack of laboratory records, and staff interview, the laboratory failed to verify the accuracy of testing done in virology or general immunology for SARS-CoV-2. Findings include: 1. Review of the CMS 116 revealed the laboratory performs 500 virology tests and 50 general immunology tests per year. 2. The lab was unable to produce records to verify the accuracy of testing done for the subspecialty of virology or general immunology at the time of the survey. 3. Video conference interview with the compliance officer assigned to the survey team on 8/24/21, at approximately 11:22 AM, confirmed the lab did not have documents to verify the accuracy of testing for the subspecialty of virology and general immunology at the time of the survey.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the lack of a laboratory policy and procedure manual (SOP), lack of testing accuracy, and staff interview, at the time of survey, the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as required. Findings include: For details refer to D5391
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the lack of a laboratory policy and procedure manual (SOP), lack of testing accuracy, and staff interview, at the time of survey, the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as required. Findings include: 1. The laboratory failed to provide documents of a SOP, or testing accuracy for an ongoing program to monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as required. 2. Video conference interview with the compliance officer assigned to the survey team on 8/24/21, at approximately 11:30 AM, confirmed the lab did not have the aforementioned documents at the time of the survey.

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: Based on the lack of the laboratory policy and procedure manual (SOP), lack of quality control (QC) and maintenance documents, and staff interview, at the time of survey, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as required. Findings include: For details refer to D5401, D5429, D5441, and D5423
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 lack of a standard operating procedure manual (SOP) and staff interview, the laboratory director (LD) failed to ensure an approved SOP was available, at the time of survey, as required. Findings include: 1. The laboratory was unable to provide an approved SOP at the time of the survey. 2. Video conference interview with the compliance officer assigned to the survey team on 8/24/21 at approximately 11:30 AM, confirmed the lab did not have an approved SOP at the time of the survey.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation, lack of documentation, and staff interviews, the laboratory

	failed to establish performance specifications (validation) prior to patient testing for the LuminUltra GeneCount Q-96 (quantitative Polymerase Chain Reaction (qPCR)), and the three (3) LuminUltra GeneCount E-32 auto purification instruments for use in the detection of Sars-Cov-2 ribonucleic acid (RNA) and for the Eppendorf Xplorer Plus auto pipet. Findings include: 1. Observation during the initial lab tour on 8/24/21, at approximately 10:40 am, revealed: 1- Air Science Hood (no installation date or certification date indicated); 1- LuminUltra GeneCount Q-96 (SN# MDW6.6.19E-651614); 3- LuminUltra GeneCount E-32 auto purification instruments (E-1: SN#MDW6.637E-155, E-2:SN#MDW6.637E-152; E-3:SN#MDW6.637E-154); 1-Eppendorf Xplorer Plus auto pipet. 2. Observation during the same lab tour, revealed several pages of a transport log system, recording dates and times specimens were received at this facility. 3. The laboratory was unable to provide documentation of install dates or validation data at the time of the survey. 4. Video conference interview, with the compliance officer assigned to the survey team on 8/24/21, at approximately 11:04 AM, confirmed the lab did not have the aforementioned documents requested at the time of the survey. 4. In person, phone, and video interviews revealed the lab was performing and resulting patient test results prior to establishing performance specifications. Interviews were performed by 2 State of Georgia Department of Community Health (DCH) compliance specialists and the DCH Diagnostics Services Director. * In person interview with the mobile unit laboratory supervisor, located at 803 Forest Parkway, Forest Park, Georgia on 8/24/21 at approximately 11 AM, indicated patient testing was performed at the lab located in Fayetteville, Georgia. Statement made to the Georgia DCH Diagnostic Services director, indicated specimens were only sent to the mobile lab when the testing personnel was not available to perform the testing at the Fayetteville lab. * Video interview with the compliance officer assigned to the survey team on 8/24/21 at approximately 11:45 AM, indicated patient testing began in April 2021, but was stopped late August due to contamilation. *Phone interview with a co-owner on 8/24 /21 at approximately 12 PM, indicated patient testing began May 2021.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the lack of analyzer maintenence documents and staff interview, at the time of survey, the laboratory failed to perform and document maintenance on the test systems as defined by the manufacturer. Findings include: 1. The laboratory failed to provide documents of test systems maintenance. 2. Video conference interview with the compliance officer assigned to the survey team on 8/24/21, at approximately 11:30 AM, confirmed the lab did not have the aforementioned documents at the time of the survey.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials

	using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of analyzer Quality Control (QC) documents and staff interview, at the time of survey, the laboratory failed to perform and document QC on the test systems. Findings include: 1. The laboratory failed to provide QC documents performed on the test systems used for SARS COV-2 patient testing. 2. Video conference interview with the compliance officer assigned to the survey team on 8/24 /21, at approximately 11:30 AM, confirmed the lab did not have the aforementioned documents at the time of the survey.
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 deficiencies found during a complaint investigation on 8/24/21, the lab director failed to provide overall management and direction to the laboratory. Findings include: For details see D2000, D5010, D5014, D5200, D300, D5400, D6094, D6095, D6102
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the lack of Quality Management (QM) Manual, the laboratory director failed to ensure quality assesment programs for the equipment used in the detection of SARS-COV-2 were established and followed. Findings include: 1. The laboratory was unable to provide an approved QM manual at the time of the survey. 2. Video conference interview, with the compliance officer assigned to the survey team on 8/24 /21, at approximately 12:30 PM, confirmed the lab did not have an approved QM manual at the time of the survey.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable

	levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on observation, lack of documentation, and staff interview, the laboratory director failed to ensure performance specifications (validation) were established for the LuminUltra GeneCount Q-96 (quantitative Polymerase Chain Reaction (qPCR)), and the three (3) LuminUltra GeneCount E-32 auto purification instruments for use in the detection of Sars-Cov-2 ribonucleic acid (RNA). Findings include: For details refer to D5423
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the lack of training documents, and staff interview, the lab director failed to ensure testing personnel were appropriately trained prior to performing patient testing. Findings include: 1. The laboratory was unable to provide training documents for the testing personnel on the CMS-209. 2. Video conference interview with the compliance officer assigned to the survey team on 8/24/21 at approximately 2:30 PM, confirmed the lab did not have training documents at the time of the survey.