Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1007477	12/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Alexandria Women's Center	3304 Masonic Drive, Suite 4001, Alexandria, LA	

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
D0000	A Validation survey was performed at Alexandria Women's Center, CLIA ID # 19D1007477, on December 12, 2022 through December 13, 2022. Alexandria Women's Center was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing, Laboratory Director
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: I. Based on observation by surveyors, review of the operator's manual and laboratory maintenance records as well as interview with personnel, the laboratory failed to perform the weekly maintenance for the Piccolo Xpress chemistry analyzer as required by the manufacturer for one (1) of fifty (50) weeks reviewed. Findings: 1. Direct observation by surveyors during the laboratory tour on December 12, 2022 at 1: 30 pm revealed the laboratory utilizes the Piccolo Xpress analyzer for the following waived chemistry testing: Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Calcium, Blood Urea Nitrogen, Creatinine, Alkaline Phosphatase, Alanine Transaminase, Aspartate Transferase, Total Bilirubin, Albumin, Total Protein, Total Cholesterol, Low Density Lipoprotein, High Density Lipoprotein, Triglycerides 2. Review of the operator's manual for the Piccolo Xpress Chemistry analyzer revealed the following weekly maintenance: a) Clean the analyzer's external case and display at least weekly. Inspect the instrument casing during cleaning to ensure it is free of damage or cracks. 3. Review of the laboratory's maintenance records for the Piccolo Xpress chemistry analyzer from January 1, 2022 through December 13, 2022 revealed

	the laboratory did not perform the weekly maintenance for the week of November 21, 2022 through November 25, 2022. 4. In interview on December 13, 2022 at 9:30 am, Testing Personnel 6 confirmed the weekly maintenance was not performed for the identified week in November 2022. II. Based on observation by surveyors and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration dates set by the manufacturer. Findings: 1. Direct observation by surveyors during the laboratory tour on December 12, 2022 at 1:30 pm revealed the following expired items: a) Hemocue Cleaner swabs Lot 1195203902 Expiration 9/20/22 Quantity: 5 swabs 2. In interview on December 12, 2022 at 1:45 pm, Testing Personnel 6 confirmed the identified supplies had exceeded the expiration date.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a system for handling complaints and problems reported to the laboratory. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written instructions for the investigation of complaints. 2. In interview on December 12, 2022 at 4:10 pm, Testing Personnel 6 confirmed the laboratory did not have a written procedure for reporting/handling complaints.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a system in place to ensure that the documentation of communication problems are reported to the laboratory. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written instructions to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. In in interview on December 12, 2022 at 4:10 pm, Testing Personnel 6 confirmed the laboratory did not have a communication policy in place.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include frequency of performance and the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on December 12, 2022 at 4:10 pm, Testing Personnel 6 confirmed the laboratory did not include a competency assessment policy for testing personnel.
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 observation by surveyors, review of laboratory policies and records as well as interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: a) The laboratory failed to ensure maintenance was performed as required for the Cepheid GeneXpert for three (3) of twelve (12) months reviewed. Refer to D5429. b) The laboratory failed to establish procedures for monitoring timer function checks utilized for kit testing prior to patient testing. Refer to D5435. c) The laboratory failed to perform quality control (QC) for the Cepheid GeneXpert analyzer every thirty (30) days per policy for two (2) of twenty four (24) months reviewed. Refer to D5445. d) The laboratory failed to perform corrective actions for room temperatures not documented for seven (7) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 I. e) The laboratory failed to perform corrective actions for freezer temperatures not documented for five (5) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 II. f) The laboratory failed to perform corrective actions for freezer temperatures not documented for nine (9) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 III. g) The laboratory failed to perform corrective actions for refrigerator temperatures not documented for nine (9) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 IV. h) The laboratory failed to perform corrective actions for refrigerator temperatures not documented for five (5) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 V. i) The laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for one (1) day of four

	hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 VI. j) The laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for three (3) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 VII. k) The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
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 observation by surveyors, review of maintenance logs and interview with personnel, the laboratory failed to ensure maintenance was performed as required for the Cepheid GeneXpert for three (3) of twelve (12) months reviewed. Findings: 1. Direct observation by surveyors during the laboratory tour on December 12, 2022 at 9: 30 am revealed the laboratory utilizes the Cepheid GeneXpert for Neisseria gonorrhoeae (GC) and Chlamydia trachomatis (CT) patient testing. 2. Review of the laboratory's maintenance logs for the Cepheid GeneXpert analyzer revealed the following maintenance tasks: a) Weekly: * Power down the GeneXpert instrument * Power down the GeneXpert computer b) Quarterly: * Clean plunger rod and cartridge bays * Clean instrument surfaces 3. Further review of the laboratory's maintenance logs for the Cepheid GeneXpert analyzer revealed the following maintenance was not performed as required for three (3) of twelve (12) months reviewed: a) March 2022: * Weekly - missing for the week of March 21, 2022 through March 25, 2022 b) September 2022: * Weekly - missing for the week of September 26, 2022 through September 30, 2022 c) April 2022: * Quarterly maintenance 4. In interview on December 13, 2022 at 9:30 am, Testing Personnel 6 confirmed the above identified weekly and quarterly maintenance was not performed as required.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation by surveyors, and interview with personnel, the laboratory failed to establish function checks to monitor timers utilized for serum hCG testing. Findings: 1. Direct observation by surveyors during the laboratory tour on December 12, 2022 at 9:30 am revealed the laboratory utilizes a timer for the ICON and McKesson hCG combo test kits for serum patient testing. 2. In interview on

	December 12, 2022 at 10:00 am, Testing Personnel 6 stated that she purchases the handheld timers at WalMart or Dollar Store and did not realize that some type of function check should be performed on the timers prior to patient testing. 3. In further interview on December 12, 2022 at 10:00 am, Testing Personnel 6 confirmed the laboratory did not perform function checks for timers utilized for patient testing.
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 observation by surveyors, review of the laboratory's Individualized Quality Control Plan (IQCP), quality control records and interview with personnel, the laboratory failed to perform quality control (QC) for the Cepheid GeneXpert analyzer every thirty (30) days per policy for two (2) of twenty four (24) months reviewed. Findings: 1. Observation by surveyors during the laboratory tour on December 12, 2022 at 9:30 am revealed the laboratory utilizes the Cepheid GeneXpert analyzer for Neisseria gonorrhea (GC) and Chlamydia (CT) patient testing. 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed the laboratory performs quality control (QC) every 30 days or with new lot/shipment. 3. Review of the laboratory's quality control (QC) records from January 2021 through December 2022 revealed the laboratory did not perform external QC every 30 days for the following two (2) of twenty four (24) months reviewed: a) January 2022: performed QC on December 20, 2021 then not again until February 7, 2022 b) May 2022: performed QC on April 21, 2022 then not again until June 15, 2022 4. In interview on December 13, 2022 at 1:45 pm, Testing Personnel 6 confirmed the laboratory did not perform external QC as required per policy for the identified months.
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: I. Based on review of the laboratory's policy, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for room temperatures not documented for seven (7) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Findings: 1. Review of the "Laboratory Temperature Monitoring" policy revealed "Alexandria Women's Center laboratory will appropriately monitor on a daily basis the operating temperatures of appropriate equipment: * Temperatures will be documented by NIST traceable thermometers * AWC will monitor refrigerator

temperature, freezer temperature for any out-sourced frozen specimens, and ambient room temperatures * The laboratory technician's responsibility each opening day of the laboratory is to document in the temperature log book the appropriate temperatures * Acceptable ranges for the refrigerator and freezer have been determined by evaluation of all laboratory media utilized * Anticipated range for the refrigerator and freezer are 2 to 8 degrees celsius and 0 to -20 degrees celsius respectively. The #2 freezer temperature will change to 0 to -25 degrees celsius * Attempts shall be made to maintain consistency in room temperature at approximately 68 to 86 degrees fahrenheit * Any identified transitioning of temperatures will be formally investigated and remedied." 2. Review of the laboratory's room #1 temperature logs for the room temperature revealed the following seven (7) days of four hundred eighty six (486) days in 2021 and 2022 were not documented per policy: a. March 31, 2021: no documented temperature b. April 2, 2021: no documented temperature c. April 29, 2021: no documented temperature d. April 30, 2021: no documented temperature e. September 30, 2021: no documented temperature f. July 29, 2022: no documeted temperature g. August 31, 2022: no documented temperature 3. In interview on December 12, 2022 at 3:50 pm, Testing Personnel 6 confirmed the laboratory did not document or perform corrective actions for room temperatures on the above identified dates. II. Based on review of the laboratory's policy, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for freezer temperatures not documented for five (5) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Findings: 1. Review of the "Laboratory Temperature Monitoring" policy revealed "Alexandria Women's Center laboratory will appropriately monitor on a daily basis the operating temperatures of appropriate equipment: * Temperatures will be documented by NIST traceable thermometers * AWC will monitor refrigerator temperature, freezer temperature for any out-sourced frozen specimens, and ambient room temperatures * The laboratory technician's responsibility each opening day of the laboratory is to document in the temperature log book the appropriate temperatures * Acceptable ranges for the refrigerator and freezer have been determined by evaluation of all laboratory media utilized * Anticipated range for the refrigerator and freezer are 2 to 8 degrees celsius and 0 to -20 degrees celsius respectively. The #2 freezer temperature will change to 0 to -25 degrees celsius * Attempts shall be made to maintain consistency in room temperature at approximately 68 to 86 degrees fahrenheit * Any identified transitioning of temperatures will be formally investigated and remedied." 2. Review of the laboratory's freezer #1 temperature logs revealed the following five (5) days of four hundred eighty six (486) days in 2021 and 2022 were not documented per policy: a. March 31, 2021: no documented temperature b. April 2, 2021: no documented temperature c. September 30, 2021: no documented temperature d. October 22, 2021: no documented temperature e. October 28, 2021: no documented temperature 3. In interview on December 12, 2022 at 3:50 pm, Testing Personnel 6 confirmed the laboratory did not document or perform corrective actions for freezer #1 on the above identified dates. III. Based on review of the laboratory's policy, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for freezer temperatures not documented for nine (9) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Findings: 1. Review of the "Laboratory Temperature Monitoring" policy revealed "Alexandria Women's Center laboratory will appropriately monitor on a daily basis the operating temperatures of appropriate equipment: * Temperatures will be documented by NIST traceable thermometers * AWC will monitor refrigerator temperature, freezer temperature for any out-sourced frozen specimens, and ambient room temperatures * The laboratory technician's responsibility each opening day of the laboratory is to document in the temperature log book the appropriate temperatures * Acceptable ranges for the refrigerator and

freezer have been determined by evaluation of all laboratory media utilized * Anticipated range for the refrigerator and freezer are 2 to 8 degrees celsius and 0 to -20 degrees celsius respectively. The #2 freezer temperature will change to 0 to -25 degrees celsius * Attempts shall be made to maintain consistency in room temperature at approximately 68 to 86 degrees fahrenheit * Any identified transitioning of temperatures will be formally investigated and remedied." 2. Review of the laboratory's freezer #2 temperature logs revealed the following nine (9) days of four hundred eighty six (486) days in 2021 and 2022 were not documented per policy: a. January 18, 2021: no documented temperature b. March 31, 2021: no documented temperature c. April 2, 2021: no documented temperature d. April 29, 2021: no documented temperature e. April 30, 2021: no documeted temperature f. September 30, 2021: no documented temperature g. October 29, 2021: no documented temperature h. July 29, 2022: no documented temperature i. August 31, 2022: no documented temperature 3. In interview on December 12, 2022 at 3:50 pm, Testing Personnel 6 confirmed the laboratory did not document or perform corrective actions for freezer #2 on the above identified dates. IV. Based on review of the laboratory's policy, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for refrigerator temperatures not documented for nine (9) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Findings: 1. Review of the "Laboratory Temperature Monitoring" policy revealed "Alexandria Women's Center laboratory will appropriately monitor on a daily basis the operating temperatures of appropriate equipment: * Temperatures will be documented by NIST traceable thermometers * AWC will monitor refrigerator temperature, freezer temperature for any out-sourced frozen specimens, and ambient room temperatures * The laboratory technician's responsibility each opening day of the laboratory is to document in the temperature log book the appropriate temperatures * Acceptable ranges for the refrigerator and freezer have been determined by evaluation of all laboratory media utilized * Anticipated range for the refrigerator and freezer are 2 to 8 degrees celsius and 0 to -20 degrees celsius respectively. The #2 freezer temperature will change to 0 to -25 degrees celsius * Attempts shall be made to maintain consistency in room temperature at approximately 68 to 86 degrees fahrenheit * Any identified transitioning of temperatures will be formally investigated and remedied." 2. Review of the laboratory's refrigerator #1 temperature logs revealed the following nine (9) days of four hundred eighty six (486) days in 2021 and 2022 were not documented per policy: a. March 31, 2021: no documented temperature b. April 2, 2021: no documented temperature c. April 29, 2021: no documented temperature d. April 30, 2021: no documented temperature e. May 31, 2021: no documented temperature f. September 30, 2021: no documented temperature g. October 22, 2021: no documented temperature h. October 28, 2021: no documented temperature i. August 31, 2022: no documented temperature 3. In interview on December 12, 2022 at 3:50 pm, Testing Personnel 6 confirmed the laboratory did not document or perform corrective actions for refrigerator #1 on the above identified dates. V. Based on review of the laboratory's policy, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for refrigerator temperatures not documented for five (5) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Findings: 1. Review of the "Laboratory Temperature Monitoring" policy revealed "Alexandria Women's Center laboratory will appropriately monitor on a daily basis the operating temperatures of appropriate equipment: * Temperatures will be documented by NIST traceable thermometers * AWC will monitor refrigerator temperature, freezer temperature for any out-sourced frozen specimens, and ambient room temperatures * The laboratory technician's responsibility each opening day of the laboratory is to document in the temperature log book the appropriate temperatures * Acceptable ranges for the refrigerator and freezer have been

determined by evaluation of all laboratory media utilized * Anticipated range for the refrigerator and freezer are 2 to 8 degrees celsius and 0 to -20 degrees celsius respectively. The #2 freezer temperature will change to 0 to -25 degrees celsius * Attempts shall be made to maintain consistency in room temperature at approximately 68 to 86 degrees fahrenheit * Any identified transitioning of temperatures will be formally investigated and remedied." 2. Review of the laboratory's refrigerator #2 temperature logs revealed the following five (5) days of four hundred eighty six (486) days in 2021 and 2022 were not documented per policy: a. April 30, 2021: no documented temperature b. September 30, 2021: no documented temperature c. October 22, 2021: no documented temperature d. July 29, 2022: no documented temperature e. August 31, 2022: no documented temperature 3. In interview on December 12, 2022 at 3:50 pm, Testing Personnel 6 confirmed the laboratory did not document or perform corrective actions for refrigerator #2 on the above identified dates. VI. Based on review of the laboratory's policy, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for one (1) day of four hundred eighty six (486) days reviewed in 2021 and 2022. Findings: 1. Review of the "Laboratory Temperature Monitoring" policy revealed "Alexandria Women's Center laboratory will appropriately monitor on a daily basis the operating temperatures of appropriate equipment: * Temperatures will be documented by NIST traceable thermometers * AWC will monitor refrigerator temperature, freezer temperature for any out-sourced frozen specimens, and ambient room temperatures * The laboratory technician's responsibility each opening day of the laboratory is to document in the temperature log book the appropriate temperatures * Acceptable ranges for the refrigerator and freezer have been determined by evaluation of all laboratory media utilized * Anticipated range for the refrigerator and freezer are 2 to 8 degrees celsius and 0 to -20 degrees celsius respectively. The #2 freezer temperature will change to 0 to -25 degrees celsius * Attempts shall be made to maintain consistency in room temperature at approximately 68 to 86 degrees fahrenheit * Any identified transitioning of temperatures will be formally investigated and remedied." 2. Review of the laboratory's refrigerator #2 temperature logs revealed the laboratory documented the acceptable range to be 2 degrees celsius to 8 degrees celsius. 3. Further review of the laboratory's refrigerator #2 temperature logs revealed the following one (1) day of four hundred eighty six (486) days in 2021 and 2022 exceeded the acceptable range per laboratory policy: a. May 16, 2022: temperature documented as 0 degrees celsius 4. In interview on December 12, 2022 at 3:50 pm, Testing Personnel 6 confirmed the laboratory did not perform corrective actions for refrigerator #2 on the above identified day. VII. Based on review of the laboratory's policy, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for three (3) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Findings: 1. Review of the "Laboratory Temperature Monitoring" policy revealed "Alexandria Women's Center laboratory will appropriately monitor on a daily basis the operating temperatures of appropriate equipment: * Temperatures will be documented by NIST traceable thermometers * AWC will monitor refrigerator temperature, freezer temperature for any out-sourced frozen specimens, and ambient room temperatures * The laboratory technician's responsibility each opening day of the laboratory is to document in the temperature log book the appropriate temperatures * Acceptable ranges for the refrigerator and freezer have been determined by evaluation of all laboratory media utilized * Anticipated range for the refrigerator and freezer are 2 to 8 degrees celsius and 0 to -20 degrees celsius respectively. The #2 freezer temperature will change to 0 to -25 degrees celsius * Attempts shall be made to maintain consistency in room temperature at approximately

	68 to 86 degrees fahrenheit * Any identified transitioning of temperatures will be formally investigated and remedied." 2. Review of the laboratory's refrigerator #1 temperature logs revealed the laboratory documented the acceptable range to be 2 degrees celsius to 8 degrees celsius. 3. Further review of the laboratory's refrigerator #1 temperature logs revealed the following three (3) days of four hundred eighty six (486) days in 2021 and 2022 exceeded the acceptable range per laboratory policy: a. November 9, 2021: temperature documented as 0 degrees celsius (acceptable range of 2 to 8 degrees celsius) b. November 10, 2021: temperature documented as 1 degrees celsius (acceptable range of 2 to 8 degrees celsius) c. November 11, 2021: temperature documented as 0 degrees celsius (acceptable range of 2 to 8 degrees celsius) 4. In interview on December 12, 2022 at 3:50 pm, Testing Personnel 6 confirmed the laboratory did not perform corrective actions for refrigerator #1 on the above identified day.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory policy, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Observation by surveyors, review of records, and interview with personnel revealed the laboratory did not identify the following issues with the analytic system: a) The laboratory failed to ensure maintenance was performed as required for the Cepheid GeneXpert for three (3) of twelve (12) months reviewed. Refer to D5429. b) The laboratory failed to establish procedures for monitoring timer function checks utilzed for kit testing prior to patient testing. Refer to D5435. c) The laboratory failed to perform quality control (QC) for the Cepheid GeneXpert analyzer every thirty (30) days per policy for two (2) of twenty four (24) months reviewed. Refer to D5445. d) The laboratory failed to perform corrective actions for room temperatures not documented for seven (7) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 I. e) The laboratory failed to perform corrective actions for freezer temperatures not documented for five (5) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 II. f) The laboratory failed to perform corrective actions for freezer temperatures not documented for nine (9) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 III. g) The laboratory failed to perform corrective actions for refrigerator temperatures not documented for nine (9) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 IV. h) The laboratory failed to perform corrective actions for refrigerator temperatures not documented for five (5) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 V. i) The laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for one (1) day of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 VI. j) The laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for three (3) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 VII.

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 observation by surveyors, review of laboratory policy and records, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that a complete quality control program was established to assure the quality of laboratory testing. Refer to D6020. 2. The Laboratory Director failed to ensure that a complete quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6021. 3. The Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D6023. 4. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 5. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
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 observation by surveyors, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that a complete quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform quality control (QC) for the Cepheid GeneXpert analyzer every thirty (30) days per policy for two (2) of twenty four (24) months reviewed. Refer to D5445.
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 observation by surveyors, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that a complete quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5793.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of laboratory policy and records as well as interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to ensure maintenance was performed as required for the Cepheid GeneXpert for three (3) of twelve (12) months reviewed. Refer to D5429. 2. The laboratory failed to establish procedures for monitoring timer function checks utilzed for kit testing prior to patient testing. Refer to D5435.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of laboratory's policies, temperature logs, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Findings: 1. The laboratory failed to perform corrective actions for room temperatures not documented for seven (7) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 I. 2. The laboratory failed to perform corrective actions for freezer temperatures not documented for five (5) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 II. 3. The laboratory failed to perform corrective actions for freezer temperatures not documented for nine (9) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 III. 4. The laboratory failed to perform corrective actions for refrigerator temperatures not documented for nine (9) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 IV. 5. The laboratory failed to perform corrective actions for refrigerator temperatures not documented for five (5) days of four hundred eighty

	six (486) days reviewed in 2021 and 2022. Refer to D5785 V. 6. The laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for one (1) day of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 VI. 7. The laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for three (3) days of four hundred eighty six (486) days reviewed in 2021 and 2022. Refer to D5785 VII.
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 policies, personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The Technical Consultant failed to evaluate the competency assessment for one (1) of seven (7) Testing Personnel in 2022. Refer to D6046. 2. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to have a system for handling complaints and problems reported to the laboratory. Refer to D5205. 2. The laboratory failed to have a system in place to ensure that the documentation of communication problems are reported to the laboratory. Refer to D5207.
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 the CMS-209 (Laboratory Personnel Report) form, personnel records and interview with personnel, the Technical Consultant failed to evaluate the competency assessment for one (1) of seven (7) Testing Personnel in 2022. Findings: 1. Review of the CMS-209 form revealed the Laboratory Director serves as the Technical Consultant. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for testing personnel competency assessments. 3. Review of personnel records for Testing Personnel 6 revealed an annual competency assessment was performed on June 20, 2022; however, the competency assessment for Testing Personnel 6 was not performed by qualified personnel. 4. In interview on December 13, 2022 at 2:00 pm, the Laboratory Director confirmed that he did not perform the competency assessment for the identified personnel in 2022.