Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0245700	04/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wilmington Health	2421 Silverstream Lane, 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
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 API(American Proficiency Institute) proficiency testing records and interview with the TC(technical consultant) 4/29/21, the laboratory failed to ensure 2 of 3 testing personnel participated in 7 of 7 PT (proficiency testing) events. Findings: Review of 2019, 2020, and 2021 API PT records revealed TP#1 was the only testing personnel who participated in proficiency testing for the following events: a. 2019 events: Hematology 1st and 3rd events; b. 2020 events: Hematology 1st, 2nd, and 3rd events; c. 2021 events: Hematology 1st event and Chemistry 1st event: At approximately 10:22 a.m., the TC confirmed TP#2 and TP#3 had not participated in proficiency testing in 2019, 2020, and 2021. She also confirmed all testing personnel were performing patient testing at time of survey.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2019, 2020 and 2021 hematology QC (quality control) records, the absence of documentation, and interview with the TC(technical consultant) 4/29

	/21, the laboratory failed to retain all required hematology QC assay sheets in 2019, 2020 and 2021. Findings: Review of 2019, 2020 and 2021 Sysmex XN 1000 QC records revealed the laboratory failed to retain copies of the XN-check control assay sheets containing the control assay values and expiration dates for the following lot numbers: 1. lot # 9091; 2. lot # 9147; 3. lot # 9203; 4. lot # 9261; 5. lot # 9317; 6. lot # 0008; 7. lot # 0064; 8. lot # 0120; 9. lot # 0176; 10. lot # 0232; 11. lot # 0288; 12. lot # 0344; 13. lot # 1034. At approximately 1:30pm, the TC confirmed the control assay sheets were not retained.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's IQCP(Individualized Quality Control Plan), absence of documentation, and interview with the TC(technical consultant) 4/29/21, the laboratory director failed to approve, sign, and date the QCP(Quality control plan) for the Abaxis Piccolo BMP(Basic Metabolic Panel) and MG(Magnesium) before it was put into use in April 2020. Findings: Review of the laboratory's IQCP revealed it was established for the Abaxis Piccolo to test plasma samples for BMP and MG approximately 2/26/20 and put into use 4/7/20. There was no documentation that the laboratory director approved, signed, or dated the QCP before it was put into use. During interview at approximately 11:30am, the TC stated that she thought the QCP had been approved and signed.
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 review of laboratory's QCP(Quality Control Plan), review of QC(quality control) records, and review of patient logs 4/29/21, the laboratory failed to perform control procedures as established by the laboratory for the Abaxis Piccolo BMP(Basic Metabolic Panel) and MG(magnesium) testing. Findings: The review of the laboratory's QCP revealed the laboratory performs two levels of external QC with each new lot, with each new shipment, and/or every 30 days. 1. Review of the laboratory's QC records revealed the laboratory failed to perform two levels of the BRT(Bioresource Technology) liquid assayed Chemistry control with each new lot number for the following reagent lot numbers: a) lot # 0075AC2 - review of patient logs revealed approximately 29 patients tested with lot 4/6/20- 8/20/20; b) lot# 0052BC0 - review of patient logs revealed approximately 9 patients tested with lot 4

	/15/20- 5/14/20; c) lot # 0142BC4 - review of patient logs revealed approximately 29 patients tested with lot 7/23/20-8/14/20; d) lot # 0255AC2- review of patient logs revealed approximately 39 patients tested with lot 10/2/20-11/30/20; e) lot# 0392AC2 - review of patient logs revealed approximately 22 patients tested with lot 2/17/21- 4 /28/21; f) lot # 0492BC2 - review of patient logs revealed approximately 39 patients tested with lot 2/22/21-4/27/21. 2. Review of QC records revealed the laboratory failed to perform two levels of the BRT(Bioresource Technology) liquid assayed Chemistry control every 30 days for the following lot numbers: g) lot #0352EC2- QC tested 10/6/20, review of patient logs revealed approximately 12 patients tested with lot 11/9/20-11/17/20; QC tested 11/19/20, review of patient logs revealed approximately 31 patients tested with lot 12/21/20-4/12/21. h) lot #0413AC2- QC tested 1/12/21, review of patient logs revealed approximately 22 patients tested with lot 2/15/21-3/19/21.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Piccolo Basic Metabolic Panel Plus manufacturer's instructions, review of the BRT(bioresource technology) Liquid assayed chemistry control assay sheets, review of 2020 and 2021 QC(quality control) records, and review of patient logs 4/29/21, the laboratory failed to ensure the results of QC testing were acceptable before reporting patient results. Findings: The Piccolo Basic Metabolic Panel Plus manufacturer's instructions states, "Quality Control....If control results are out of range, repeat one time. If still out of range, call Technical Support. Do not report results if controls are outside their labeled limits..." Review of 2020 and 2021 QC records and the BRT Liquid assayed chemistry control assay sheets revealed QC results were unacceptable for the following and patient results were reported: 1) Reagent lot # 0095AC4 had Quality Control tested on 5/27/20 and level 2 control (control lot# 1910004-2) results were unacceptable for Sodium, Potassium, Chloride, Calcium, BUN (blood urea nitrogen), Glucose, and Magnesium. Review of patient logs revealed approximately 62 patients were tested with the reagent lot # 0095AC4 from 5/28/20-8/20/20; 2) Reagent lot # 0282BB2 had Quality Control tested on 8/18 /20 and level 2 control (control lot# 1910004-2) results were unacceptable for Magnesium. Review of patient logs revealed approximately 67 patients were tested with reagent lot # 0282BB2 from 8/24/20-10/19/20.
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 2019, 2020, and 2021 laboratory records 4/29/21, the laboratory director failed to provide overall management and direction for the laboratory.

	Findings: 1. The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for Routine Chemistry in 2020 (See D6015). 2. The laboratory director failed to ensure the proficiency testing samples were tested as required (See D6016). 3. The laboratory director failed to ensure that a quality control program was established and followed to assure quality of laboratory services provided (See D6020). 4 The laboratory director failed to ensure that all testing personnel received appropriate training prior to testing patients' specimens (See D6029). 5. The laboratory director failed to establish competency procedures for evaluating the delegated responsibilities of the TC and failed to ensure testing personnel 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)
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of CMS(Centers for Medicare and Medicaid Services) Casper Report 155D, review of 2019, 2020, and 2021 PT (Proficiency testing) records, and interview with TC(Technical Consultant) 4/29/21, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for Routine Chemistry in 2020 . Findings: Review of laboratory records on 4/29/21 revealed the laboratory began testing plasma samples for BMP(Basic Metabolic Panel) and Mg(Magnesium) on 2/26/20. Review of CMS Casper Report 155D revealed scores for 2020 did not include Routine Chemistry. Review of the laboratory's API(American Proficiency Institute) PT records revealed no documentation for Routine Chemistry in 2020. During interview at approximately 10:15am, the TC confirmed the laboratory failed to enroll for Routine Chemistry in 2020. She stated the PT enrollment was overlooked until time to renew PT for 2021.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by:

	Based on review of 2019, 2020, and 2021 proficiency testing records 4/29/21, the laboratory director failed to ensure the proficiency testing samples were tested as required (See D2007).
D6020	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 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 2019, 2020, and 2021 laboratory records 4/29/21, the laboratory director failed to ensure that a quality control program was established and followed to assure quality of laboratory services provided. 1. The laboratory director failed to ensure the laboratory retained all quality control records(See D3031). 2. The laboratory director failed to ensure the QCP(Quality control plan) for the Abaxis Piccolo BMP(Basic Metabolic Panel) and MG(Magnesium) was approved, signed, and dated before put into use (See D5407). 3. The laboratory director failed to ensure control procedures were performed as established by the laboratory for the Abaxis Piccolo BMP(Basic Metabolic Panel) and MG(magnesium) testing (See D5445). 4. The laboratory director failed to ensure the laboratory obtained acceptable quality control results before reporting patient results (See D5481).
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 laboratory's procedures, review of personnel records, absence of documentation, and interview with the TC(technical consultant) 4/29/21, the laboratory director failed to ensure that 3 of 3 TP(testing personnel) received the appropriate training for the Abaxis Piccolo analyzer prior to testing patients' specimens. Findings: Review of laboratory records on 4/29/21 revealed the laboratory began testing plasma samples for BMP(Basic Metabolic Panel) and Mg(Magnesium) on the Abaxis Piccolo analyzer on 2/26/20. Review of personnel records revealed there was no training documentation for the Abaxis Piccolo analyzer for TP#1, TP#2, and TP#3. At approximately 9:15am on 4/29/21, the TC confirmed there was no training documentation on file for the Piccolo analyzer. She stated the TP participated in virtual training that was performed in January 2020.

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 the absence of documentation 4/29/21, the LD(laboratory director) failed to establish competency procedures for evaluating the delegated responsibilities of the TC and failed to ensure testing personnel 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 procedure 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 2019. 2. Review of 2020 testing personnel competency records revealed competency assessments were performed by testing personnel evaluating each other. See D6046. 3. Review of testing personnel competency records revealed a competency form 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.
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 laboratory records, review of laboratory director's "Delegation of Responsibility", review of TP(testing personnel) competency records, the absence of documentation, and interview with the TC(technical consultant) 4/29/21, the current TC failed to evaluate the competency of 3 of 3 TP in 2020 and the previous TC failed to evaluate competency of 3 of 3 TP in 2018 and 2019. Findings: Review of the 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. 1. Current TC failed to evaluate the competency of 3 of 3 TP in 2020 for the semiannual competency of the Piccolo analyzer and the annual competency for the Sysmex XN. Review of laboratory records revealed the laboratory began testing BMP(Basic Metabolic Panel) and Mg(magnesium) on the Piccolo analyzer in February 2020. Review of personnel records revealed there was no semiannual competency assessment completed for TP#1, TP#2, or TP#3 during the first year of testing patient specimens on the Piccolo analyzer. Review of 2020 TP Competency records revealed TP#1 performed the competency assessment for TP#2 and TP#3 and TP#2 performed the competency assessment for TP#1 in June 2020. Review of personnel records revealed TP#1 and TP#2 have a high school diploma and do not meet TC qualifications to perform TP competency assessments. At approximately 9:15am, the TC confirmed semiannual competency assessments were not performed for the TP during the first year of testing specimens on the Piccolo analyzer. She also confirmed that the competency assessments performed in June 2020 were done by the testing personnel. 2. Previous TC failed to evaluate the competencies of 3 of 3 TP in 2018 and 2019. Review of personnel records revealed no documentation of competency assessments for TP#1, TP#2, and TP#3 in 2018 and 2019. Interview with the TC at approximately 9:20 am, confirmed there was no documentation of competency assessments performed by the previous TC for the 3 TP in 2018 and 2019.