Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2110804	03/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Vista Medical Center North Arlington	5335 Langston Blvd, Arlington, VA	

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 announced CLIA validation survey was conducted at Urgent Care Center of Arlington on March 12, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), the laboratory's proficiency testing (PT) records and an interview with Testing Personnel (TP) A, the laboratory failed to rotate PT among testing personnel performing patient testing for nine (9) of nine (9) PT events during calendar years 2017 and 2018. Findings include: 1. Review of the CMS Form 209 revealed five (5) testing personnel performing patient testing in 2017 and 2018. 2. Review of the laboratory's 2017 and 2018 American Proficiency Institute (API) PT documentation (a total of 9 events) revealed TP A performed the following PT Events: 2017 API Core Chemistry Event 2; 2017 API Hematology/Coagulation Event 1; 2017 API Hematology/Coagulation Event 2; 2017 API Hematology/Coagulation Event 3; 2018 API Virology Event 3; 2018 API Core Chemistry Event 1; 2018 API Hematology/Coagulation Event 1; 2018 API Hematology/Coagulation Event 2 and 2018 API Hematology/Coagulation Event 3. 9 of 9 PT events were performed by TP A. (See Personnel Code Sheet.) 3. In an exit interview at approximately 1:45 PM, TP A confirmed the above findings.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and an interview with Testing Personnel (TP) A, the Laboratory Director (LD) and testing personnel failed to sign five (5) of nine (9) PT attestation statements during calendar years 2017 and 2018. Findings include: 1. Review of the American Proficiency Institute (API) records for 2017 and 2018 revealed the following: 2017 API Core Chemistry Event 2 attestation signed by LD and TP A; 2017 API Hematology /Coagulation Event 1 attestation signed by LD and TP A; 2017 API Hematology /Coagulation Event 2 attestation signed by LD and TP A; 2017 API Hematology /Coagulation Event 3 attestation not signed by Laboratory Director and TP A; 2018 API Virology Event 3 attestation not signed by Laboratory Director and TP A; 2018 API Core Chemistry Event 1 attestation signed by LD and TP A; 2018 API Hematology/Coagulation Event 1 attestation not signed by Laboratory Director and TP A; 2018 API Hematology/Coagulation Event 2 attestation not signed by Laboratory Directore and TP A; and 2018 API Hematology/Coagulation Event 3 attestation not signed by Laboratory Director and TP A. Five (5) of the 9 attestation statements were not signed by Laboratory Director and TP A. 2. In an exit interview at approximately 1:45 PM, TP A confirmed the above findings.
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 the review of the laboratory's proficiency testing (PT) records and interview with Testing Personnel (TP) A, the Laboratory Director (LD) failed to review and sign one (1) of nine (9) PT events during calendar years 2017 and 2018. Findings include: 1. Review of the American Proficiency Institute (API) PT records for four (4) events in 2017 and five (5) events in 2018 revealed that the LD failed to review and sign API 2018 Hematology/Coagulation Event 3 PT results. 2. In an exit interview at approximately 1:45 PM, TP A confirmed the above findings.
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 a review of the policy and procedure manual, instrument package inserts and operators guide, Quality Control records, Quality Assessment records, temperature records, instrument maintenance records, calibration records, and interviews, the laboratory failed: to document temperatures (Cross Reference D5413); perform and document instrument maintenance (Cross Reference D5429); perform calibration every 6 months for Horiba Micros 60+ (Cross Reference D5437); perform a positive and negative control each day of patient testing on the Cepheid GeneXpert (Cross Reference D5449); verify new lots of quality control for the Horiba Micros 60+ (Cross Reference D5469); and address analytic failures in the quality assessment system (Cross Reference D5791).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual, Cepheid GeneXpert validation records and interview with Testing Personnel (TP) A, the laboratory failed to have a written procedure for the Cepheid GeneXpert prior to reporting patients from June 20, 2018 until February 8, 2019. Findings include: 1. Review of the policy and procedure manual revealed a procedure for the Cepheid GeneXpert signed by the Laboratory Director on February 9, 2019. In an interview, TP A stated they did not have a procedure for the Cepheid GeneXpert prior to testing patients. He/she stated they did not have a procedure until February 9, 2019. 2. Review of the Cepheid GeneXpert validation records revealed the instrument was installed on June 8 2018 and patient testing began on June 20, 2018. 3. In an exit interview at approximately 1:45 PM, TP A confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of manufacturer's quality control package inserts, Horiba Micros 60+ operator's guide, temperature records, and interview with Testing Personnel (TP) A, the laboratory failed to monitor and document room temperature, relative humidity, and refrigerator temperatures according to manufacturer's specifications for six (6) of thirty (30) days in November 2017 and four (4) of thirty-one (31) days in December 2018. Findings include: 1. Review of the package insert for the Horiba Minotrol 16

	quality control material revealed the following statement, "Minoitrol and Minocal vials should be tightly covered and stored at 2-8 degrees Celsius." 2. Review of the Horiba Micros 60+ operator's guide revealed the following statement, "Operating ambient room temperature 16-34 degrees Celsius (61-93 degrees Fahrenheit), relative humidity less than 80%." 3. Review of the temperature records for November 2017 revealed the lack of documentation of room temperature, relative humidity and refrigerator temperature for 11/1/17, 11/2/17, 11/3/17, 11/12/17, 11/14/17 and 11/23 /17 (a total of 6 days). Review of the temperature records for December 2018 revealed the lack of documentation of room temperature, relative humidity and refrigerator temperature for 12/2/19, 12/9/19, 12/29/19 and 12/30/19 (a total of 4 days). 4. In an exit interview at approximately 1:45 PM, TP A confirmed the above findings.
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 the review of the Horiba Micros 60+ procedure, available maintenance documentation, and an interview, the laboratory failed to follow the laboratory's Horiba Micros 60+ procedure for performing and documenting instrument maintenance procedures from July 1, 2018 to March 12, 2019. 1. Review of the Horiba Micros 60+ procedure revealed the following statements: "Daily-Check reagent levels; Check Waste level-empty if needed; Perform Start-up Cycle and verify acceptable; Run Control and verify acceptable; Perform Shut-down Cycle at end of day; Document with initials on Chart for Horiba Micros 60. Weekly-to help ensure reliability of analyzer and results generated-Perform Concentrated Cleaning; Perform Backflush of system; Document with initials on Maintenance Chart for Horiba Micros 60. As Needed-Annually-Preventative Maintenance via Service Rep." The surveyor requested maintenance documentation from the laboratory. At approximately 1:00 PM, TP A stated: "We perform maintenance on the Horiba but have not been recording it." 2. Review of the available maintenance documentation revealed a lack of documentation of the daily, weekly and monthly maintenance performed by testing personnel on the Horiba Micros 60+ from July 1, 2018 to March 12, 2019. 3. In an exit interview at approximately 1:45 PM, TP A confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on review of policy and procedure manual, Horiba Micros 60+ calibration records, and an interview with Testing Personnel (TP) A, the laboratory failed to document calibration procedures every six (6) months for Complete Blood Count (CBC) testing according to their policy from 11/18/16 until 2/8/19. Findings include: 1. Review of the laboratory's procedure manual revealed a Horiba Micros 60+ policy that stated: "Calibration must be done every 6 months (or more often if conditions dictate, or major maintenance is performed). Document lot #s and Dates of calibration." 2. Review of the laboratory's 2016, 2017 and 2018 calibration records revealed calibrations were performed on the Horiba Micros 60+ on 11/18/16, 6/28/17, 3/5/18, 6/1/18 and 2/8/19. The surveyor requested additional documentation records for calendar year 2017, 2018 and 2019 demonstrating calibration for the Horiba Micros every 6 months. No additional calibration documentation was available between 6/28/17 to 3/5/18 and 6/1/18 and 2/8/19. 3. In an exit interview at approximately 1:45 PM, TP A confirmed the above findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of the package insert for the Cepheid GeneXpert Chlamydia trachomatis and Neisseria gonorrhea (CT/NG) assay kit, Cepheid GeneXpert quality control records, instrument data file and interview with Testing Personnel (TP) A, the laboratory failed to perform external positive and negative quality control (QC) materials each day of patient testing for CT/NG from August 19, 2018 until February 8, 2019, while reporting thirty-seven (37) patients. Findings include: 1. Review of the package insert for the Cepheid GeneXpert Chlamydia trachomatis and Neisseria gonorrhea (CT/NG) assay kits revealed no manufacturer recommendations were given for external QC and the statement: "External controls may be used in accordance with local, state, and federal accrediting organizations, as applicable." was noted. 2. Review of the Cepheid GeneXpert quality control records for CT/NG from June 20, 2018 until February 8, 2019 revealed QC was performed on the following days: 10/3 /18, 11/14/18 and 1/22/19. The surveyor requested further documentation of QC. At approximately 12:30 PM, TP A stated: "We had an IQCP that we used from 8/18/18 to 2/8/19, that stated QC was to be performed every month, new shipment or lot of assay kits". The surveyor requested to review the IQCP. The laboratory provided an IQCP dated 2/8/19. No other IQCP was available for review. 3. Review of the GeneXpert's data file revealed CT/NG patient testing was performed on the following days: 08/20/18 1 patient #21598; 08/21/18 1 patient #30036; 08/22/18 1 patient #26145; 08/29/18 1 patient #20643; 09/08/18 1 patient #27215; 09/12/18 1 patient #21598; 09/29/18 1 patient #24545; 10/04/18 2 patients #30315 and 29337; 10/11/18 2 patients #30333 and 30395; 10/14/18 1 patient #30419; 10/23/18 1 patient #30491; 10/30/18 1 patient #27778; 10/31/18 1 patient #30545; 11/16/18 2 patients #30662 and 30636; 11/20/18 1 patient #30690; 11/23/18 1 patient #27215; 11/27/18 1 patient #20643; 12/04/18 1 patient #30791; 12/19/18 5 patients #30378, 30872, 30946,

	29376, and 30978; 12/21/18 2 patients #22562 and 30945; 12/24/18 1 patient #30945; 12/26/18 1 patient #31037; 12/27/18 1 patient #31053; 12/28/18 1 patient #27780; 01 /03/19 1 patient #31125; 01/06/19 1 patient #31160; 01/07/19 1 patent #23519; 02/01 /19 1 patient #31239; 02/02/19 1 patient #23573; A total of 37 patients. The surveyor requested to review the documentation of the laboratory performing positive and negative external quality control materials each day of patient testing listed above. No documentation was not available for review. 3. In an exit interview at approximately 1: 45 PM, TP A confirmed the above findings. B. Based on review of the package insert for the Cepheid GeneXpert Trichomonas Vaginalis (TV) assay kit, Cepheid GeneXpert quality control records, instrument data file and interview with Testing Personnel (TP) A, the laboratory failed to perform external positive and negative quality control (QC) materials each day of patient testing for TV from August 19, 2018 until February 8, 2019, while reporting sixteen (16) patients. Findings include: 1. Review of the package insert Cepheid GeneXpert Trichomonas Vaginalis (TV) assay kit revealed no manufacturer recommendations were given for external QC and the statement, "External controls may be used in accordance with local, state, and federal accrediting organizations, as applicable." was noted. 2. Review of the Cepheid GeneXpert quality control records for TV from June 20, 2018 until February 8, 2019 revealed QC was performed on the following days: 10/3/18, 11/14/18 and 1/22/19; The surveyor requested further documentation of QC. At approximately 12:30 PM, TP A stated: "We had an IQCP that we used from 8/18/18 to 2/8/19, that stated QC was to be performed every month, new shipment or lot of assay kits". The surveyor requested to review the IQCP. The laboratory provided an IQCP dated 2/8/19. No other IQCP was available for review. 3. Review of the GeneXpert's data file revealed patient testing was performed on the following days: 08/20/18 1 patient #21598; 08/21 /18 1 patient #30036; 09/12/18 1 patient #21598; 09/29/18 1 patient #24545; 10/23/18 1 patient #30491; 10/30/18 1 patient #27778; 11/12/18 1 patient #30635; 11/13/18 1 patient #19978; 11/16/18 1 patient #30662; 11/20/18 1 patient #30690; 12/04/18 1 patient #30791; 12/19/18 1 patient #30946; 12/26/18 1 patient #31037; 12/27/18 1 patient #31053; 01/07/19 1 patent #23519; 01/28/19 1 patient #31299. The surveyor requested to review the documentation of the laboratory performing positive and negative external quality control materials each day of patient testing listed above. No documentation was not available for review. 3. In an exit interview at approximately 1: 45 PM, TP A confirmed the above findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on the review of policy and procedure manual, Horiba Micros 60+ quality control (QC) data and interview with the Testing Personnel (TP) A, the laboratory failed to follow the established policy for performing verification of each new lot number of QC material prior to use for seven (7) of seven (7) lot numbers received in the calendar years 2018 and 2019. Findings include: 1. Review of the policy and procedure manual revealed a policy, "Quality Control", which stated: "Parallel testing of new lot numbers of QC should be performed for preferably 5 days to confirm the validity of new controls before putting into use. This should be documented accordingly." 2. Review of the Micros 60+ hematology analyzer's QC records revealed the following lot numbers of Horiba Minotrol 16 tri-level QC material were received in 2018 and 2019: MX410 expiration date 6/5/18; MX411 expiration date 8/6 /18; MX412 expiration date 10/6/18; MX413 expiration date 12/5/18; MX414 expiration date 2/5/18; MX415 expiration date 4/5/19; and MX416 expiration date 6/5 /19. The surveyor requested to review documentation of the verification of the new lot numbers of QC prior to use. No documentation was available for review. 3. In an exit interview at approximately 1:45 PM, TP A confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Quality Assurance (QA) plan, manufacturer's operating guide, package inserts, calibration records, Quality Control (QC) records, instrument data files, and interviews, the laboratory's established QA plan failed to identify and address analytic issues in the specialties of hematology, and bacteriology (Cross Reference D5413, D5429, D5437, and D5449). Findings include: 1. Review of the manufacturer's operating guide, package inserts, calibration records, quality control (QC) records, instrument patient data files revealed the following analytic issues: - No documentation of the laboratory monitoring or documenting temperatures for six (6) days in November 2017 and four (4) days in December 2018. - No documentation of the laboratory performing and documenting maintenance on the Horiba Micros 60+ from July 1, 2018 until March 12, 2019. - No documentation of the laboratory performing calibration on the Horiba Micros 60+ according to their policy in 2017 and 2018. - No documentation of the laboratory performing positive and negative quality controls each day of patient testing for the Cepheid GeneXpert from August 19, 2018 until February 2019. 2. Review of the QA plan revealed a schedule/checklist used by the laboratory for quality assessment monitoring The schedule/checklist listed the following monitors: "Environmental, Maintenance, QC/Levy Jennings, Log Reviews, QA Policy Review, Patient Test Management, Competency/Personal Training, Calibration/Calibration Verification, Lab Safety/OSHA review, Proficiency Testing Reviews, and Procedure Manual Review." The checklist was not completed from October 2017 until the date of the survey. The surveyor requested to review documentation of the completed checklist. No documentation was provided by the laboratory. 3. In an exit interview at approximately 1:45 PM, TP A confirmed the findings.
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 a review of the laboratory's policy and procedure manuals, Quality Control (QC) records, Quality Assessment (QA) records, personnel records, temperature records, maintenance records, and interviews, the laboratory director failed: to ensure the staff followed the established QC policy to print out monthly the Hematology Levy-Jennings graphs for the Horiba Micros 60+ (Cross Reference D6020 A) ; to ensure external quality control was performed each day of patient testing on the Cepheid GeneXpert (Cross Reference D6020 B and C); to ensure the QA Plan was maintained (Cross Reference D6021); to ensure the established competency policy was followed for new testing personnel (Cross Reference D6029); to ensure a step-wise procedure was available for the Cepheid GeneXpert analyzer used for patient testing (Cross Reference 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: A. Based on the review of the policy and procedure manual, Horiba Micros 60+ Quality Control (QC) records, and interviews with Testing Personnel (TP) A, the laboratory director failed to ensure the staff followed the established QC policy to print out monthly the Hematology Levy Jennings graphs for the eight (8) months reviewed between July 2018 and the date of the survey on 3/12/19. Findings: 1. Review of the policy and procedure manual revealed a policy, "Quality Control", which stated: "Levy Jennings graphs will be printed and reviewed for shifts and trends and corrective actions necessary will be determined." 2. Review of the laboratory's QC records revealed no documentation of Levy Jennings graphs for the Horiba Micros 60+ Hematology analyzer from July 2018 until the date of survey (8 months). The surveyor requested documentation of the Levy Jennings graphs for the Micros analyzer. At approximately 12:30 PM, TP A stated: "We do not printout the Micros Levy Jennings monthly or when I change lots. We review QC daily." 3. At approximately 1:45 PM, TP A confirmed the above findings. B. Based on review of the package insert for the Cepheid GeneXpert Chlamydia trachomatis and Neisseria gonorrhea (CT/NG) assay kit, Cepheid GeneXpert quality control records, instrument data file and interview with Testing Personnel (TP) A, the laboratory director failed to ensure external positive and negative quality control (QC) materials were performed each day of patient testing for CT/NG (Cross Reference D5449 A). C. Based on review of the package insert for the Cepheid GeneXpert Trichomonas Vaginalis (TV) assay kit, Cepheid GeneXpert quality control records, instrument data file and

	interview with Testing Personnel (TP) A, the laboratory director failed to ensure external positive and negative quality control (QC) materials were performed each day of patient testing for TV (Cross Reference D5449 B).
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 the review of the quality assurance (QA) plan, manufacturer's operating guide, package inserts, calibration records, quality control (QC) records, instrument data files, personnel records and interviews, the laboratory director failed to ensure the laboratory's established QA plan was maintained (Cross Reference D5791, D6020, D6029, D6053 and D6055).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and procedure manual, and interview with Testing Personnel (TP) A, the laboratory director failed to ensure one (1) of one (1) new TP had documented training and competency assessments prior to performing patient testing procedures from January 2018 to March 12, 2019. Findings include: 1. Review of CLIA CMS-209 form revealed that TP C was a new TP hired in January 2018 (See attached TP Code Sheet). 2. Review of the testing personnel competency records revealed a lack of training documentation and competency assessments available for review for TP C. The surveyor requested documentation of the initial training and competencies for TP C. No documentation was provided by the laboratory. 3. Review of the QA Training and Competency Assessment policy revealed the following statement: "Competency testing will be performed after the initial training for procedures, at 6 months of independent work, and annually thereafter." 4. In an exit interview at approximately 1:45 PM, TP A confirmed the findings.
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 a review of the policy and procedure manual, Cephied GeneXpert analyzer validation records, and interviews with TP A, the laboratory director (LD) failed to ensure a step-wise procedure was available for the Cepheid GeneXpert analyzer used for patient testing from June 20, 2018 until February 8, 2019 (Cross reference D5401).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory's policy and procedure manual, testing personnel records, and interviews, the Technical Consultant (TC) failed to follow the laboratory's established policy and perform the semiannual competency assessment for one (1) of one (1) testing personnel hired in calendar year 2018. Findings include: 1. Review of CLIA CMS-209 form revealed that TP C was a new TP hired in January 2018 (See attached TP Code Sheet). 2. Review of the QA Training and Competency Assessment policy revealed the following statement: "Competency testing will be performed after the initial training for procedures, at 6 months of independent work, and annually thereafter." 3. Review of the testing personnel competency records revealed a lack of semi-annual competency documentation for TP C. The surveyor requested documentation of the semi-annual competency for TP C. No documentation was provided by the laboratory. 4. In an exit interview at approximately 1:45 PM, TP A confirmed the findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, analyzer validation records, testing personnel (TP) records, and interviews with TP A, the technical consultant (TC) failed to document

	initial Cepheid GeneXpert training and competency evaluations for five (5) of five (5) testing personnel (TP) after an instrument installation occurred in the laboratory on June 8, 2018. Findings include: 1. During at tour of the laboratory, the surveyor observed a Cepheid GeneXpert. The surveyor asked who performs testing on the Cepheid. TP A stated that TP A, B, C, D and E performed testing on the Cepheid GeneXpert. (See Personnel Code Sheet.) 2. Review of the laboratory's instrument validation records revealed the Cepheid GeneXpert (Serial number 22128) installation was performed by a field service technical specialist on 6/8/18. 3. Review of the laboratory personnel records and validation records revealed that TP A, B, C, D and E lacked a Cepheid GeneXpert training checklist and competency evaluation. The surveyor requested to review the training and competency evaluations for TP A, B, C, D and E. No documentation was provided by the laboratory. 4. In an exit interview at approximately 1:45 PM, TP A confirmed the findings.