Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0655419	04/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Wilmington Health Associates	1202 Medical Center Drive, 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 IFU (instructions for use), and interview with TS (technical supervisor) 4/27/21, the laboratory failed to follow manufacturer's instructions for the SARS-CoV-2 testing performed to ensure 7 of 7 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 6/30/20. 1. The laboratory failed to ensure 7 of 7 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 and TP #7 revealed no documentation of training for the SARS-CoV- 2 testing performed. Interview with TS at approximately 9:00 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 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 TS at approximately 9:00 a.m. confirmed the laboratory does not provide the authorized Fact Sheets to patients and providers with the SARS-CoV-2 test result reports. She stated they distribute information to patients regarding 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.
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 QC (quality control) records, the absence of documentation, review of manufacturer's instructions, and interview with the TS and TP 4/28/21, the laboratory failed to retain QC assay sheets in 2019, 2020, and 2021. Findings: A. Review of 2019, 2020 and 2021 QC records revealed the laboratory failed to retain copies of the QC assay sheets for the following: 1. TOSOH G8 HgbA1c (glycosylated hemoglobin) analyzer- normal and abnormal control set lot numbers: a. lot # 7082; b. lot #7085; c. lot #7090; d. lot #7097. 2. Siemens CA660 Coagulation analyzer- Citrol 1 and 3 control lot numbers: a. Citrol 1 lot # 548058/ Citrol 3 lot # 548440; b. Citrol 1 lot # 548086A/ Citrol 3 lot # 556512A. 3. Alcor iSED ESR (Erythrocyte Sedimentation Rate) analyzer- Seditrol Sed Rate control level 1 and level 2. a. Seditrol level 1 lot # C131/ Seditrol level 2 lot# C231; b. Seditrol level 1 lot # C133/ Seditrol level 2 lot # C233; c. Seditrol level 1 lot # C136/ Seditrol level 2 lot # C236; d. Seditrol level 1 lot # C137/ Seditrol level 2 lot # C237. At approximately 1:30 pm on 4/28/21, the TS confirmed the QC assay sheets are not kept for older lot numbers after values are stored in the Orchard LIS (laboratory information system). B. The laboratory installed a replacement Phadia 250 in February 2020 and the instrument was approved for use by the TS 2/18/20. The Phadia 250 online instructions state "... Quality Control Targets and Limits When a new QC is introduced, use limits stated in the Directions for Use, on the QC bottle label, or on the certificate that the QC bottle contains. ..." There were no QC assay sheets available for the Phadia 250 from 2/18/20 (the date the replacement analyzer was installed) to 4/28/20. During interview 4/28/21 at approximately 12:55 p.m., TP #1 stated that they use the manufacturer's QC ranges printed on the bottles. She stated they do not receive assay sheets with each new lot number of control material, and the only documentation of QC ranges for each lot number is in the instrument.
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) PT (proficiency testing) records and interview with the TS 4/27/21, the laboratory failed to evaluate all ungraded and unacceptable PT testing results. Findings: Review of API proficiency testing results revealed the laboratory failed to evaluate all ungraded and proficiency testing results. Examples: a. On the 2019 Hematology/Coagulation 1st event, there was no documentation that the laboratory evaluated 5 of 5 educational blood cell identification samples to determine whether corrective action was needed. b. On the 2019 Immunology 2nd event, there was no documentation that the laboratory evaluated multiple ungraded allergens tested on the Phadia ImmunoCAP to determine whether corrective action was needed. c. On the 2019 Immunology 3rd event, there was no documentation that the laboratory evaluated 1 of 2 unacceptable Thyroglobulin Antibody results. No corrective action was documented. d. On the 2020 Chemistry Core 1st event, there was no documentation that the laboratory evaluated 1 of 5 ungraded ALT (alanine aminotransferase) results to determine whether corrective action was needed. e. On the 2020 Chemistry Core 2nd event there was no documentation that the laboratory evaluated 1 of 5 unacceptable TIBC (total iron binding capacity) results. No corrective action was documented. f. On the 2020 Immunology 2nd event, there was no documentation that the laboratory evaluated the ungraded 1 of 5 Anti dsDNA (double stranded deoxyribonucleic acid), 1 of 2 Anti-CCP (cyclic citrullinated peptide), 1 of 2 Thyroid Microsomal Antibody/Anti-TPO (thyroid peroxidase), and multiple Phadia ImmunoCAP allergen results to determine whether corrective action was needed. During interview at approximately 10:10 a.m., the TS stated that she now understands that they need to document evaluation of all ungraded and unacceptable PT results and take corrective action if needed.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and interview with TS 4/28/21, the laboratory failed to follow manufacturer's instructions for the pre-analytic processing of Intact Parathyroid Hormone (PTH). Approximately 5,510 patient specimens were tested for PTH from 2/11/19 - 4/28/21. Findings: Review of manufacturer's instructions for PTH revealed "...Centrifuge samples at greater than or equal 1000 x g for 15-20 minutes." Interview with TS at approximately 10:20 a.m. confirmed the laboratory was not centrifuging the specimens for PTH for 15-20 minutes as required since testing began on the Siemens Atellica Solution 2/11/19. She stated approximately 5,510 patients had been tested from 2/11/19 until date of survey, 4/28 /21.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on review of laboratory records 4/27/21 and 4/28/21, the laboratory failed to monitor and evaluate the ongoing and overall quality of the analytic systems to identify and correct problems and prevent their recurrence. Findings: 1. The laboratory failed to have a complete procedure manual available for all aspects of the testing process (see D5403, D5405). 2. The laboratory failed to ensure manufacturers' instructions were followed for proper storage of reagents (see D5411). 3. The laboratory failed to define acceptable ranges for temperature and humidity that were consistent with manufacturers' requirements for the BD Affirm VPIII, the Quidel Traige MeterPro, and the Tosoh G8 (see D5413). 4. The laboratory failed to perform and document quarterly maintenance as required for the Siemens CA 660 coagulation analyzer (see D5429). 5. The laboratory failed to perform and document calibration of the Sysmex XN1000 hematology analyzer every six months as required (see D5437). 6. The laboratory failed to perform and document calibration verification at least every six months for the glycosolated hemoglobin performed on the Tosoh G8 analyzer (see D5439). 7. The laboratory failed to test external positive and negative controls each day of patient testing for the McKesson Consult Diagnostics hCG Combo Cassette serum pregnancy test (see D5449). 8. The laboratory failed to take and document corrective action for the room temperatures out of range for performance of the BD Affirm VPIII test (see D5785).
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 TS 4/27 /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. Findings: 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 fails to include normal ranges. Findings: 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. The procedure manual failed to include a procedure for entering all laboratory performed test results into the patient medical record. 4. The procedure manual failed to include a procedure for reporting positive and negative SARS-CoV-2 test results to local or state health departments. During interview 4/27/21 at approximately 1:50 p.m., the TS stated she is still working on the laboratory's policies and procedures.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, manufacturer's instructions and interview with TS 4/28/21, the laboratory procedures for testing performed on the Siemens Atellica chemistry and immunoassay analyzers failed to include how often QC and calibrations are performed, the corrective action to follow if QC or calibrations fail, the type and levels of QC and/or calibration reagent used and the laboratory's established normal ranges for each analyte tested. Findings: Review of laboratory procedure manual for the testing performed on the Siemens Atellica chemistry and immunoassay analyzers revealed the laboratory utilizes the manufacturers' instructions for each analyte tested. The manufacturer's instructions failed to include how often QC and calibrations are performed, the corrective action to follow if QC or calibrations fail, the type and levels of QC and/or calibration reagent used and the laboratory's established normal ranges for each analyte tested. For example: The procedure for Albumin states "...Calibrator Material...Atellica CH CHEM CAL...Quality Control Material...Commercially available quality control materials...". The procedure failed to include how often QC and Calibrations are performed, the corrective action to follow if QC or Calibrations fail, the levels of

	calibrators or QC used, the type of QC reagent used, and the laboratory's established normal ranges. The procedure for Vitamin B12 states "...Calibrator Material...Atellica IM CAL C...Quality Control Material...Commercially available quality control materials...". The procedure failed to include how often QC and Calibrations are performed, the corrective action to follow if QC or Calibrations fail, the levels of calibrators or QC used, the type of QC reagent used, and the laboratory's established normal ranges. Interview with TS 4/28/21 at approximately 9:30 a.m. confirmed the procedures were incomplete. She stated that QC is on board for most analytes and she is in the process of revising many of the laboratory's policies and procedures.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions and surveyor observation 4/28/21, the laboratory failed to store reagents at the appropriate temperature as specified by the manufacturer. Findings: Review of the manufacturers' instructions revealed the manufacturers specify the following storage requirements: a. Siemens Atellica CH Enz 3 Cal: -15 to -25 degrees Celsius b. Maine Standards Validate products: -10 to -25 degrees Celsius During tour of the laboratory at approximately 4:00 pm on 4/28 /21, surveyors observed the following reagents stored at the incorrect temperature range of -20 to -40 degrees Celsius: a. Siemens Atellica CH Enz 3 Cal, 1 partial box, 1 unused vial- lot # OHD061, exp. 8/1/21; b. Maine Standards Validate GC4 test set, 5 levels- lot # 14BI199200, exp 8/7/21; c. Maine Standards Validate GC1 test set, 5 levels- lot # 11AX109200, exp. 8/21/21; d. Maine Standards Validate GC3 test set, 5 levels - lot # 13AR213200, exp. 8/24/21- 2 boxes; e. Maine Standards Validate LP test set, 5 levels- lot #5CAF182200, exp. 9/17/21; f. Maine Standards Validate SP1 test set, 5 levels- lot #61AX168200, exp. 10/4/21; g. Maine Standards Validate HgbA1c test set, 5 levels- lot # 65A0206200, exp. 11/5/21; h. Maine Standards Validate TIBC test set, 5 levels- lot # 23AP259200, exp. 12/30/21; i. Maine Standards Validate HgbA1c test set, 5 levels- lot #65AH307200, exp. 2/18/22.
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 manufacturers' instructions, review of the 2019, 2020, and 2021 Affirm logs, and review of the laboratory's 2019, 2020, and 2021 temperature logs,

	the laboratory failed to define acceptable ranges for room temperature and humidity that were consistent with manufacturers' instructions for the BD Affirm VPIII, the Quidel Triage MeterPro, and the Tosoh G8. Findings: 1. BD Affirm VPIII The BD Affirm VPIII Microbial Identification Test product insert states on page 4 "... Automated Processing Note: Before proceeding, ensure that all reagents are at 22-28 degrees C. With each test run, verify that the testing environment is between 22 and 28 degrees C. ..." Review of the laboratory's 2019, 2020, and 2021 Affirm logs revealed that the acceptable range for room temperature was listed as 15-30 degrees Celsius. Review of the laboratory's 2019, 2020, and 2021 temperature logs revealed that the acceptable range for room temperature was listed as 18-28 degrees Celsius. 2. Quidel Triage MeterPro The Triage Cardiac Panel product insert states "WARNINGS AND PRECAUTIONS ... Optimal results will be achieved by performing testing at temperatures between 20 degrees C to 24 degrees C (68 degrees F to 75 degrees F). ... STORAGE AND HANDLING REQUIREMENTS ... Before using refrigerated Test Devices, allow individual foil pouches to reach operating temperature (20 degrees C to 24 degrees C or 68 degrees F to 75 degrees F). ..." Review of the laboratory's 2019, 2020, and 2021 temperature logs revealed that the acceptable range for room temperature was listed as 18-28 degrees Celsius. 3. Tosoh G8 The Tosoh Bioscience, Inc. G8 Variant Analysis Mode Operator's Manual v. 3.0 states on page 194 "... Operating Environment Conditions ... Humidity: 40%-80% R.H. (without condensation) ..." Review of the laboratory's 2019, 2020, and 2021 temperature logs revealed that the acceptable range for room humidity was listed as 20-80%.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's maintenance schedule for the Siemens CA660 analyzer, review of the 2019, 2020, and 2021 coagulation maintenance records, absence of documentation, and interview with TS 4/28/21, the laboratory failed to perform and document required quarterly maintenance for the Siemens CA660 coagulation analyzer. Findings: Review of the maintenance schedule in Siemens CA660 reference guide revealed the LED Calibration and rinse container clean is performed quarterly. Review of the CA660 maintenance logs revealed the quarterly maintenance was documented on 6/4/20 and not again until 3/8/21. There was no documentation that the quarterly maintenance was performed in September or December 2020. Interview with TS at approximately 12:00 p.m. confirmed that the coagulation maintenance was delayed in 2020. She stated that the LED calibrations are not printed each time they are performed. She confirmed the analyzer only shows back to the last calibration where all channels were acceptable.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2)

	Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory's Sysmex XN1000 procedure , review of 2019, 2020, and 2021 Hematology installation and calibration records, and interview with TS 4/27/21, the laboratory failed to perform and document calibration of the Sysmex XN 1000 hematology analyzer every six months. The laboratory's Sysmex XN1000 CLSI procedure states, "Calibration verification, generally required at least every 6 months..." Review of the laboratory's initial Sysmex Certificate of Calibration states, "... initial calibration is performed during installation by the Sysmex representative. Following installation calibration, the operator is requested to verify the instrument calibration every 6 months or on an 'as needed basis', and maintain good QC practices, to ensure the accuracy of the system." Review of installation and calibration records revealed the Sysmex XN1000 was calibrated during the installation of the analyzer on 11/21/19. The analyzer was not calibrated again until 8/12/20, a gap of 9 months. There was no documentation of calibrations being performed after 8/12/20. Interview with TS at approximately 4:20 p.m. confirmed the calibrations were delayed because the service contract renewal had not been signed in time. She stated the Sysmex representative is scheduled to come in to perform the calibration. She also confirmed that Sysmex does not perform managed calibrations for their analyzer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the manufacturer's operator manual, review of 2019, 2020, and

	2020 calibration records for the TOSOH G8 analyzer and interview with TP #3 4/28 /21, the laboratory failed to perform and document calibration verification at least every six months for HgbA1c on the TOSHO G8 analyzer. Findings: Review of the TOSOH G8 operator manual revealed the analyzer has a two-point automatic calibration function. Review of 2019, 2020, and 2021 calibration verification records revealed the laboratory performed calibration verifications on 10/31/19 and 10/30/20, a period of approximately 12 months in which calibration verification was not performed. Interview with TP #3 at approximately 4:30 p.m. confirmed the calibration verification was not performed in April 2020 when due. She stated the laboratory thought it was completed by the service representative when the preventative maintenance was performed, and it was not realized in time to complete as required.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's IQCP (Individualized Quality Control Plan) records, review of patient records, and interview with the TS 4/28/21, the laboratory failed to test positive and negative external controls each day of patient testing for the McKesson Consult Diagnostics hCG Combo Cassette serum pregnancy test. Approximately 42 patients had serum pregnancy tests performed from 7/24/19 - 4/28 /21 on days when external positive and negative controls were not tested. Findings: Review of the laboratory's IQCP records for serum pregnancy revealed the IQCP was established in 2018 for the the Quidel QuickVue + One-Step hCG serum pregnancy kit previously used by the laboratory. The laboratory did not have an IQCP in place for their current serum pregnancy kit, McKesson Consult Diagnostics hCG Combo Cassette, in use since 7/24/19. Review of serum pregnancy patient records revealed approximately 42 patients had serum pregnancy tests performed from 7/24/19 - 4/28 /21 on days when external positive and negative controls were not tested. During interview 4/28/21 at approximately 2:25 p.m., the TS confirmed that the laboratory had not established an IQCP for their current serum pregnancy test. She verified that positive and negative external controls were not tested each day that patient serum pregnancy tests were performed. She stated that positive and negative external controls are tested monthly and with each new lot number of kits.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and review of 2019, 2020, and 2021 Affirm logs 4/27/21, the laboratory failed to document corrective action for room

	temperatures outside the acceptable limits for 147 of 503 days of testing from January 2, 2019 through April 26, 2021. Findings: The BD Affirm VPIII Microbial Identification Test product insert states on page 4 "... Automated Processing Note: Before proceeding, ensure that all reagents are at 22-28 degrees C. With each test run, verify that the testing environment is between 22 and 28 degrees C. ..." Review of the laboratory's 2019, 2020, and 2021 Affirm logs revealed that the acceptable range for room temperature was listed as 15-30 degrees Celsius. Review of the laboratory's 2019, 2020, and 2021 Affirm logs revealed room temperature was outside the acceptable limits of 22-28 degrees Celsius with no corrective action documented for: a. 8 of 22 days in January 2019 (2,3,4,7,8,14,25,29); b. 7 of 20 days in February 2019 (4,7,11,13,14,15,18); c. 4 of 20 days in March 2019 (1,4,12,26); d. 8 of 22 days in April 2019 (8,16,17,18,22,23,25,26); e. 7 of 22 days in May 2019 (3,17,21,28,29,30,31); f. 3 of 20 days in June 2019 (3,4,6); g. 1 of 22 days in July 2019 (17); h. 2 of 21 days in December 2019 (23,26); i. 3 of 20 days in January 2020 (7,29,31); j. 4 of 20 days in February 2020 (5,12,18,20); k. 6 of 23 days in March 2020 (1,3,4,5,9,16); l. 5 of 22 days in April 2020 (17,20,28,29,30); m. 7 of 20 days in May 2020 (11,13,14,15,22,28,29); n. 13 of 23 days in June 2020 (1,2,3,4,5,9,10,11,12,17,22,27,29); o. 13 of 22 days in July 2020 (2,6,7,10,13,14,15,20,21,22,24,27,29) p. 13 of 20 days in August 2020 (3,5,6,14,18,20,21,24,25,26,27,28,31); q. 6 of 22 days in September 2020 (1,9,10,11,29,30); r. 5 of 20 days in October 2020 (1,7,13,26,28); s. 7 of 19 days in November 2020 (4,5,10,11,12,16,18); t. 2 of 22 days in December 2020 (21,24); u. 6 of 21 days in January 2021 (11,12,13,14,20,27); v. 7 of 20 days in February 2021 (1,2,5,9,17,18,22); w. 7 of 21 days in March 2021 (1,12,16,17,18,19,29); x. 3 of 19 days in April 2021 (2,8,26). Approximately 2817 patients were tested on days when the room temperature was outside acceptable limits.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records 4/27/21 - 4/28/21, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure that quality control programs were established and maintained to assure the quality of laboratory services provided (see D6093). 2. The laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program (see D6094). 3. The laboratory director failed to ensure the establishment of procedures for evaluating the competency of the technical supervisor and testing personnel (see D6103). 4. The laboratory director failed to specify in writing the authorized duties for the technical supervisor and testing personnel (see D6107).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 manufacturers' instructions, review of IQCP records, review of personnel records, review of 2019, 2020, and 2021 Affirm and serum hCG (human chorionic gonadotropin) logs, and interview with the TS (technical supervisor) 4/27 /21 - 4/28/21, the laboratory director failed to ensure that quality control programs were established and maintained to assure the quality of laboratory services provided. Findings: 1. BD Affirm VPIII Microbial Identification Test a. The BD Affirm VPIII Microbial Identification Test product insert states on page 4 "... Automated Processing Note: Before proceeding, ensure that all reagents are at 22-28 degrees C. With each test run, verify that the testing environment is between 22 and 28 degrees C. ..." The Risk Assessment for the BD Affirm VPIII IQCP lists the following "Potential Error" for the test system: "Environment Room temperature must be at 22-28 degrees. ... Reagents Improper storage - requires storage at 22-28 degrees. ..." The "QC Plan" states "... 7. Monitor room temperature daily and take corrective action if out of range. ..." Review of the laboratory's 2019, 2020, and 2021 Affirm logs revealed that the acceptable range for room temperature was listed as 15-30 degrees Celsius. Room temperature was outside the manufacturer's specified range of 22-28 degrees Celsius for 147 of 503 days of testing from January 2, 2019 through April 26, 2021 with no corrective action documented. Approximately 2817 patients were tested on days when the room temperature was outside acceptable limits. See D5785. b. The Risk Assessment for the BD Affirm VPIII IQCP lists the following "Potential Error" for the test system: "... Testing Personnel Staff not trained and/or not competent ...". The "QC Plan" states "... Competency evaluations done as required - plus each newly trained lab testing personnell undergo additional direct observation. ..." Review of personnel records revealed testing personnel competency evaluations were not performed at the required frequency. See D6120. c. The IQCP for the BD Affirm VPIII states "QC Plan: 1. Internal QC with each test must be acceptable in order to report results. ..." Review of the Affirm patient log printed from the LIS (laboratory information system) revealed the laboratory failed to document the internal positive and negative control results with each patient test. During interview 4/27/21 at approximately 2:20 p.m., the TS verified that the laboratory did not document internal positive and negative controls with each patient test. 2. Cepheid GeneXpert The "CEPHEID GENEXPERT CT/NG QUALITY CONTROL PLAN" states the frequency for competency asseessment is "Six months and one year after initial training, annually thereafter". The plan states "Criteria for Acceptability ... All testing personnel must successfully meet all COLA elements for competency assessment." Review of personnel records revealed testing personnel competency evaluations were not performed at the required frequency. See D6120. 3. McKesson Consult Diagnostics hCG Combo Cassette a. Review of the laboratory's IQCP records for serum hCG revealed the IQCP was established in 2018 for the the Quidel QuickVue + One-Step hCG serum pregnancy kit previously used by the laboratory. The laboratory did not have an IQCP in place for their current serum pregnancy kit, McKesson Consult Diagnostics hCG Combo Cassette, in use since 7/24/19. Review of serum hCG quality control and patient logs revealed the laboratory did not test positive and negative external controls each day that patients were tested. Approximately 42 patients had serum hCG tests performed from 7/24/19 - 4/28/21 on days when external controls were not tested. See D5449. During interview 4/28/21 at approximately 2:25 p.m., the TS confirmed that the laboratory had not established an IQCP for their current serum pregnancy test. She stated that the quality control requirements are the same as they were with the previous kit: positive and negative external controls are tested monthly and with each new lot number of kits.

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, review of 2019, 2020, and 2021 laboratory records, and interview with the TS 4/28/21, the laboratory director failed to ensure that an effective quality assessment program was established to identify problems and prevent their recurrence. Review of the laboratory's "QUALITY CONTROL AND QUALITY ASSURANCE" procedure revealed "... It is the responsibility of each person performing the tests within the laboratory setting to insure accurate and precise measurements of all tests performed. ... If, however, the error was not recognized at the time performed and is noted by the supervisor, the investigation must still be carried out as appropriate. All efforts to find the cause of error and most importantly to notify the person who performed the test of the problem must be done so the problem will not happen again. ... On-Going Corrective Action Logs Proficiency Testing QC Calibrations ..." The plan did not include how assessment activities are conducted, the frequency, or who is responsible. Review of 2019, 2020, and 2021 laboratory records revealed the laboratory's quality assessment program failed to identify problems identified during the survey in the following areas: a. Record retention (see D3031); b. Proficiency testing (see D5211); c. Specimen handling (see D5311); d. Procedures (see D5403, D5405); e. Reagent storage (see D5411); f. Temperature and humidity (see D5413); g. Maintenance (see D5429); h. Calibration and Calibration verification (see D5437, D5439); i. Quality control (see D5449, D6093); j. Corrective action (see D5785); k. Competency evaluations (see D6103, D6120); l. Job descriptions (see D6107). During interview at approximately , the TS stated that one of the testing personnel is responsible for each section of the laboratory.
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 laboratory procedures, review of personnel competency records and interview with TS 4/27/21, the LD failed to establish competency procedures for evaluating the delegated responsibilities of the TS and failed to ensure TP competency procedures were established that meet the regulations as stated in section 493.1413(b)(8) of 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 TS. Review of TS competency records revealed no documentation of TS competency assessments since TS 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 TS or were not not delegated by the LD to perform competency assessments. See D6120. 2. Review of TP competency records revealed a competency form entitled "... Clinical Laboratory Technical Competency Testing" which included checklists for "Procedures, Manual", "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 TS at approximately 11:15 a.m. confirmed there was no procedure established for TS competency assessments. She stated she was not aware that TS 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 meet regulatory requirements because they were in place and used by the previous TS since at least 2012 when the laboratory was accredited.
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 LD "Delegation of Responsibility", review of "Lab Manager" (technical supervisor) and TP job descriptions, and review of TP personnel records 4 /27/21, the LD failed to specify what duties the TS is authorized to perform and what testing procedures each TP is authorized to perform. Findings: The "Lab Manager" serves as TS for the laboratory. 1. The LD failed to specify what duties the "Lab Manager" is authorized to perform as TS for the laboratory. Review of "Lab Manager" job description revealed a list of responsibilities, for example; "...Responsible for Quality Assurance, Quality Control, Policy and Procedure Manual and Proficiency Testing Review as delegated by Laboratory Director." And "...Reviews, initials and dates QC records,..". "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 "Lab Manager" 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 although the "Lab Manager" job description does state "reviews, initials and dates QC records...". 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.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 TS (Lab Manager) job description, review of TP competency records and interview with TS 4/26/21, the current TS failed to evaluate the competency of 5 of 5 TP in 2020 and the previous TS failed to evaluate the competency of 4 of 4 TP in 2018 and 2019. 1. Current TS failed to evaluate the competency of 5 of 5 TP in 2020. Current TS assumed the role of TS in December of 2019. Review of TS "Lab Manager" job description revealed "Responsibilities:... conducts competency reviews and testing of technical staff in compliance with CLIA-88." Review of 2020 TP competency records revealed TP #2 performed the competency assessment of TP #1. TP #2 has a bachelors degree in medical laboratory science, but has not been delegated by the LD to perform competency assessments. TP #1 performed the competency assessments of TP #2, TP #3, TP #4 and TP #5. TP #1 has an associates degree in medical technology and does not meet TS qualifications to perform TP competency assessments. Interview with TS at approximately 11:15 a.m. confirmed she did not perform the competencies of 5 of 5 TP in 2020. She stated she was not aware TP could not assess the competency of each other. 2. Previous TS failed to evaluate the competencies of 5 of 5 TP in 2018 and 2019. Review of personnel records revealed no documentation of competency assessments for TP #1, TP #2, TP #3, TP #4 and TP #5 for 2018 and 2019. Interview with current TS at approximately 11:15 a.m. confirmed there was no documentation of competency assessments for the 5 TP in 2018 and 2019.