Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0913723	04/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wilmington Health (Porters Neck - 8108)	8108 - B Market Street, Wilmington, 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 personnel records, review of instructions for use (IFU), and interview with technical consultant (TC) 4/26/21, the laboratory director (LD) failed to follow manufacturer's instructions for the SARS-CoV-2 testing performed to ensure 5 of 5 TP had received appropriate training for the performance of SARS-CoV-2 testing and to ensure authorized Fact Sheets for patients and providers were included with SARS-CoV-2 test result reports. The laboratory began testing for SARS-CoV-2 using the Quidel Sophia2 Flu and SARS test system and the Cepheid GeneXpert Xpress SARS-CoV-2 test system on 1/29/21. 1. The LD failed to ensure 5 of 5 TP received appropriate training for the performance of SARS-CoV-2 testing. Findings: Review of IFU for Quidel Sophia2 Flu and SARS test system revealed on page 14 "Conditions of Authorization for the Laboratory and Patient Care Settings...All operators using your product must be appropriately trained in performing and interpreting the results of your product...and use your product in accordance with the authorized labeling." Review of IFU for Cepheid GeneXpert Xpress SARS-CoV-2 revealed under section 21 "Conditions of Authorization for Laboratories...All operators using your product must be appropriately trained in performing and interpreting the results of your product...and use your product in accordance with the authorized labeling." Review of personnel records for TP #1, TP #2, TP #3, TP #4 and TP #5 revealed no documentation of training for the SARS-CoV- 2 testing performed. Interview with TC at approximately 11:50 a.m. confirmed the personnel records did not contain documentation of training. She stated that all TP were trained but she was unaware the training for SARS-CoV-2 testing needed to be documented. 2. The LD

	failed to ensure authorized Fact Sheets for patients and providers were included with SARS-CoV-2 test result reports. Findings: Review of IFU for Quidel Sophia2 Flu and SARS test system revealed on page 14 "Conditions of Authorization for the Laboratory and Patient Care Settings...Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets." Review of IFU for Cepheid GeneXpert Xpress SARS-CoV-2 revealed under section 21 "Conditions of Authorization for Laboratories...Authorized laboratories using your product must include with test result reports all authorized Fact Sheets." Interview with TC at approximately 3:00 p.m. confirmed the laboratory does not provide the authorized Fact Sheets to patients and providers with the SARS-CoV-2 test result reports. She stated they distribute to patients information in regards to infection control for SARS-Cov-2 after they have been swabbed for testing, but no authorized Fact Sheets are provided to patients or providers with the test result reports.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of 2019, 2020 and 2021 American Proficiency Institute (API) proficiency testing (PT) records and interview with technical consultant (TC) 4/26/21, the laboratory failed to ensure 2 of 5 testing personnel (TP) participated in 7 of 7 Hematology PT events for the performance of Complete Blood Count (CBC). Findings: Review of 2019, 2020 and 2021 API PT records revealed TP #4 and TP #5 had not participated in 7 of 7 Hematology PT events. Interview with TC at approximately 2:30 p.m. confirmed TP #4 and TP #5 had not participated in 7 of 7 Hematology PT events. She stated they occasionally perform CBC testing and she was not aware they should be participating in PT.
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 laboratory records, and interview with TC 4/26/21, the laboratory failed to verify the accuracy of the D-dimer testing from the time testing began, February 4, 2020, until January of 2021, a period of approximately 10 months in which patient testing was performed.. Findings: The laboratory began D-dimer testing on the Quidel Triage - Meter Pro analyzer February 4, 2020. Review of laboratory records revealed the laboratory verified the accuracy of the D-dimer testing in January of 2021 by participating in American Proficiency Institute (API) proficiency testing (PT) for D-dimer. There was no documentation the laboratory had verified the accuracy of the D-dimer testing prior to January of 2021. Interview with TC at approximately 3:45 pm confirmed the laboratory had not performed a verification of

	accuracy for D-dimer testing from February 4, 2020 until January of 2021. She stated she did not realize the facility was not enrolled in PT for D-dimer but once realized she enrolled them in API to meet the performance verification requirements.
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 laboratory procedure manual and interview with TC 4/26/21, the laboratory procedure manual failed to include a procedure for the laboratory's process of entering results into the patient medical record, and failed to include a procedure for reporting positive and negative SARS-CoV-2 test results to the local or state health departments. Findings. 1. Review of procedure manual revealed the manual failed to include a procedure for entering all laboratory performed test results into the patient medical record. 2. Review of procedure manual revealed the manual failed to include a procedure for reporting positive and negative SARS-CoV-2 test results to local or state health departments. Interview with TC at approximately 4:30 p.m. confirmed the procedure manual failed to include a procedure for entering test results into the patient medical record and failed to include a procedure for reporting positive and negative SARS-CoV-2 test results to local or state health departments. She stated she has been in the process of updating procedures since she began as TC. She also stated that she was aware that positive results were being reported to the local health departments, but she was unsure exactly who is responsible or how the reporting is performed.
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 review of manufacturer's instructions, surveyor observation, review of laboratory temperature logs and interview with TC 4/26/21, the laboratory failed to monitor and document the temperature of the freezer in refrigerator "B" where D-dimer quality control (QC) reagents were stored for a period of approximately 14 months. Findings: Review of manufacturer's instructions "Top 10 Tips For optima use of the Quidel Triage MeterPro" revealed "2. Place Controls and/or Calibration Verification materials immediately into a negative (-) 20 degrees Celcius (C), or colder, non-defrosting freezer, away from the freezer door." Review of manufacturer's instructions "Quidel Triage MeterPro" revealed "How to Run External Liquid Quality Control Samples...Storage and Handling Requirements...Store frozen at -20 degrees C or colder in a non-defrosting freezer. During laboratory tour at approximately 4:30 p. m. the surveyor observed D-dimer QC reagents in the freezer of refrigerator "B". The surveyor also observed that the freezer in refrigerator "B" did not have an internal thermometer for monitoring the temperature. Review of laboratory temperature logs revealed no documentation the laboratory had monitored and recorded the freezer temperature of refrigerator "B" since D-dimer testing began February 4, 2020. Approximately 14 months in which freezer temperatures were not monitored or documented. Interview with TC at approximately 4:30 p.m. confirmed D-dimer QC reagents were stored in the freezer of refrigerator "B". She also confirmed freezer temperature was not monitored or documented since D-dimer testing began February 4, 2020. She stated she was unaware the freezer had no thermometer and that the temperature was not being monitored or documented.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory procedures, review of laboratory records and interviews with TC 4/26/21, the LD failed to provide overall management and direction for the laboratory services provided. Findings: 1. The LD failed to ensure quality assessment programs were established for the pre-analytical, analytical and post-analytical processes and testing performed. See D6021. 2. The LD failed to ensure TP had received appropriate training for the performance of CBC and SARS-CoV-2 testing. See D6029. 3. The LD failed to establish competency procedures for evaluating the delegated responsibilities of the TC and failed to ensure TP competency procedures were established that meet the regulations as stated in section 493.1413(b)(8) of the 42 CFR Part 493 Requirements for Laboratories. See D6030. 4. The LD failed to specify what duties the TC is authorized to perform and what testing procedures each TP is authorized to perform. See D6032. 5. The LD failed to ensure past TC and current TC had completed TP competency assessments as required. See D6046. 6. The LD failed to ensure all TP met the minimum education requirements for performing moderate complexity testing. See D6065.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of laboratory records and interview with TC 4/26/21, the LD failed to ensure quality assessment (QA) programs were established for the pre-analytical, analytical and post-analytical processes and testing performed. Findings: Review of laboratory procedure manual revealed no documentation of policies or procedures for the QA of pre-analytical, analytical and post-analytical processes and testing performed. Review of laboratory records for QA activities revealed the TC was periodically, approximately every 30 days, reviewing quality control (QC)records, temperature logs, PT and TP competency. Interview with TC at approximately 2:30 p.m. confirmed the laboratory does not have QA policies and procedures. She stated the ambulatory sites do not have specific QA policies or procedures but the main laboratory does and that is the model she had been using for her performance of QA activities.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 TC 4/26/21, the LD failed to ensure 2 of 5 TP had received appropriate training for the performance of Complete Blood Count (CBC) testing. Findings: Review of personnel records revealed TP #4 began employment on 11/11/13 and TP #5 began employment 2/1/11. The personnel records had no documentation of training for the performance of CBC testing. Interview with TC at approximately 11:50 a.m. confirmed the personnel records did not contain documentation of training. She stated TP #4 and TP #5 occasionally run CBC's on the weekend because laboratory personnel do not work on the weekends. She also stated she was unaware that they did not have documented training in their personnel files.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 laboratory procedures, review of personnel competency records and interview with TC 4/26/21, the LD failed to establish competency procedures for evaluating the delegated responsibilities of the TC. And failed to ensure TP competency procedures were established that meet the regulations as stated in section 493.1413(b)(8) of the 42 CFR Part 493 Requirements for Laboratories. Section 493.1413(b)(8) states: "The procedures for evaluation of the competency of the staff (testing personnel) must include, but are not limited to.... Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills; Findings: 1. Review of laboratory procedures revealed no procedure for the competency assessment of the TC. Review of TC competency records revealed no documentation of TC competency assessments since TC accepted the position in December of 2019. Review of 2020 TP competency records revealed competency assessments were performed by TP who did not meet the education qualifications of a TC. See D6046. 2. Review of testing personnel competency records revealed a competency form entitled "... Health Satellite Laboratory Competency Testing" which included checklists for "Manual Procedures", "Analyzer Operation", "General" and "Orchard (LIS) Operation". The checklists indicated either "Acceptable" or "Needs Improvement". The competency form fails to indicate how the evaluations are conducted, fails to include documentation for all requirements as stated in Section 493.1413 (b)(8) and fails to indicate the criteria used to determine if TP would require remedial training to improve skills. Interview with TC at approximately 11:50 a.m. confirmed there was no procedure established for TC competency assessments. She stated she was not aware that TC competency assessments were required and the LD had not assessed her delegated responsibilities since she accepted the position in December of 2019. She also stated she was not aware that TP competency assessment policies and documentation would not met regulatory requirements because they were in place and used by the previous TC since at least 2012 when the laboratory was accredited.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of LD "Delegation of Responsibility", review of TC and TP job descriptions, and review of TP personnel records 4/26/21, the LD failed to specify what duties the TC is authorized to perform and what testing procedures each TP is authorized to perform. Findings: 1. The LD failed to specify what duties the TC is authorized to perform. Review of TC job description revealed a list of "responsibilities", the list states "All duties must be delegated from the CLIA laboratory director." "Review of LD "Delegation of Responsibility" revealed "Effective December 16, 2019, I hereby delegate the responsibility of Quality Assurance, Quality Control, Policy and Procedure Manuals, Proficiency Testing Review, and any other duties that can be delegated to the Manager of Laboratory Services...". The delegation is signed and dated by the LD 4/13/21 and signed and dated by the current TC 4/8/21. The delegation is not specific. For example; "Quality Assurance" does not specify what duties are to be performed for quality assurance, "Quality Control" does not specify what duties are to be performed for quality control. And "any other duties that can be delegated" does not specify what duties are to be performed. 2. The LD failed to specify what testing procedures each TP is authorized to perform. Review of TP job description "Testing Personnel" revealed "Duties...2. Performs only those tests that are authorized by the laboratory director...". Review of TP personnel records revealed no documentation of the specific testing each TP was authorized to perform.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 review of TC job description, review of TP competency records and interview with TC 4/26/21, the current TC failed to evaluate the competency of 4 of 5 TP in 2020 and the previous TC failed to evaluate the competency of 4 of 4 TP in 2018 and 2019. 1. Current TC failed to evaluate the competency of 4 of 5 TP in 2020. Current TC assumed the role of TC in December of 2019. Review of TC job description revealed "Responsibilities:...Evaluation and documentation of testing personnel competency at least semiannually during the first year the employee tests patient specimens and annually thereafter. Direct observation must be performed by someone meeting Technical Consultant qualifications." Review of 2020 TP competency records revealed TP #1 performed the competency assessment of TP #2 and TP #2 performed the competency assessment for TP #1. Review of personnel records revealed TP #1 has a high school transcript and TP #2 has a high school diploma. TP #1 and TP #2 do not meet TC qualifications to perform TP competency

	assessments. Review of 2020 TP competency records revealed no competency documentation was available for TP #4 and TP #5. Interview with TC at approximately 11:50 confirmed she did not perform the competencies of TP #1 and TP #2. She also stated that TP #4 and TP #5 only occasionally run CBC's on the weekend, so she was unsure if their competency needed assessed. She also stated that she assumed this because they had no previous competency assessments in their personnel files. 2. Previous TC failed to evaluate the competencies of 4 of 4 TP in 2018 and 2019. Review of personnel records revealed no documentation of competency assessments for TP #1, TP #2, TP #4 and TP #5 for 2018 and 2019. Interview with current TC at approximately 11:50 a.m. confirmed there was no documentation of competency assessments for the 4 TP in 2018 and 2019.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records 4/26/21 and the deficiency cited at D6065, the laboratory failed to verify 2 of 5 TP met the minimum education requirements for performing moderate complexity testing. Findings: See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official 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); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TC 4/26/21, the laboratory failed to verify that 2 of 5 TP met the minimum education requirements for performing moderate complexity testing. Review of personnel records revealed TP #3 had a transcript from a technical college for phlebotomy and patient care technician and TP #4 had no education documentation for review. Interview with TC at approximately 11:50 a.m. confirmed TP #4 did not have education documentation on site. She also stated she was unaware that the transcript for TP #3 would not meet the education documentation requirements.