

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2192795	(X3) Date Survey Completed 10/13/2020
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	<p>Complaint investigations were conducted simultaneously in North Carolina and Minnesota 10/13/20. The North Carolina investigation was conducted at 839 Majestic Court Suite 3, Gastonia, NC 28054. There was no operational laboratory with CLIA #34D2192795 found at this location. The Minnesota investigation was conducted in a laboratory in an RV (recreational vehicle) located in a parking lot at 202 Industrial Park, Jackson, MN 56143. The laboratory performed COVID-19 testing at this Minnesota location under CLIA #34D2192795. The deficiencies cited were identified at this location.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:</p> <ul style="list-style-type: none"> . Based on review of laboratory policies and procedures, quality control logs, direct observation and interview with laboratory personnel, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings are as follows: 1. The laboratory failed to include a procedure in the procedure manual for one of one tests performed by the laboratory. See D5401 2. The laboratory failed to document storage temperatures for test cartridges for one of one tests performed by the laboratory. D5413 3. The laboratory failed to establish performance specifications for one of one tests performed by the laboratory. See D5423. 4. The laboratory failed

to perform quality control procedures for one of one tests performed by the laboratory each day of patient testing. See D5445. The cumulative effect of the deficient practices constitutes Condition-level noncompliance. .

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 observation, document review and interview with laboratory personnel, the laboratory failed to include a procedure in the procedure manual for one of one tests performed by the laboratory. Findings are as follows: 1. The laboratory performed COVID serology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 10/13/20, at 8:15 a.m. 2. Test cassettes for COVID-19 IgG / IgM Rapid Test Cassette (Whole Blood / Serum / Plasma), Product Number: GCCOV-402a, Lot Number: 2005213, Expiration Date: 2022-04-30, Manufacturer: Zhejiang Orient Gene Biotech, LTD were observed as present and available for use during a tour of the laboratory. 3. During an interview on 10/13/20 at 8:15 a.m., TP1 confirmed that the product noted above was currently being used for COVID serology testing. 4. A written procedure for COVID-19 IgM / IgG Antibody Testing was not found during the survey. The laboratory was given an opportunity to provide the procedures. 5. The test procedures (Approved Test Kits: Healgen Rapid IgG/IgM Antibody Cassette & Rightsign Rapid Antibody Cassette) noted in the procedure manual (COVID-19 LABORATORY POLICIES AND PROCEDURES, Author: Align Lab Services, Lasted Updated: July 27, 2020) provided did not correspond to the actual test kit found in the laboratory. .

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to document storage temperatures for test cartridges for one of one tests performed since date testing was initiated to date of survey. Findings are as follows: 1. The laboratory performed COVID serology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 10/13/20, at 8:15 a.m. 2. Test cassettes for COVID-19 IgG / IgM Rapid Test Cassette (Whole Blood / Serum / Plasma), Product Number: GCCOV-402a, Lot Number: 2005213, Expiration Date: 2022-04-30, Manufacturer: Zhejiang Orient Gene Biotech, LTD were observed as

present and available for use during a tour of the laboratory. 3. The laboratory facility was observed to be a non-motorized recreational vehicle. TP 1 stated that the laboratory environment was not being actively climate controlled, either during or outside of normal hours of operation. 4. Test cassette outer packaging indicated the storage temperature defined by the manufacturer as being 2-30C. 5. Storage temperature documentation was not found in laboratory records. The laboratory was unable to provide the missing records upon request. 6. During an interview on 10/13 /20 at 8:15 a.m., TP1 stated that test cassettes were stored in a cooler, but that storage temperatures in the cooler were not monitored or recorded. .

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, document review and interview with laboratory personnel, the laboratory failed to establish performance specifications for one of one tests performed. Findings are as follows: 1. The laboratory performed COVID serology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 10/13/20, at 8:15 a.m. 2. Test cassettes for COVID-19 IgG / IgM Rapid Test Cassette (Whole Blood / Serum / Plasma), Product Number: GCCOV-402a, Lot Number: 2005213, Expiration Date: 2022-04-30, Manufacturer: Zhejiang Orient Gene Biotech, LTD were observed as present and available for use during a tour of the laboratory. 3. In a 11/02/20 email communication between the CMS Chicago Regional Office and the Food and Drug Administration (FDA), it was confirmed that the test method observed as being in use during the tour of the laboratory did not possess a current and valid Emergency Use Authorization (EUA), and thus is classified as being a High Complexity test method 4. Laboratory performance specification (PS) studies were not available during a tour of the laboratory. The laboratory was given an opportunity to provide the PS studies. 5. In three emails received on 10/21/20, the PS studies were not provided by Individual 4 (I 4), who was listed on the Laboratory Personnel Report (CLIA), Form CMS-209, as holding the role of Technical Supervisor. .

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when

they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to perform quality control procedures for one of one tests performed by the laboratory each day of patient testing. Findings are as follows: 1. The laboratory performed COVID serology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 10/13/20, at 8:15 a.m. 2. Test cassettes for COVID-19 IgG / IgM Rapid Test Cassette (Whole Blood / Serum / Plasma), Product Number: GCCOV-402a, Lot Number: 2005213, Expiration Date: 2022-04-30, Manufacturer: Zhejiang Orient Gene Biotech, LTD were observed as present and available for use during a tour of the laboratory. 3. The Quality Control (QC) section of the manufacturer's Instruction For Use (IFU - Document # B21886-01, Revision Date: 2020-03-26) revealed that control standards were not supplied with the kit. 4. During an interview on 10/13/20 at 8:15 a.m., TP1 stated the laboratory did not obtain external control materials, and did not analyze this type of external QC material during each day of patient testing. .

D6141

GENERAL SUPERVISOR
CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:

. Based on review of education documents and interview with laboratory personnel, the laboratory failed to ensure one of one Immunology General Supervisor met the qualification requirements of 493.1461. Findings are as follows: The laboratory failed to ensure the Immunology General Supervisor (GS) met the qualification criteria required to perform GS responsibilities. See D6143. .

D6143

GENERAL SUPERVISOR QUALIFICATIONS
CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii)

Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to ensure one of one General Supervisor (GS) met the qualification criteria required to perform GS responsibilities. Findings are as follows: 1. The laboratory performed COVID-19 IgG / IgM antibody testing under the subspecialty of Immunology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 10/13/20, at 8:15 a.m. 2. Individual 5 (I 5) was listed on the Laboratory Personnel Report (CLIA), Form CMS-209, as holding the role of General Supervisor. 3. Laboratory records revealed that I 5 was responsible for Immunology General Supervisor activities from the date of the Certificate of Registration (9/24/20) through date of survey. 4. Education credentials were not available on-site for the GS on date of survey. The laboratory was given an opportunity to provide the education credentials. Education credentials received via email on 10/21/20 from Individual 4 (I 4), who was listed on the Laboratory Personnel Report (CLIA), Form CMS-209, as holding the role of Technical Supervisor, indicated that I 5 held a Bachelor of Science degree, but did not specify the required area(s) of study. .

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

. Based on review of education documents and interview with laboratory personnel, the laboratory failed to ensure personnel performing high complexity testing meet the qualification requirements of 493.1489. Findings are as follows: The laboratory failed to ensure all testing personnel met the qualification criteria to perform highly complex testing. See D6171 The performance of highly complex testing procedures by unqualified personnel constitutes Condition - level noncompliance. The laboratory performed an unknown number of high complexity tests annually. .

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and

storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to ensure 1 of 2 testing personnel met the qualification criteria required to perform high complexity testing. In addition, the laboratory failed to ensure 2 of 2 testing personnel received documented laboratory training for the high complexity testing they performed. Findings are as follows: 1. The laboratory performed COVID-19 IgG / IgM antibody testing under the subspecialty of Immunology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 10/13/20, at 8:15 a.m. 2. Training documents for 2 of 2 TP were not found during review of laboratory records. The laboratory was unable to provide training documents upon request. 3. Education credentials were not available on-site for 2 of 2 TP on date of survey. TP1 indicated she and TP2 were Register Nurses. The laboratory was given an opportunity to provide the education credentials. Education credentials received via email on 10/20/20 from TP1 confirmed 1 of 2 TP did not meet the minimum educational requirements needed to perform high complexity testing. 4. In three emails received on 10/21/20, the training documents for TP1 and TP2 were not provided by Individual 4 (I 4), who was listed on the Laboratory Personnel Report (CLIA), Form CMS-209, as holding the role of Technical Supervisor. .