

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2192795	(X3) Date Survey Completed 10/18/2021
Name of Provider or Supplier Lablnq Diagnostics/Mobile	Street Address, City, State 3540 Toringdon Way, Charlotte, NC	
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 Lablnq Mobile Lab, currently located at 803 Forest Parkway, Forest Park, Georgia 30297 on October 18, 2021. The Laboratory was not in compliance with applicable CLIA requirements. The following condition level deficiencies were found: D5300 - 493.1241 Condition: Pre-analytic systems D5400 - 493.1250 Condition: Analytic systems D6076 - 493.1441 Condition: Laboratory Performance of High Complexity Testing: Laboratory Director
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the SOP.0100, LuminUltra GeneCount COVID-19 RT-qPCR Assay Test Procedure (Assay Procedure) and staff interview, the laboratory failed to list saliva as a specimen sample type in the Assay Test Procedure. Refer to: 1. D5311- The laboratory failed to list saliva as a specimen sample in the Assay Test Procedure. 2. D5393 - The laboratory director failed to review and sign the policy.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)</p>

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 review of the SOP.0100, LuminUltra GeneCount COVID-19 RT-qPCR Assay Test Procedure (Assay Procedure) and staff interview, the laboratory did not list saliva as a specimen sample type in the Assay Test Procedure. The laboratory did not provide any documentation of specimen storage, preservation, conditions for specimen transport, or specimen integrity for the specimen type saliva. Findings: 1. The Assay Procedure list the patient sample type as nasopharyngeal/oropharyngeal. 2. Interview with staff #4 (CMS 209 Personnel Form) on October 18, 2021, at approximately 11:45 am in the mobile unit, located in Forest Park, Georgia, confirmed that testing was being performed on both nasopharyngeal and saliva samples.

D5393

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(b)(c)

The preanalytic systems 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 preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:
Based on the review of the Preanalytic Systems Assessment Policy and Procedure manual, the laboratory director failed to review and sign the policy. Findings: 1. The Laboratory Quality Assessment Policy was unsigned/not approved by the laboratory director, at the time of the complaint investigation. 2. The Quality Assessment Policy, received from the Quality Manager, on 10/18/2021, by email, confirmed that the laboratory did not have an approved policy.

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 review of the validation report for the LuminUltra GeneCount Q-96 (SN: MDW6.6 19E-651372) and the LuminUltra GeneCount E-32(#10) instruments, that were in service at the time of the complaint investigation, the laboratory failed to provide documentation of instrument testing and sample specifications, as documented in the Laboratory General Standard Operating Procedures (SOP.0008.02)

	<p>or evidence of the laboratory director approval, before initiating testing in the detection of Sars-Cov-2 ribonucleic acid (RNA) Refer to: 1. D5401- The laboratory failed to provide SOP documents specifically written for the mobile unit. 2. D5407- The laboratory failed to provide SOP documents that were signed as reviewed and accepted by the current Laboratory Director (LD). Refer to D5401 3. D5423-The laboratory failed to establish initial performance specifications (validation) prior to patient testing for the LuminUltra GeneCount Q96 (Q-96) (serial #MDW6.6.19E-651372), and the 10 LuminUltra GeneCount E-32 (E-32). Refer to D5401</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Standard Operating Policies (SOP), the laboratory failed to provide SOP documents written specifically for the mobile unit, located in Forest Park, Georgia at the time of the complaint investigation . Findings: 1. Review of the Standard Operating Policies and Procedure documents and staff notification, the policy and procedures were written as laboratory general SOPs, as stated in the header of the procedures and were not specific for the Mobile unit (VIN # 4fGB44531KC151921) located in Forest Park, Georgia. 2. SOP document review, received by email, on 10/18/2021, at 2:28 pm, from the Quality Management Manager, confirmed that the policies were not specific to the Mobile unit (VIN # 4fGB44531KC151921) located in Forest Park, Georgia.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Standard Operating Policies (SOP), the laboratory failed to provide SOP documents that were signed as reviewed and accepted by the current Laboratory Director (LD). Findings: 1. Review of the Document Details Page for each Policy in the SOP, the LD's name had been typed in, but not signed or dated electronically or manually. There is no date entered in the Implementation Date field. 2. SOP documents were received by email, after the onsite investigation, on 10/18 /2021, at 2:28 pm, from the Quality Management Manager.</p>
<p>D5423</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>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</p>

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 document review of the Method Validation Procedure (SOP.0008.02), and staff interview, the laboratory failed to establish initial performance specifications (validation) prior to patient testing for the LuminUltra GeneCount Q-96(Q-96) (serial # MDW6.6.19E-651372), and the 10 LuminUltra GeneCount E-32 (E-32). Findings: 1. Review of the General Laboratory Policy SOP.0008.02, the reference points stated in the SOP.0008.02 were not addressed in the provided validation documents. 2. The raw data validation spreadsheets provided confirmed that the laboratory did not follow their laboratory validation policy. 3. The laboratory validation policy states that a signed, validation summary report should be included with the validation report. The policy indicates that the validation report should include validation/verification review and approval by the laboratory director for each test, intended for clinical use, prior to initiating patient testing. 4. Interview with staff #4 (CMS 209 Personnel Form), on October 18, at approximately 11:30am, in the mobile unit, located in Forest Park, Georgia stated that the validation procedure consisted of correlation studies between a validated Q-96 analyzer and there were no validations required for the 10 E-32 analyzers. Staff #4 also verified that patient testing started around April 15, 2021. 5. SOP documents and validation documents were received by email, on 10/18/2021, by the Quality Management Manager.

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 policy and procedure manual and staff interview, the laboratory director failed to approve testing and sample specifications for saliva testing and sign the procedure manual. Refer to: 1. D6095-The laboratory director failed to approve testing and sample specifications for saliva. 2. D6106- The laboratory director failed to sign procedure manual.

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 review of the Standard Operation Procedures, and staff interview, the laboratory director failed to ensure and approve testing and sample specifications for

saliva on the LuminUltra GeneCount Q-96 or the 10 LuminUltra GeneCount E-32 (E-32) auto purification instruments for the use in the detection of Sars-Cov-2 ribonucleic acid (RNA). 493.1445(e)(6) Refer to: D5423

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on review of the policy and procedure manual and staff interview, the laboratory director failed to approve and sign each policy and procedure manual for SARS-CoV-2 before testing began in April 2021. Refer to: D5407