

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1048184	(X3) Date Survey Completed 04/29/2021
Name of Provider or Supplier Wilmington Health	Street Address, City, State 1000 Brabham Avenue, Jacksonville, 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	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records, review of IFU (instructions for use), and interviews with testing personnel (TP #1) and laboratory director (LD) 4/29/21, the laboratory failed to follow manufacturer's instructions for the SARS-CoV-2 testing performed to ensure 11 of 11 TP (testing personnel) 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 1/29/21 and the Cepheid GeneXpert Xpress SARS-CoV-2 test system on 2/2/21. 1. The laboratory failed to ensure 11 of 11 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, TP #5, TP #6, TP #7, TP #8, TP #9, TP #10 and TP #11 revealed no documentation of training for the SARS-CoV- 2 testing performed. Interview with TP #1 at approximately 10:45 a.m. confirmed the personnel records did not contain documentation of training. She stated that she had verbally</p>

trained everyone and then observed them run quality control (QC), but she did not have documentation of the training. 2. The laboratory 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 LD at approximately 10:00 a.m. confirmed the laboratory does not provide the authorized Fact Sheets to patients and providers with the SARS-CoV-2 test result reports. He stated the facility was unaware that Fact Sheets should have been provided to patients and providers.

D3000

FACILITY ADMINISTRATION
CFR(s): 493.1100

Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:
Based on review of SARS-CoV-2 test records, review of SARS-CoV-2 reporting documentation and interview with laboratory director (LD) 4/29/21, the laboratory failed to report SARS-CoV-2 negative test results for 3 of 3 days reviewed in February and March of 2021. Findings: 1. Review of SARS-CoV-2 test records and reporting documentation for 2/16/21, 2/17/21 and 3/1/21 revealed the laboratory tested approximately 58 patients. 2. Review of SARS-CoV-2 test records and reporting documentation for 2/16/21, 2/17/21 and 3/1/21 revealed approximately 53 negative test results were not reported. 3. Interview with LD at approximately 11:00 a.m. confirmed the laboratory failed to report the negative SARS-CoV-2 test results. He stated he has been made aware of the problem cited at previous surveys occurring earlier in the week.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on review of 2019, 2020, and 2021 API (American Proficiency Institute) proficiency testing records and interview with TP #1 on 4/29/21, the laboratory failed to evaluate all ungraded proficiency testing results. Findings: Review of API proficiency testing results revealed the laboratory failed to evaluate the following

ungraded results: 1. 2019 1st Hematology/Coagulation event - no evaluation of ungraded urine sediment sample US-02 and vaginal wet prep sample VKP-01; 2. 2020 3rd Hematology/Coagulation event - no evaluation of ungraded urine sediment sample US-06. During interview at approximately 10:45 a.m., TP #1 confirmed there was no documentation that the ungraded results were evaluated to determine whether corrective action was needed.

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's procedure manual and interview with the LD 4/29 /21, the laboratory's procedure manual was not complete for the testing performed. Findings: 1. The laboratory's procedure for potassium hydroxide preparation (KOH) testing failed to state whether elements should be reported (white blood cells, squamous epithelial cells, clue cells, trichomonas) or how to quantitate them. The "MANUAL WET PREP (KOH)" procedure states "... 3. Switch to high power (45x) and examine the saline specimen for: -quantity and type of bacteria -white blood cells -squamous epithelial cells -'Clue' cells: small bacteria (rods and coccobacilli) adhering to sloughed epithelial cells -Trichomonas vaginalis: round to pear-shaped flagellates ... 4. Examine the KOH specimen under low and high power for Candida albicans ... Reportable Range: No fungal elements seen Rare fungal elements seen Few fungal elements seen Moderate fungal elements seen Many fungal elements seen ...". 2. The laboratory's procedure for urine microscopic testing failed to state what "urinary elements" should be reported and failed to include normal ranges. The "MANUAL URINE MICROSCOPIC" procedure states "... 5. Using low power (10x), scan the edges for urinary casts. 6. Switch to high power (45x) and observe several fields for all urinary elements. Estimate the number per high powered field (hpf) and report the range. 7. Each manual urine microscopic must have at least WBC, RBC, epithelial cells, mucus, and bacteria reported." 3. Review of procedure manual revealed the manual failed to include a procedure for entering all laboratory performed test results into the patient medical record. 4. 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 LD at approximately 11:00

	<p>a.m. confirmed there was no procedure established for entering test results into the patient medical record. He also confirmed the facility did not have a procedure for reporting positive and negative SARS-CoV-2 test results.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2019, 2020, and 2021 quality assessment records, review of 2019, 2020, and 2021 BD Affirm VPIII records, and interview with TP #1 on 4/29/21, the laboratory failed to verify performance specifications for the new BD Affirm VPIII analyzer before use. Review of the laboratory's 2019, 2020, and 2021 quality assessment records revealed the July 2019 "Quality Assurance Documentation Log" had the following notation: "7-23-19 Replaced current affirm machine with brand new machine. New processor serial #A581011 lysis block serial #C2044190100523". Review of 2019, 2020, and 2021 BD Affirm VPIII records revealed there was no documentation that the laboratory verified the performance specifications of the new analyzer prior to use for patient testing. During interview at approximately 11:40 a.m., TP #1 confirmed that there were no records available to show the new BD Affirm VPIII analyzer's performance was verified prior to use for patient testing.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory procedures, review of laboratory records and interviews with TP #1 and LD 4/29/21, the LD failed to provide overall management and direction for the laboratory services provided. Findings: 1. The LD failed to ensure the laboratory's IQCP's for BD Affirm VPIII and Alere Triage Meter were maintained. See D6020. 2. The LD failed to establish a competency procedure for evaluating the 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. 3. 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. 4. The LD failed to ensure the TC completed TP competency assessments as required. See D6046.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of IQCP (Individualized Quality Control Plan) records and interview with the laboratory director 4/29/21, the laboratory director failed to ensure that quality control programs were maintained to assure the quality of laboratory services provided. Findings: 1. Review of IQCP records revealed the laboratory established an IQCP for the BD Affirm VPIII 1/5/16. Review of IQCP records revealed that the laboratory performed an annual review of the IQCP as part of their quality assessment activities. The review included a checklist with items to be reviewed such as: "Quality Control performed appropriately and reviewed monthly ... Maintenance logs completed and reviewed monthly ... Proficiency testing performed and reviewed, Sampling of personnel training/competency reviewed ...". The checklist also included space for documenting which records were reviewed or adding comments. Review of the 2020 annual review checklist for the BD Affirm VPIII revealed the checklist was signed by the laboratory director 3/17/21, but the checklist was incomplete. Only one (proficiency testing) of the eleven items listed had been reviewed. 2. Review of IQCP records revealed the laboratory established an IQCP for the Alere Triage Meter 6/7/17. Review of IQCP records revealed that the laboratory performed an annual review of the IQCP as part of their quality assessment activities. The review included a checklist with items to be reviewed such as: "Quality Control performed appropriately and reviewed monthly ... Maintenance logs completed and reviewed monthly ... Proficiency testing performed and reviewed, Sampling of personnel training /competency reviewed ...". The checklist also included space for documenting which records were reviewed or adding comments. Review of the 2020 annual review checklist for the Alere Triage Meter revealed the checklist was signed by the laboratory director 3/25/21, but the checklist was incomplete. Only four (maintenance logs, instrument issues, proficiency testing, occurrence reports) of the eleven items listed had been reviewed. During interview at approximately 1:30 p.m., the laboratory director acknowledged that the reviews were incomplete.

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 TP competency records and interview with LD 4/29/21, the LD failed to establish competency procedures for evaluating the responsibilities of the technical consultant (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 the 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 TP 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 failed to indicate how the evaluations are conducted, failed to include documentation for all requirements as stated in Section 493.1413 (b)(8) and failed to indicate the criteria used to determine if TP would require remedial training to improve skills. Interview with LD at approximately 11:00 a.m. confirmed there was no procedure established for TC competency assessments. He stated he had been made aware of the problem cited at previous surveys occurring earlier in the week.

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 laboratory records, 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: The current LD assumed the position of LD in August of 2020. 1. The LD failed to specify what duties the TC is authorized to perform. Review of TC job

description revealed a list of "responsibilities", and the list states "All duties must be delegated from the CLIA laboratory director." Review of laboratory records revealed no documentation of a delegation of responsibility from the current LD to the current TC. 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 TP #1 4/29/21, the current TC failed to evaluate the competency of 11 of 11 TP in 2020 and the previous TC failed to evaluate the competency of 11 of 11 TP in 2018 and 2019. 1. The current TC failed to evaluate the competency of 11 of 11 TP in 2020. The 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, TP #3, TP #4, TP #5, TP #6, TP #7, TP #8, TP #9, TP #10 and TP #11. Review of personnel records revealed TP #1 has an associates degree in medical technology and does not meet TC qualifications to perform TP competency assessments. 2. The previous TC failed to evaluate the competencies of 11 of 11 TP in 2018 and 2019. Review of 2018 and 2019 TP competency records revealed TP #1 performed the competency assessment of TP #2, TP #3, TP #4, TP #5, TP #6, TP #7, TP #8, TP #9, TP #10 and TP #11. Review of personnel records revealed TP #1 has an associates degree in medical technology and does not meet TC qualifications to perform TP competency assessments. Interview with TP #1 at approximately 11:00 a.m. confirmed she performed the competency assessments of all TP in 2018, 2019 and 2020. She stated that she has always done the competency assessments of the TP at this facility.