Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2157780	12/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Homa Family Medicine	19650 Club House Rd #201a, Gaithersburg, MD	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory did not ensure that a copy of all PT documents were maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of PT records from 2019 showed that a signed attestation statement was not available at the time of the survey for the 1st PT event of 2019 in hematology; and 2. Hematology instrument printouts for 2 of 3 PT events, and PT program report forms used by the laboratory to record PT results for 1 of 3 PT events in 2019 were not available for review at the time of the survey. 3. During an interview on 11/21/19 at 3:15 PM, the LD confirmed that the laboratory did not maintain all PT documents for a minimum of two years from the date of the PT testing event.
D3011	FACILITIES CFR(s): 493.1101(d)

	Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation and interview with the laboratory director (LD), the laboratory did not ensure that an eye wash station was located in the laboratory area where testing occurs. Findings: 1. During a tour of the laboratory at 9:10 AM, it was observed that there was no eye wash station available in the laboratory where laboratory testing is performed. 2. During an interview on 11/21/19 at 3:15 PM, the LD confirmed that the eye wash station was not located in the room where laboratory testing is performed.
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 record review and interview with the laboratory director (LD), the laboratory failed to ensure that the written procedures in the standard operating procedure manual (SOPM) accurately reflected the current practice in the laboratory (D5401); failed to ensure that there was an approved policy for all procedures performed in the laboratory (D5403); failed to ensure that the SOPM was approved, signed, and dated by the LD (D5407); failed to ensure that the date of discontinuance for written procedures that were not performed was documented (D5409); failed to define, monitor, and document laboratory reagent refrigerator temperature and room humidity to ensure proper reagent storage and reliable test system operation (D5413); failed to ensure that hematology reagents were labeled with opened and expiration dates to ensure quality testing (D5415); failed to ensure that hematology QC was not used after it exceeded its expiration date (D5417); failed to ensure that the hematology analyzer was validated for use before reporting patient results (D5421); failed to document performance of routine preventive maintenance checks on the Sysmex XP-300 hematology analyzer (D5429); failed to ensure that daily background checks were performed and documented prior to performing patient testing on the hematology analyzer (D5431); and failed to ensure that calibrations for the hematology instrument were verified at least once every 6 months (D5439).
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 standard operating procedure manual (SOPM) and record review and interview with the laboratory director (LD), the laboratory did not ensure that the "Quality Assessment Program" procedure accurately reflected the current practice in the laboratory. Findings: 1. The procedure, "Patient test management/Record keeping" states that "Records of each test performed will be maintained in the lab." During an interview at 10:00 AM, the LD stated that they had stopped recording patients on the laboratory logs and that all original instrument print outs and records were stored in the patient chart. The LD stated that they were not keeping a separate record of laboratory results in the laboratory. 2. The procedure, "Quality Assessment Program" states that "A QA review is performed each month using the Monthly Quality Assurance Review Form." 3. Record review showed that there were no quality assurance (QA) forms available at the time of the survey. During an interview at 11: 45 AM, the LD stated that they had not performed QA reviews and confirmed that the SOPM did not accurately reflect the current practice of the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) and record review and interview with the laboratory director (LD), the laboratory did not ensure that there was an approved policy for all procedures performed in the laboratory. Findings: 1. SOPM review showed that there was no approved policy for taking temperature and humidity readings in the laboratory. A review of laboratory temperature logs showed that there were no acceptable ranges listed on the log. 2. There was no written policy for how to run quality control (QC) on the hematology analyzer (which controls with what frequency), how to determine if QC was acceptable, or for what corrective actions to take if QC was out of range. 3. During an interview on 11/21/19 at 3:15 PM, the LD confirmed that the SOPM did not have policies for all procedures performed in the laboratory.
D5407	PROCEDURE MANUAL

	CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with the laboratory director (LD), the laboratory did not ensure that the SOPM was approved, signed, and dated by the LD. Findings: 1. The laboratory has 2 SOPM, the "HOMA Lab Quick Reference Guide" and the "Procedure Manual." A review of these SOPMs showed that neither the procedures nor the procedure manuals were approved (signed and dated) by the LD. 2. During an interview on 11/21/19 at 3:15 PM, the LD confirmed that the current SOPM was not approved for use in the laboratory.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(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 standard operating procedure manual (SOPM) review and interview with the laboratory director (LD), the laboratory did not document the date of discontinuance for written procedures that were not performed. Findings: 1. The laboratory's SOPM included procedures for the OSOM BVBlue Test, Fast Pack IP TSH, Free T4, Total PSA, and Vitamin D, Abbott Afinion HbA1c, and the Silaris Influenza A&B test. 2. During an interview on 11/21/19 at 3:15 PM, the LD stated that the laboratory had never performed testing using the above kits or instrumentation. The procedures for these tests were not identified as discontinued and were not dated to show when they were discontinued.
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 standard operating procedure manual (SOPM) and temperature log record review and interview with the laboratory director (LD), the laboratory failed to define, monitor, and document laboratory reagent refrigerator temperature and room humidity to ensure proper reagent storage and reliable test system operation. Findings: 1. The laboratory has been in operation from September, 2018 to present; however, a review of temperature log records showed that "Room Temperature," "Lab Refrigerator," and "Nurse's Station Refrigerator" temperatures were documented for 4 days in December,

	2018. No other laboratory temperatures or humidity readings were documented; and 2. It could not be determined if the temperatures documented on those 4 days were acceptable because there were no temperature ranges listed on the temperature log. 3. A review of the SOPM showed that there was no procedure for taking temperatures in the laboratory. 4. During an interview on 11/21/19 at 3:15 PM, the LD stated that they did not know if room humidity could affect the current testing systems and confirmed that the laboratory failed to define acceptable temperature ranges and document temperatures in the laboratory
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, standard operating procedure manual (SOPM) review, and interview with the laboratory director (LD), the laboratory did not ensure that hematology reagents were labeled with opened and expiration dates to ensure quality testing. Findings: 1. The laboratory uses a Sysmex XP-300 hematology analyzer for hematology testing. During a tour of the laboratory at 2:15 PM, it was observed that the opened and in use "Cellpack" diluent was not labeled with the date that it was put in to use or with the expiration date; and 2. The in-use bottle of "Stromatolyser-WH" was labeled with the opened date but the expiration date was not documented. SOPM review showed that the "Stromatolsyer-WH" reagent expires after 60 days once opened. 3. During an interview on 11/21/19 at 3:15 PM, the LD confirmed that the hematology reagents in use were not labeled with the date that they were opened or with the expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: A. Based on observation, quality control (QC) record review, and interview with the laboratory director (LD), the laboratory failed to ensure that hematology QC was not used after it exceeded its expiration date. Findings: 1. The laboratory uses a Sysmex XP-300 hematology analyzer to perform hematology testing. The laboratory runs "Eightcheck-3WP X-TRA" hematology controls from Sysmex which expire 14 days after opening. 2. During a tour of the laboratory at 9:15 AM, it was observed that there were 2 bottles of opened hematology QC which were labeled with the opened date but no expiration date. Both bottles were expired: lot #9029, expiration date 5/8 /19, opened date 4/11/19, and lot #9197, expiration date 10/23/19, opened date 9/27 /19. 3. A review of hematology QC records from February through November, 2019 showed that expired hematology QC (lot #8310, expiration date 2/13/19) was run on

	the analyzer on 2/26/19 and 2/28/19; and 4. Expired QC (lot #9029, expiration date 5/8 /19) was run on the analyzer until 9/10/19. 5. Record review showed that 18 patients were reported on the analyzer during the time when expired QC was being run. This information was provided by the LD on 12/6/19 at 11:00 AM via phone call. 6. During an interview on 11/21/19 at 3:15 PM, the LD confirmed that hematology QC was run after controls had expired. B. Based on observation, record review, and interview with the laboratory director (LD), the laboratory failed to ensure that urinalysis testing was not performed on expired urine Multistix test strips. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that the in-use bottle of "Siemens Multistix 10 SG Reagent Strips for Urinalysis," lot #802079 had expired 8 /31/19. 2. Record review showed that urinalysis testing had been performed on 3 patients with the expired reagents. 3. During an interview on 11/21/19 at 3:15 PM, the LD confirmed that urinalysis testing had been performed on patients with expired reagents. C. Based on observation and interview with the laboratory director (LD), the laboratory failed to ensure that phlebotomy supplies used for drawing blood for patient testing were not expired. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that the laboratory's phlebotomy supplies included expired blood tubes: BD Vacutainer SST tubes, lot #8228900 expired 8/31/19, and BD Vacutainer Buff-Na Citrate tubes, lot #8187607 expired 4/30/19. 2. During an interview on 11/21 /19 at 3:15 PM, the LD confirmed that the laboratory was using expired blood tubes to collect blood for laboratory testing. D. Based on observation and interview with the laboratory director (LD), the laboratory failed to ensure that testing kits used for patient testing were not expired. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that 3 test kits used for patient testing were expired: OSOM Ultra Strep A Test, lot #181173 and OSOM Mono Test, lot #181297 expired 7/31/19, and OSOM BVBlue Test, lot #132411 expired 10/2019. 2. During an interview on 11 /21/19 at 3:15 PM, the LD confirmed that test kits available for patient testing were expired.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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: Based on record review and interview with the laboratory director (LD), the laboratory did not have documentation that the hematology analyzer was validated for use before reporting patient results. Findings: 1. The laboratory began testing with the Sysmex XP-300 hematology analyzer in September, 2018. 2. Record review showed that there was no documentation that the laboratory had verified the accuracy, precision, reportable range of test results, or that the manufacturer's reference intervals were appropriate for the laboratory's patient population. 3. During an interview on 11 /21/19 at 3:15 PM, the LD stated that the instrument had been validated but that they did not know where the documentation was.
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 hematology instrument maintenance record review and interview with the laboratory director (LD), the laboratory did not document performance of routine preventive maintenance checks on the Sysmex XP-300 hematology analyzer. Findings: 1. During an interview on the day of the survey, the LD stated that hematology quality control (QC) is only run on the days that the instrument is used for patient testing. 2. A review of "XP-300 Maintenance Logs" from December, 2018 to October, 2019 showed that QC was run 71 times; however, "Daily Maintenance" was documented 59 times; and 3. "Weekly" maintenance was documented 30 out of 35 weeks that QC was run and the instrument was in operation. 4. The LD stated that preventative maintenance had been performed by the Sysmex instrument technician; however, no maintenance records were available at the time of the survey. 5. During an interview on 11/21/19 at 3:15 PM, the LD confirmed that maintenance had not been performed and documented on the Sysmex hematology analyzer according to manufacturer specifications.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) and record review and interview with the laboratory director (LD), the laboratory did not ensure that daily background checks were performed and documented prior to performing patient testing on the Sysmex XP-300 hematology analyzer. Findings: 1. The procedure, "Daily Operating Procedures" in the SOPM states that after the instrument is powered on, "Three automatic rinse cycles are performed followed by a background check" and that the laboratory should "Record the background check on a daily checklist or keep a copy of the printout for documentation." 2. A review of hematology records from December, 2018 to October, 2019 showed that the "background check" was documented 11 out of 71 times that hematology quality control was performed and the instrument was operational. 3. During an interview on 11/21/19 at 3:15 PM, the LD confirmed that the laboratory did not ensure that daily background checks were performed and documented prior to performing hematology testing.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on calibration record review and interview with laboratory director (LD), the laboratory failed to ensure that calibrations for the hematology instrument were verified at least once every 6 months. Findings: 1. A review of calibration records from September, 2018 to November, 2019 for the Sysmex XP-300 hematology analyzer showed that one calibration verification was performed 3/2019. There was no indication in the documents that the calibration verification had passed. 2. Documentation of any additional calibration verifications was not available at the time of the survey. 3. During an interview on 11/21/19 at 3:15 PM, the LD stated that a second calibration verification had been performed but that they did not know where the documentation was.
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 record review and interview with the laboratory director (LD), the LD failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards (D6011); failed to ensure that calibrations for the hematology instrument were verified at least once every 6 months (D6013); failed to ensure that quality control (QC) and quality assurance procedures monitored overall operation of the laboratory to identify immediate QC failures and ensure that effective corrective actions are taken when failures are identified (D6022); failed to ensure that the maintenance was being performed and documented on the hematology analyzer (D6023); and failed to ensure that all policies and procedures followed in the laboratory were approved (D6031).
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2)

	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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: The laboratory director did not provide a safe environment in which employees are protected from physical, chemical, and biological hazards. Cross-refer to D3011
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: The laboratory director failed to ensure that calibrations for the hematology instrument were verified at least once every 6 months. Cross-refer to D5439
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) plan and interview with the laboratory director (LD), the LD failed to ensure that quality control (QC) and QA procedures monitored overall operation of the laboratory to identify immediate QC failures and ensure that effective corrective actions are taken when failures are identified. Findings: 1. The LD stated that they had not performed QA reviews since the laboratory opened in September, 2018. Cross-refer to D5401, #2 and #3 2. The LD did not review hematology QC to detect errors or shifts and trends. 3. Proficiency testing (PT) documents were not maintained for at least 2 years from the date of the PT event. Cross-refer to D2015 4. Laboratory room and refrigerator temperatures and humidly readings were not documented. Cross-refer to D5413 5. Laboratory reagents were not labeled with opened and expiration dates. Cross-refer to D5415 6. Hematology QC was run on the Sysmex XP-300 analyzer after the QC had expired and patients were report out. Cross-refer to D5417, Part A 7. Patient urinalysis testing was performed

	and reported out using expired Multistix reagent strips. Cross-refer to D5417, Part B 8. Phlebotomy supplies used for patient testing were expired. Cross-refer to D5417, Part C 9. Waived testing kits were expired. Cross-refer to D5417, Part D 10. The laboratory did not have documentation that the hematology analyzer had been validated before using for patient testing. Cross-refer to D5421 11. Required instrument maintenance was not performed or documented on the hematology analyzer. Cross-refer to D5429 12. Daily background checks were not documented prior to hematology patient testing. Cross-refer to D5431 13. Calibration verification procedures were not performed at least every 6 months on the hematology analyzer. Cross-refer to D5439 14. During an interview on 11/21/19 at 3:15 PM, the LD confirmed that the QC and QA program was not maintained to identify failures in quality in the laboratory as they occur.
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: The laboratory director failed to ensure that the maintenance was being performed and documented on the Sysmex XP-300 hematology analyzer to provide quality laboratory services. Cross-refer to D5429
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: The laboratory director did not ensure that all policies and procedures followed in the laboratory were approved (signed and dated). Cross-refer to D5407
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by:

	Based on record review and interview with the laboratory director (LD), the LD, acting as technical consultant failed to provide technical and scientific oversight of the laboratory (D6036); failed to ensure that the hematology analyzer was validated for use before reporting patient results (D6040); and failed to establish acceptable parameters for ensuring that analytical performance standards were maintained throughout the entire testing process (D6042).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on quality assurance (QA) record review and interview with the laboratory director (LD), the LD acting as technical consultant failed to provide technical and scientific oversight of the laboratory. Cross-refer to D6022
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: The laboratory director acting as technical consultant failed to ensure that the hematology analyzer was validated for use before reporting patient results, demonstrating that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: accuracy, precision, reportable range of test results for the test system, and verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Cross-refer to D5421
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the LD acting as technical consultant failed to establish acceptable parameters for ensuring that analytical performance standards were maintained throughout the entire testing process. Cross-refer to D6022