Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2274413	01/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Emerge Quick Care Llc	20180 S Lagrange Rd, Frankfort, IL	

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	An initial survey was completed on 01-27-2025. Immediate Jeopardy existed for the following condition level deficiencies: 42 C.F.R. 493.801 Condition: Enrollment and testing of samples 42 C.F.R. 493.1230 Condition: General laboratory systems 42 C.F.R. 493.1250 Condition: Analytic systems 42 C.F.R. 493.1403 Condition: Laboratories performing Moderate complexity testing; laboratory director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: 2000 A Based on direct observation, review of laboratory policy and procedures, review of American Proficiency Institute (API) records, and interview with testing personnel (TP) #2, the laboratory failed to enroll in proficiency testing challenges in 2023 through 2025 for four of four microbiology sub-specialties: bacteriology (0005), mycology (0025), parasitology (0035), and virology (0045). Findings Include: 1. Direct observation during a tour of the laboratory on 01-22-2025, at 11:10 am, the surveyor identified the GeneXpert Dx analyzer (serial number 120000042). The surveyor also identified four cartridge types being utilized by the laboratory these included the Xpert Xpress MVP (ref XPRSMVP-10), Xpert Xpress Strep A (ref XPRSTREPA-10), Xpert Xpress SARS-CoV-2_Flu_RSV plus (ref XPRS4PLEX-10) and Xpert CT/NG (ref GXCT/NG-10). 2. Review of each GeneXpert cartridge

	instructions for use (IFU) revealed that they were used to test the analytes as follows: a. Xpert Xpress Strep A (ref XPRSTREPA-10) Streptococcus pyogenes group A b. Xpert Xpress SARS-CoV-2_Flu_RSV plus (ref XPRS4PLEX-10) SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, Influenza B. c. Xpert Xpress MVP (ref XPRSMVP-10) Bacterial Vaginosis (BV), Candida species, Trichomonas Vaginalis d. Xpert CT/NG (ref GXCT/NG-10) Chamydia trachomatis, Neisseria gonorrhoeae 3. Review of laboratory policies and procedures revealed a document titled "Proficiency Testing" which stated, "The laboratory will be enrolled in an approved Proficiency testing program for all regulated analytes as specified in Subpart I, Proficiency testing Programs for non waived testing, of the CLIA regulations. For each unregulated analyte tat the laboratory is not enrolled in a CMS approved PT program, we will perform and compare the results of external split- specimen testing on at least five specimens twice a year in periodic intervals." 4. Review of laboratory's API proficiency testing records revealed the laboratory failed to enroll in PT for bacteriology (0005) for group A streptococcus, bacterial vaginosis screening, Neisseria gonorrhoeae and chlamydia trachomatis; mycology (0025) for Candida species; parasitology (0035) for trichomoniasis; and virology (0045) for Sars-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, Influenza B. 5. Review of laboratories test volume worksheet revealed the laboratory performed 1010 patient tests in the specialty of microbiology from July 2024 through January 2025. 6. During the survey on 01-22-2025, at 01:13 pm, TP #2 confirmed the surveyor's findings that the laboratory had failed to enroll in or perform proficiency testing for the sub-specialties of bacteriology, mycology, parasitology, and virology. D2000 B Based on review of the federal CASPER report 0096D, American Proficiency Institute (API) proficiency test (PT) records, and interview with testing personnel (TP) #2, the laboratory failed to attain a score of 80% for Red Blood Cell count (RBC) in the specialty of hematology for testing event 2 of 2024 (see D2121).
D2121	HEMATOLOGY CFR(s): 493.851(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the federal CASPER report 0096D, American Proficiency Institute (API) proficiency test (PT) records, and interview with testing personnel (TP) #2, the laboratory failed to attain a score of 80% for Red Blood Cell count (RBC) in the specialty of hematology for testing event 2 of 2024. Findings Include: 1. Review of the federal CASPER report 0096D revealed the following unsatisfactory scores for API PT event 2 of 2024: a.60% - Red blood cell count (RBC) 2. Review of the laboratory's API records for hematology event 2 of 2024 confirmed the laboratory had unacceptable scores (60%) for red blood cell count for event 2 of 2024 and no corrective actions were documented. 3. Review of laboratories test volume worksheet revealed the laboratory performed 1260 patient tests in the specialty of hematology from July 2024 through January 2025. 4. During the survey on 01-22-2025, at 01:13 pm, TP #2 confirmed the surveyor's findings that the laboratory failed to have corrective actions for the unacceptable scores for API hematology event 2 of 2024.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230

	Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory records, policy and procedure manual, laboratory American Proficiency Institute (API) record and interview with testing personnel (TP) #2, the laboratory failed to establish policies and procedures to assess employee competency for four of four testing personnel (see D5209), the laboratory failed to document review for two of two proficiency testing (PT) events for hematology in 2024 (see D5211), the laboratory failed to verify the accuracy of artificially scored proficiency testing (PT) analyte performance for the third hematology API PT event of 2024 (see D5215), the laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting problems with malfunctioning equipment including the Diatron Abacus 3CP and an i-STAT analyzer starting in 2022 through 01-22-2025 (see D5291).
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 records and interview with testing personnel (TP) #2, the laboratory failed to establish policies and procedures to assess employee competency for four of four testing personnel. Findings Include: 1. Review of the laboratory's policy and procedure manual found no policy had been established to assess the competency of personnel listed on the CMS-209 (Laboratory Personnel Report). 2. On survey date 01-22-2025, at 01:04 pm, TP #2 confirmed the laboratory failed to establish or perform a competency assessment for four of four testing personnel.
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 laboratory American Proficiency Institute (API) records and interview with testing personnel (TP) #2, the laboratory failed to document review for two of two proficiency testing (PT) events for hematology in 2024. Findings Include: 1. Review of the laboratory's API PT records from event two and three of 2024 revealed the laboratory failed to document review of PT results for hematology which

	included the following analytes: a. Erythrocyte Count b. Hematocrit c. Hemoglobin d. Leukocyte Count/ White Blood Cell count e. Platelet Count f. White Blood Cell Differential 2. Review of Laboratory's policy and procedure titled "Proficiency Testing" states "All PT results will be reviewed and evaluated by the laboratory director or other qualified designee in a timely manner" 3. On survey date 01-22-2025, at 01:13 pm, TP #2 confirmed the laboratory failed to document review of PT results for the two hematology events performed in 2024
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of laboratory American Proficiency Institute (API) records, laboratory policy and procedures, and interview with testing personnel (TP) #2, the laboratory failed to verify the accuracy of artificially scored proficiency testing (PT) analyte performance for the third hematology API PT event of 2024. Findings Include: 1. Review of American Proficiency Institute (API) Hematology/Coagulation PT documentation for event 3 of 2024 found that the laboratory's performance was not evaluated by API for the following analytes: Erythrocyte Count, Hematocrit, Hemoglobin, White Blood Cell/ Leukocyte Count, Platelet Count, and White Blood Cell Differential. The laboratory had been artificially scored as 100% for all analytes due to the laboratory not participating in the PT event due to "instrument out of service". 2. Review of the laboratory's PT policy titled, "Proficiency Testing", states the following: "PT results that are not graded will be self-graded by comparing the results to the expected results of the PT agency or peer results". 3. No corrective actions were documented in 2024 for the API hematology event 3 artificially scored PT event. 4. On survey date 01-22-2025, at 01:13 pm, TP #2 confirmed that a self-evaluation was not performed for event 3 of 2024, Hematology analytes.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory records, laboratory policy and procedures, and interview with testing personnel (TP) #2, the laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting problems with malfunctioning equipment including the Diatron Abacus 3CP and an i-STAT analyzer starting in 2022 through 01-22-2025. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy titled "Incident Management Plan" which states, " The laboratory must address incidents that occur as a result of: non-

	compliance with expected laboratory policies and procedures resulting in a significant negative impact on patient care or the safety of patients or staff; and errors, accidents or unexpected events that have caused or have the potential to cause, death or serious injury to patients or staff .....4. The designated incident investigator will analyze the impact of the incident during the time prior to the initial report of the incident, during the investigation of the incident, and for future testing. It may be prudent to suspend testing or make other treatment decisions until the true cause has been determined and corrected. There may be need to notify affected patients and re-evaluate their medical care. 5. The incident investigator will perform a root cause analysis. Ask "what happened, when did it happen, who was involved, where did it happen, how did it happen, and why did it happen." Continue to ask" Why" at least five times to discover the true underlying cause.6. The incident investigator documents the facts, findings and conclusion, and the report is given to the laboratory director for review and signature. 7.Based upon the findings, the laboratory director determines the appropriate corrective actions that will be taken to prevent a recurrence of the incident. A timeline for implementation of corrective actions should be established. The laboratory should document the date that each corrective action step is completed 8. The investigation findings and outcome are communicated to the staff. Complete any necessary policy or procedure revision or retraining of personnel. 9. Within a pre-determined amount of time, the laboratory director or designee will perform a follow-up evaluation of the corrective actions to ensure that they were effective". 2.On survey date 01-22-2025, at 01:12 pm, the surveyor requested an incident report for the Abacus 3CP not functioning during the 3rd proficiency testing event from API (see D5215). This document was not provided until 01-27-25. The documentation failed to follow the incident management plan as follows: a. No root cause analysis of the event with five "why's". b. No review signature by the laboratory director. c. No timeline for the corrective actions was provided. d. No documentation was provided for dates that the corrective actions was completed. e. No proof of communication to staff was provided and no documented evidence of revisions to procedures or retraining of personnel was provided. f. No follow up evaluation of the corrective actions was documented. 3. On survey date 01-22-2025, at 01:12 pm, the surveyor requested an incident report for the i-STAT analyzer being removed from use at the site. This document was not provided until 01-27-25. The documentation failed to follow the incident management plan as follows: a. No root cause analysis of the event with five "why's". b. No review signature by the laboratory director. c. No plan of action and no timeline for the corrective actions was documented. d. No documentation was provided for dates that the corrective actions were completed. e. No proof of communication to staff was provided and no documented evidence of revisions to procedures or retraining personnel was provided. f. No follow up evaluation of corrective actions was documented. 4. On survey date 01-22-2025, at 01: 14 pm, TP# 2 confirmed the surveyors finding that no quality assessment documentation for any adverse events existed.
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 direct observation, review of laboratory's policy and procedure manual, laboratory records, manufacturer's instructions and interview with testing personnel (TP) #2, the laboratory failed to outline all components of test procedure for all testing on the Cepheid GeneXpert Dx and Diatron Abacus 3CP analyzer for the specialties of microbiology and hematology (see D5403), the laboratory failed to document the initial use and discontinuance for testing performed on the Abbott i-STAT analyzer (see D5409), the laboratory failed to demonstrate it can obtain performance specification comparable to those established by the manufacturer for ten of ten tests performed including testing for group A streptococcus, bacterial vaginosis screening, neisseria gonorrhea. chlamydia trachomatis, Candida species, Trichomonas Vaginalis, SARS-CoV-2, respiratory syncytial virus, influenza A, and influenza B testing on one Cepheid GeneXpert Dx analyzer (see D5421 A), the laboratory failed to demonstrate it can obtain performance specification comparable to those established by the manufacturer for White blood cell differential on the Diatron Abacus 3CP (see D5421 B), the laboratory failed to perform and document preventive maintenance for 9 of 12 months for microbiology testing on the Cepheid GeneXpert Dx in 2024 (see D5429 A), the laboratory failed to perform and document preventative maintenance for 12 of 12 months for hematology testing on the Diatron Abacus 3CP analyzer in 2024 through 2025 (see D5429 B), the laboratory failed to follow the manufacturer's instructions for quality control (QC) testing for 15 of 15 patient records reviewed for influenza A, influenza B, streptococcus A, bacterial vaginosis, neisseria gonorrhea, chlamydia trachomatis, Candida species, Trichomonas Vaginalis, SARS-CoV-2, and respiratory syncytial virus on the GeneXpert Dx (see 5445 A), the laboratory failed follow the laboratory's quality control (QC) procedure for the Diatron Abacus 3CP for Complete Blood Count (CBC) testing for four of four patient test dates reviewed (see 5445 B).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by:

	Based on review of laboratory's policy and procedure manual and interview with testing personnel (TP) #2, the laboratory failed to outline all components of test procedure for all testing on the Cepheid GeneXpert Dx and Diatron Abacus 3CP analyzer for the specialties of microbiology and hematology. Findings Include: 1. Review of the laboratory's policy and procedure titled "Abacus 3CP Machine Guide" and the manufacturer's instructions titled "A3CPC-1 Abacus 3CP User Manual v 1.3" which failed to outline: a. The reportable range for test results for the test system as established. b. The imminently life-threatening test results, or panic or alert values. c. The laboratory's system for entering results in the patient record and reporting patient results including, When appropriate, the protocol for reporting imminently life threating results, or panic. or alert values. 2. Review of the manufacturer's instructions for the GeneXpert Dx failed to outline the following for four of four cartridges in use at the laboratory which included the Xpert Xpress Strep A cartridge, Xpert Xpress SARS-CoV-2_Flu_RSV plus cartridge, Xpert Xpress MVP cartridge, and Xpert CT /NG cartridge a. The laboratory's system for entering results in the patient record and reporting patient results including, When appropriate, the protocol for reporting imminently life threating results, or panic. or alert values. b. Control procedures and corrective actions to take when controls fail to mee the laboratory's established criteria. 3. During survey date 01-22-2025, at 01:22 pm, TP#2 confirmed the laboratory used the manufacturer's instructions for use and the laboratory's supplemental policies and procedures which failed to have the required components of a test procedure
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) (e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedure manuals and interview with testing personnel (TP) #2, the laboratory failed to document the initial use and discontinuance for testing performed on the Abbott i-STAT analyzer. Findings Include: 1. Laboratory failed to identify discontinuance of usage for the i-STAT analyzer in the year 2022. 2. On survey date 01-22-2025, at 01:12 pm, TP #2 confirmed the findings that the i-STAT hematology analyzer was no longer used on site.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: 5421 A Based on direct observation, review of laboratory policy and procedure, laboratory records, and interview with testing personnel (TP) #2, the laboratory failed

to demonstrate it can obtain performance specification comparable to those established by the manufacturer for ten of ten tests performed including testing for group A streptococcus, bacterial vaginosis screening, neisseria gonorrhea. chlamydia trachomatis, Candida species, Trichomonas Vaginalis, SARS-CoV-2, respiratory syncytial virus, influenza A, and influenza B testing on one Cepheid GeneXpert Dx analyzer. Findings Include: 1. Direct observation of laboratory testing equipment during a tour of the laboratory facility, on 01-22-2025, at 11:10 am, identified one Cepheid GeneXpert Dx analyzer (serial numbers 120000042). 2. Review of the policy and procedure manual identified the policy, "New Test Implementation Policy", which states: "Before processing patient samples for any new non-waived test, the laboratory will ensure the following prerequisites are completed by the Technical Consultant and approved by the Laboratory Director. 1. Procedure for each new test. 2. Performance verification of each new test will be completed by a technical consultant and approved by the Laboratory Director. 3.Initial training and competency of personnel on each test procedure 4. Enrollment in proficiency testing for all regulated/non-regulated analytes ..... The details of the establishment and verification of performance specifications are as follows: "This clinical laboratory shall verify each new test, method, or instrument prior to reporting patient results. These verifications shall be documented."The verification includes establishment of written quality control procedures for each testing system or methodology to include: o The range of quality control values used. o The frequency of quality control testing. o Adherence to the manufacturer's recommendations o The predicted reliability based on history o Specialty and subspecialty requirements" 3. Review of the GeneXpert Dx validation revealed the laboratory failed to have completed validations records for each of the following GeneXpert cartridges: a. Xpert Xpress Strep A: Validation records failed to include a validation report that indicated accuracy, precision, and reportable range matched the manufactures specifications and was approved by the Laboratory director. b. Xpert Xpress SARS-CoV-2_Flu_RSV plus: validation records failed to include a validation report that indicated accuracy, precision, and reportable range matched the manufactures specifications and was approved by the Laboratory director. c. Xpert Xpress MVP: validation records failed to include a validation report that indicated accuracy, precision, and reportable range matched the manufactures specifications and was approved by the Laboratory director. d. Xpert CT/NG: validation records failed to include a validation report that indicated accuracy, precision, and reportable range matched the manufactures specifications and was approved by the Laboratory director. 4. Review of test volume records revealed the laboratory performed 1010 patient tests on the Cepheid GeneXpert Dx analyzer from July 2024 through January 2025. 5. On survey date 01-22-2024, at 06:13 pm, TP #2 confirmed the laboratory validation documentation for the Cepheid GeneXpert Dx did not have the required components identified above. 5421 B Based on direct observation, review of laboratory policy and procedure, laboratory records, and interview with testing personnel (TP) #2, the laboratory failed to demonstrate it can obtain performance specification comparable to those established by the manufacturer for White blood cell differential on the Diatron Abacus 3CP. Findings Include: 1. Direct observation of laboratory testing equipment during a tour of the laboratory facility, on 01-22-2025, at 11:10 am, identified one Diatron Abacus 3CP (serial number 380123). 2. Review of the policy and procedure manual identified the policy, "New Test Implementation Policy", which states: "Before processing patient samples for any new non-waived test, the laboratory will ensure the following prerequisites are completed by the Technical Consultant and approved by the Laboratory Director. 1. Procedure for each new test. 2. Performance verification of each new test will be completed by a technical consultant and approved by the Laboratory Director. 3.Initial training and competency of personnel on each test procedure 4. Enrollment in

	proficiency testing for all regulated/non-regulated analytes ..... The details of the establishment and verification of performance specifications are as follows: "This clinical laboratory shall verify each new test, method, or instrument prior to reporting patient results. These verifications shall be documented. "The verification includes establishment of written quality control procedures for each testing system or methodology to include: o The range of quality control values used. o The frequency of quality control testing. o Adherence to the manufacturer's recommendations o The predicted reliability based on history o Specialty and subspecialty requirements" 3. Review of the Diatron Abacus 3CP validation records revealed the laboratory failed to have validation records that indicated accuracy, precision, and reportable range that matched the manufactures specifications and was approved by the laboratory director for the test white blood cell differential. 4. Review of test volume records revealed the laboratory performed 1260 patient tests on the Diatron Abacus 3CP analyzer from July 2024 through January 2025. 5. On survey date 01-22-2025, at 06:13 pm, TP #2 confirmed the laboratory validation documentation for the Diatron Abacus 3CP did not have the required components as stated by the laboratories policy and identified above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: 5429 A Based on observation, review of manufacturer's instructions for use, laboratory preventative maintenance records, and interview with testing personnel (TP) #2, the laboratory failed to perform and document preventive maintenance for 9 of 12 months for microbiology testing on the Cepheid GeneXpert Dx in 2024. Findings Include: 1. Direct observation during a tour of the laboratory on 01-22-2025, at 11:10 am, the surveyor identified the GeneXpert Dx (serial number 120000042). 2. Review of the manufacturer's instructions for use manual for the Cepheid GeneXpert Dx outlined the preventative maintenance schedule as: Daily maintenance: clean work area, close all module doors, discard used cartridges. Weekly maintenance: power down the GeneXpert computer and instrument, clean fan prefilters. Monthly maintenance: archive tests, purge tests, replace fan filters Quarterly maintenance: clean plunger rod and cartridge bays, clean instrument surfaces Yearly maintenance: check annual instrument maintenance 3. Review of preventative maintenance documentation for the Cepheid GeneXpert Dx reveled the laboratory failed to document the performance of preventative maintenance for 9 of 12 months in 2024. 4. On survey date 01-22-2025, at 04:35 pm, TP #2 confirmed the laboratory failed to document daily, weekly, and monthly preventative maintenance of the Cepheid GeneXpert Dx. 5429 B Based on observation, review of manufacturer's instructions for use, laboratory preventative maintenance records, and interview with testing personnel (TP) #2, the laboratory failed to perform and document preventative maintenance for 12 of 12 months for hematology testing on the Diatron Abacus 3CP analyzer in 2024 through 2025. Findings Include: 1. Direct observation during a tour of the laboratory on 01-22-2025, at 11:10 am, the surveyor identified the Abacus 3CP (serial number 380123). 2. Review of the manufacturer's instructions for use manual for the Diatron Abacus 3CP outlined the preventative maintenance schedule as: Daily activity: Check printer paper, Check reagents, Empty waste (if applicable), Perform and accept blank cycle, run quality control, Clean external surfaces (if needed),

	perform shutdown and power off. Weekly activities: Perform Hard cleaning with Hypoclean CC, check tubing for any leaks, Semi-annual activity: perform and print self-test, perform calibration. 3. Review of preventative maintenance documentation for the Diatron Abacus 3CP reveled the laboratory failed to document the performance preventative maintenance for 12 of 12 months in 2024. 4. On survey date 01-22-2025, at 04:35 pm, TP #2 confirmed the laboratory failed to document daily, weekly, and monthly preventative maintenance of the Diatron Abacus 3CP.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: 5445 A Based on direct observation, review of laboratory records, manufacturer's instructions, laboratory policies and procedures, and interview with testing personnel (TP) #2, the laboratory failed to follow the manufacturer's instructions for quality control (QC) testing for 15 of 15 patient records reviewed for influenza A, influenza B, streptococcus A, bacterial vaginosis, neisseria gonorrhea, chlamydia trachomatis, Candida species, Trichomonas Vaginalis, SARS-CoV-2, and respiratory syncytial virus on the GeneXpert Dx. Findings include: 1.Direct observation during a tour of the laboratory on 01-22-2025, at 11:10 am, the surveyor identified the GeneXpert Dx (serial number 120000042). 2. Review of the manufacturer's instructions for use for the test cartridges in use (Xpert Xpress Strep A, Xpert Xpress SARS-CoV-2_Flu_RSV plus, Xpert Xpress MVP, and Xpert CT/NG) on the Cepheid GeneXpert analyzer stated: "External controls described in section 9 are available but not provided and must be used in accordance with local, state, and/or federal regulations or accreditation requirements, as applicable." 3. Review of laboratory procedures found no QC testing procedure available for testing on the Cepheid GeneXpert Dx analyzer for four of four cartridges (see D5403) 4. On survey date 01-22-2025, at 04: 53 pm, TP #2 stated, "Positive and negative quality control for each test is completed monthly" for cartridges on the Cepheid GeneXpert Dx analyzer. 5. Review of QC documents from 08-13-23 through 01-22-25 for the Cephid GeneXpert Dx analyzer revealed that positive and negative external QC testing was completed for: Xpert Xpress Strep A on 08-13-23,08-19-23, 08-30-23, 09-01-23, 09-11-23, 10-03-23, 01-13-24, 2-17-24, 10-14-24,12-31-24, Xpert Xpress SARS-CoV-2_Flu_RSV plus on 08-30-23, 01-13-24, 02-17-24, 04-27-24, 10-14-24, 12-31-24 Xpert Xpress MVP on 08-17-23, 09-15-23 Xpert CT/NG on No documented evidence of external positive and negative QC for CT/NG was available to surveyors on 01-22-2025. 6. Review of patient test records revealed that QC was not performed for each cartridge on the day of testing for 15 of 15 days. Test Cartridges: SARS-CoV-2_Flu_RSV plus, strep A, CT/NG, MVP MRN Date a. 03222014 05-01-24 b. 12121659 10-24-24 c. 05071957 06-14-24 d. 06171986 09-14-24 e. 10102011 12-12-24 f. 02101987 05-21-24 g. 05231998 04-22-24 h. 09291963 01-06-24 i. 11122007 12-01-24 j. 05162004 04-17-

	24 k. 07071982 01-07-24 l. 02182000 06-24-24 m. 01311996 09-20-24 n. 06291987 05-06-24 o. 11012001 12-23-24 7. Review of the laboratory test volume worksheet indicated 1010 patient tests were performed on the Cepheid GeneXpert for influenza A, influenza B, streptococcus A, bacterial vaginosis, neisseria gonorrhea, chlamydia trachomatis, Candida species, Trichomonas Vaginalis, SARS-CoV-2, and respiratory syncytial virus (RSV) from July 2024 through January 2025. 5445 B Based on direct observation, review of laboratory quality control records, laboratory policies and procedures, and interview with testing personnel (TP) #2, the laboratory failed follow the laboratory's quality control (QC) procedure for the Diatron Abacus 3CP for Complete Blood Count (CBC) testing for four of four patient test dates reviewed. Findings include: 1.Direct observation during a tour of the laboratory on 01-22-2025, at 11:10 am, the surveyor identified the Abacus 3CP (serial number 380123). 2. Review of the laboratories policy titled "Abacus 3CP Machine Guide" stated "Everyday- turn machine on/off daily before use. Run a blank test everyday before doing the QC ...QC vials are Blue (low) Red (high) Green (normal) ....if the QC does not pass, please discard the last test and conduct another test until it passes. Make sure to hit the right level (low, high, normal, or the results level will not be in normal range, in which case you will have to start QC again." 3. Review of patient tests results for CBC testing on the Diatron Abacus 3CP found that for four of four dates reviewed that quality control procedures were not performed as required. Patient Identification Test Date QC Error 09251979 01-31-2024 High QC for Hematocrit flagged QC not retested. 03021990 06-05-2024 No Low, Normal or High QC documented. 06072004 09-01-2024 No High QC documented. 03301966 11-04-2024 No Low QC documented. 4. On survey date 01-22-2025, at 06:14 pm, TP #2 confirmed the laboratory failed to follow the laboratory's procedure for QC testing on the Diatron Abacus 3CP.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory patient test records and interview with testing personnel (TP) #2, the laboratory failed to include all the required components of a laboratory test report for 15 of 15 patient test reports reviewed. Findings Include: 1. Review of 15 of 15 patient test reports for tests analyzed on the GeneXpert Dx, found the laboratory failed to include the name and address of the laboratory location where the test was performed and specimen source. MRN Date A. 03222014 05-01-24 B. 12121659 10-24-24 C. 05071957 06-14-24 D. 06171986 09-14-24 E. 10102011 12-12-24 F. 02101987 05-21-24 G. 05231998 04-22-24 H. 09291963 01-06-24 I. 11122007 12-01-24 J. 05162004 04-17-24 K. 07071982 01-07-24 L. 02182000 06-24-24 M. 01311996 09-20-24 N. 06291987 05-06-24 O. 11012001 12-23-24 2. On survey date 01-22-2025, at 06:15 pm, TP #2 confirmed the provided documentation lacked the required components identified above.

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 CMS-209 form, laboratory verification records, proficiency testing (PT) records, academic records, and interview with testing personnel (TP) #2, the laboratory director (LD) failed to ensure verification procedures for the site were conducted prior to patient testing in the specialty of microbiology and hematology (see D6013), the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program from 2023 to 2025 for four of four subspecialties tested on the GeneXpert Dx. (see D6015), the laboratory director failed review proficiency testing (PT) for two of two American Proficiency Institute (API) events in 2024 for Hematology (see D6018), the laboratory director failed to ensure quality control and quality assessment programs were maintained in 2022 through 2025 (see D6020), the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system (see D6023), the laboratory director failed to ensure policies and procedures were established and maintained to monitor the competency of four of four testing personnel (see D6030).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on surveyor review of laboratory verification records and interview with testing personnel (TP) #2, the laboratory director (LD) failed to ensure verification procedures for the site were conducted prior to patient testing in the specialty of microbiology and hematology. Findings Include: 1. Review of laboratory verification records revealed the LD failed to follow the sites verification procedures for the GeneXpert Dx (see D5421 A). 2. Review of laboratory verification records revealed the LD failed to follow the sites verification procedures for the Diatron Abacus 3CP (see D5421 B). 3. On survey date 01-22-2025, at 06:13 pm, (TP) #2 confirmed that the laboratory verification records were not complete.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing (PT) records and interview with testing personnel (TP) #2, the laboratory director failed to ensure the laboratory was

	enrolled in an HHS approved proficiency testing program from 2023 to 2025 for four of four subspecialties tested on the GeneXpert Dx. Findings Include: 1. The director failed to ensure the site was enrolled in PT for four of four microbiology sub-specialties for all analytes performed on the GeneXpert Dx analyzer (see D2000 A). 2. On survey date 01-22-2025, at 01:13 pm, TP #2 confirmed that the laboratory did not enroll in PT for testing on the GeneXpert Dx.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel #2, the laboratory director failed review proficiency testing (PT) for two of two American Proficiency Institute (API) events in 2024 for Hematology. Findings Include: 1. The laboratory director failed to review the 2nd and 3rd API Hematology event of 2024 (see D5211). 2. The laboratory director failed to ensure corrective actions were taken for the Red Blood Cell count failure for the 2nd API Hematology event of 2024 (see D2121). 3. The laboratory director failed to verify the accuracy of artificially scored proficiency testing (PT) analyte performance for the third hematology API PT event of 2024 (see D5215).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and 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 laboratory quality control records, laboratory policy and procedures, and interview with testing personnel (TP) #2, the laboratory director failed to ensure quality control and quality assessment programs were maintained in 2022 through 2025. Findings Include: 1. Review of laboratory policy titled " Quality control monthly reports" states "We will follow manufacturer requirements for all quality control of all tests ..... All QC will be reviewed by the Laboratory Director/ Technical Consultant and signed off. QC out of control form will be filled when a problem occurs and corrective action would be taken and documented." 2. The laboratory failed to follow the manufacturer's instructions for quality control (QC) testing for 15 of 15 patient records reviewed for influenza A, influenza B, Streptococcus A, bacterial vaginosis, neisseria gonorrhea, chlamydia trachomatis, Candida species, Trichomonas Vaginalis, SARS-CoV-2, and respiratory syncytial virus on the GeneXpert Dx (see D5445 A). 3. The laboratory failed follow the laboratory's quality control (QC) procedure for the Diatron Abacus 3CP for Complete Blood Count (CBC) testing for four of four patient test dates reviewed (see D5445 B) 4. The laboratory failed to document problems with malfunctioning equipment including the Diatron Abacus #CP and an i-Stat analyzer in 2022 through 01-22-2025 (see D5291). 5. The laboratory director failed to ensure preventative maintenance

	actives were documented as required for the Diatron Abacus 3CP and Cepheid GeneXpert Dx (see D5429 A and B).
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (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 records, laboratory policy and procedures, and interview with testing personnel (TP) #2 and laboratory director (LD), the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. Findings include: 1. The laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting problems with malfunctioning equipment including the Diatron Abacus 3CP and an i-STAT analyzer starting in 2022 through 01-22-2025 (see D5291). 2. The laboratory failed to document the initial use and discontinuance for testing performed on the Abbott i-STAT analyzer (see D5409). 3.The laboratory failed to demonstrate it can obtain performance specification comparable to those established by the manufacturer for the GeneXpert Dx and the Diatron Abacus 3CP (see D5421 A and B). 4.The laboratory failed to perform and document preventive maintenance for microbiology and hematology testing 2024 (see D5429 A and B). 5. The laboratory failed follow the manufacturer's instructions and the laboratory's procedures for quality control (QC) testing (see D5445 A and B). 6. On survey date 01-22-2025, at approximately 6:10 PM, TP #2 called the laboratory director for the exit interview. It was at this time the LD stated "I don't have time for this just write it down" then ended the call.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (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 the laboratory records and interview with testing personnel (TP) #2, the laboratory director failed to ensure policies and procedures were established and maintained to monitor the competency of four of four testing personnel. Findings Include: 1. No competency assessments documentation was provided to surveyors when requested on 01-22-2025 for four of four individuals performing testing (see D5209). 2. On survey date 01-22-2025, at 01:04 pm, TP #2 confirmed the site did not have any competency records for the four TP.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the

	qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, the CMS-209 (Laboratory Personne Report), and interview with testing personnel (TP) #2, the laboratory failed to have qualifying documents for one of four testing personnel listed on the CMS-209 (see D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records, the CMS-209 (Laboratory Personnel Report), and interview with laboratory testing personnel (TP) #2, the laboratory failed to have qualifying documents for one of four testing personnel listed on the CMS-209. Findings Include: 1. No qualifying documents were available to review for one of four TP (TP #4), as listed on the CMS-209. On 01-28-25 a certificate of completion for a paramedic program was provided for TP#4. No high school diploma or equivalent degree was provided by the laboratory. 2. On survey date 01-22-25, at 01:05 pm, TP #2 confirmed the laboratory did not have qualifying education documentation on site for TP #4.