Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2150941	01/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wake Diagnostics Inc	5129 Nc Highway 55, Suites 103-104, Durham, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of personnel records, and interview with the GS (general supervisor) 1/7/21, the laboratory failed to follow manufacturer's instructions for performing the FaStep COVID-19 IgG/IgM Rapid Test Device. Findings: 1. The FaStep COVID-19 IgG/IgM Rapid Test Device manufacturer's product insert states on page 2 "LIMITATIONS OF THE TEST 1. Use of the Fastep COVID-19 IgG/IgM Rapid Test Device is limited to laboratory personnel who have been trained. ..." The FaStep COVID-19 IgG/IgM Rapid Test Device manufacturer's product insert states on page 2 "Conditions of Authorization for the Laboratory ... 6. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product. ..." Review of personnel records revealed there were no training records available for 2 of 2 testing personnel (the technical supervisor and testing personnel #1) for the FaStep COVID-19 IgG/IgM Rapid Test Device. During interview at approximately 12: 10 p.m., the GS confirmed that the laboratory did not have any documented training for the FaStep COVID-19 antibody test. 2. The FaStep COVID-19 IgG/IgM Rapid Test Device manufacturer's product insert states on page 2 "Conditions of Authorization for the Laboratory ... 1. Authorized laboratories using your product will include the test test result reports, all authorized Fact Sheets. ..." During interview at approximately 1:15 p.m. the GS verified that the laboratory did not include

	appropriate Fact Sheets (Fact Sheet for Healthcare Providers or Fact Sheet for Recipients) with patient test reports.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, the absence of records, and interview with the GS (general supervisor) 1/7/21, the laboratory failed to either enroll in proficiency testing or establish a system to verify the accuracy of its COVID-19 PCR (polymerase chain reaction) testing at least twice a year. Review of the laboratory's policies and procedures revealed the laboratory did not have a proficiency testing procedure or a policy describing their process for verifying the accuracy of the COVID-19 PCR testing at least twice a year. There were no proficiency testing records available for review at the time of the survey. There were also no accuracy verification records available to indicate that the laboratory had a system in place to verify the accuracy of the COVID-19 PCR testing at least twice a year. During interview at approximately 10:10 a.m., the GS stated that they performed a split-sample comparison with another laboratory as part of their validation, but he verified that the laboratory was not enrolled in proficiency testing and had not established a system to verify the accuracy of the COVID-19 PCR testing at least twice a year.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the GS (general supervisor) 1/7/21, the laboratory procedures for processing patient specimens and reporting patient test results were not complete and/or current. The laboratory utilizes the LIMS ABC laboratory information system (LIS) for specimen

	accessioning and reporting of patient test results for COVID-19 PCR (polymerase chain reaction) testing. 1. The laboratory procedure for processing and accessioning patient specimens failed to include the laboratory's current process utilizing the LIMS ABC LIS. Review of laboratory procedure entitled "Collection, Storage, and Shipping of NP, AN and OP specimens." revealed " 3.8. Write the name and date of birth (identifiers) onto the patient sample transport vial. Ensure patient's name and date of birth match between the completed requisition and the transportation vial. 3.9. Place both the transport vial and the complete requisition in a biohazard bag to be shipped to Wake Toxicology laboratory." The procedure failed to include the laboratory's current method of processing patient specimens and generating accession numbers using the LIMS ABC LIS. Interview with the GS at approximately 11:40 a.m. confirmed the laboratory procedure for processing patient specimens was not complete and current. He stated the current procedure in the manual is for their collection sites. 2. The laboratory's procedure manual did not include the laboratory's current step-by-step processes for reporting patient COVID-19 test results to patients via the Patient Portal, to providers, and to the state/local health department. Interview with the GS at approximately 11:40 a.m. confirmed the procedure manual failed to include the current process for reporting patient test results. He stated that the laboratory currently reports patient test results using the LIMS ABS LIS, and he stated they are in the process of updating the procedure to include the current information.
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 the absence of laboratory information system (LIS) validation records and interview with the GS (general supervisor)1/7/21, the laboratory failed to verify the performance of the LIMS ABC LIS prior to routine use. Findings: There were no validation records available for the LIMS ABC LIS. Interview with the GS at approximately 11:30 a.m. revealed the laboratory began using the LIMS ABC LIS approximately December 15, 2020 for processing off-site collections and approximately December 21, 2020 for entering patient test results for COVID-19 PCR (polymerase chain reaction) testing. He stated he had correspondence with the LIS representative regarding the performance of the validation but he had not saved the data to demonstrate how the system was validated.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of 3 random patient test reports (specimen ID #201121246, #100529, and #101870) and interview with the GS (general supervisor) 1/7/21, the laboratory failed to ensure that 2 of 3 patient COVID-19 PCR (polymerase chain reaction) test reports indicated the name and address of the laboratory that performed the tests. Review of 3 random patient test reports (specimen ID #201121246, #100529, and #101870) revealed 3 of 3 included the laboratory's name and address. During interview at approximately 1:30 p.m., the GS stated that testing was performed at an outside laboratory for specimen ID #201121246 (collected 11/21/20 and reported 11 /22/20) and #100529 (collected 12/17/20 and reported 12/19/20). He stated specimens were sent to an outside laboratory 11/18/20-11/21/20 and 11/30/20, and to another outside laboratory 12/2/20-12/19/20. He stated the outside laboratories sent them the test results and they reported them. He verified the 2 patient test reports did not indicate that the testing was performed by another laboratory.
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 review of the laboratory's policies and procedures, the absence of records, and interview with the laboratory director and GS (general supervisor) 1/7/21, the laboratory director failed to ensure that an effective quality assessment program was established and maintained to assure the quality of laboratory services provided. Review of the laboratory's policies and procedures revealed the laboratory did not have a written quality assessment plan, including the process for documentation of problems and their resolution, the process for corrected reports, and steps to take if test systems are inoperable. There was no documentation of quality assessment activity available for review. During the exit interview at approximately 3:40 p.m. the laboratory director and GS stated the laboratory does have a quality assessment plan, but it might still be packed in a box due to the laboratory's recent move. The GS stated they had not documented any quality assessmenty activity.
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 review of personnel records and interview with staff 1/7/21, the laboratory director failed to ensure that prior to testing patient specimens, 2 of 2 testing personnel (the technical supervisor and TP #1) received appropriate training and had demonstrated that they could perform all testing operations reliably to provide and report accurate test results. Findings: Review of personnel records records revealed there were no training records available for 2 of 2 testing personnel (the technical supervisor and TP #1) for the SARS-CoV-2 Real Time PCR (polymerase chain reaction) testing performed by the laboratory. During interview at approximately 11: 55 a.m., the laboratory director and the GS (general supervisor) stated that their PCR training was done onsite by a molecular biologist at the time the test was validated in September 2020, but the training was not documented.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the GS (general supervisor) 1/7/21, the laboratory director failed to ensure that policies and procedures were established for monitoring the competency of all personnel for all phases of the testing and reporting process. Review of the laboratory's policies and procedures revealed there was no written policy or procedure describing the laboratory's process for evaluating the competency of supervisors and testing personnel including the frequency, the criteria used, the threshold for acceptability, and the steps to take if evaluations are not acceptable. During interview at approximately 12:20 p.m., the GS verified that they did not have a competency evaluation policy or procedure.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the GS (general supervisor) 1 /7/21, the laboratory director failed to specify in writing the duties and responsibilities for the TS (technical supervisor), the GS, and the TP (testing personnel). Findings: Review of personnel records revealed there were no job descriptions available for the laboratory director, the TS who also serves as TP, the GS, or TP #1. During interview

	at approximately 12:25 p.m., the GS confirmed that there was no job description or list of authorized duties and responsibilities available for any of the laboratory staff.
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 personnel records 1/7/21 and the deficiency cited at D6143, the laboratory failed to ensure that 1 of 1 general supervisors met the qualification requirements to serve as general supervisor in a high complexity laboratory.
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(1)(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 review of personnel records and interview with the GS (general supervisor) 1/7/21, the laboratory failed to ensure that 1/1 GS met the qualification requirements to serve as GS in a high complexity laboratory. Findings: Review of personnel records revealed there were no education records available for the GS. During interview at approximately 11:45 a.m., the GS confirmed his education records were not available for review. He stated they were probably packed in a box at his home because of the laboratory's recent move. He also stated that his education was obtained outside the United States and he had not had a credential evaluation performed.