Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2181452	(X3) Date Survey Completed 02/16/2022
Name of Provider or Supplier Mtv Ir Interventional & Vascular Specialists	Street Address, City, State 9101 N Central Expressway Suite 550, Dallas, TX	
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 entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.801 Enrollment and testing of proficiency testing samples 493.1250 Analytic Systems 493.1403 Laboratory Director, (moderate complexity) The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: Based on review of the CMS 116 form, CMS 155 report, and confirmed in staff interview, the laboratory failed to meet the requirements of participating in proficiency testing for the specialty of Hematology for 2020, 2021 and to the date of the survey in 2022. Findings: 1. Review of the CMS 116 form submitted on the day of the survey revealed the laboratory performed PT/INR analyte testing on the Abbott i-STAT analyzer. The laboratory began patient testing on the i-STAT analyzer in June 2020. 2. Review of the CMS 155 report revealed no proficiency testing scores for the PT/INR hematology analyte. 3. During an interview on 02/16/2022 at 10:15 am, the practice manager was asked to provide proficiency testing enrollment records for 2020, 2021 and 2022. She stated that the facility was not enrolled and did not perform proficiency testing, confirming the above findings. Word Key: CMS- Center for Medicare & Medicaid Services PT/INR - prothrombin time International Normalized Ratio
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the lack of records and confirmed in interview the laboratory failed to retain the operator's guide for the i-STAT analyzer, quality control (QC) records, calibration records, package inserts and assay sheets for PT/INR and ACT control materials for 19 of 19 months from 06/2020 through 02/2022 to ensure manufacturer's instructions and requirements were being followed. Findings: 1. The laboratory was asked to provide the operator's guide for the i-STAT analyzer, quality control (QC) records, calibration records, package inserts and assay sheets for PT/INR and ACT control materials from 06/2020 through 02/2022. The laboratory was unable to provide the requested records to ensure manufacturer's requirements were being followed. 2. During an interview on 02/16/2022 at 10:15 am, the Practice Manager stated that she could not find any documentation for the i-STAT analyzer. Word key: PT/INR - prothrombin time International Normalized Ratio ACT- activated clotting time
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on the lack of records and confirmed in interview the laboratory failed to retain testing data and information related to the verification studies for the i-STAT analyzer. Findings: 1. The laboratory was asked to provide verification studies and related data for the PT/INR and ACT analytes tested on the i-STAT analyzer. The laboratory began patient testing in 06/2020. No studies or data was provided by the laboratory. 2. During an interview on 02/16/2022 at 10:15 am, the Practice Manager

	stated that she could not find any documentation for the initial installation of the i-STAT analyzer. Word key: PT/INR - prothrombin time International Normalized Ratio ACT- activated clotting time
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the CMS 116 form, the lack of twice annual accuracy assessments, and confirmed in staff interview, the laboratory failed to perform twice annual accuracy assessments for the ACT analyte for 2020 and 2021. Findings: 1. Review of the CMS 116 form submitted on the day of the survey revealed the laboratory performed ACT analyte testing on the Abbott i-STAT analyzer. The laboratory began patient testing in 06/2020. 2. The laboratory was asked to provide documentation of twice annual accuracy assessments for the ACT analyte for 2020 and 2021. No records were provided. 3. The laboratory had an annual volume of 60 ACT tests. 4. During an interview on 02/16/2022 at 10:15 am, the practice manager stated that the facility did not perform twice annual accuracy assessments in 2020 and 2021 for the ACT analyte, confirming the above findings. Word key: CMS- Center for Medicare & Medicaid Services ACT- activated clotting time
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 the lack of laboratory policies, manufacturer's instructions, the lack of quality control (QC) records, the lack of environmental logs, patient records, direct observation, and confirmed in interview, the laboratory failed to meet the requirements of the analytic systems as evidenced by: 1. The laboratory failed to have policies in place that included all required components for laboratory tests. Refer to D5403. 2. The laboratory failed to ensure the proper storage conditions of i-STAT analyzer's quality control material and cartridges were maintained according to manufacturer's instructions for 7 of 7 months in 2020 (June-December), 12 of 12 months in 2021 and 2 of 2 months in 2022 (January-February). Refer to D5413, I. 3. The laboratory failed to ensure the proper storage conditions of i-STAT analyzer was maintained according to manufacturer's instructions for 7 of 7 months in 2020 (June-December), 12 of 12 months in 2021 and 2 of 2 months in 2022 (January-February). Refer to D5413, II. 4. The laboratory failed to ensure 9 of 9 boxes of control material did not exceed their expiration date. Refer to D5417. 5. The laboratory failed to perform establishment/verification studies for the i-STAT analyzer prior to reporting patient test results. Refer to D5421. 6. The laboratory failed to establish a QC program

	for PT/INR and ACT analytes tested on the i-STAT analyzer to ensure accurate and reliable test results. Refer to D5441. 7. The laboratory failed to perform two levels of control each day of patient testing on the i-STAT analyzer for the ACT (activated clotting time) analyte for 4 of 4 days in 2020 (random sampling 09/2020, 10/2020) and 2 of 2 days in 2021 (random sampling 05/2021, 11/2021). Refer to D5447, I. 8. The laboratory failed to perform two levels of control each day of patient testing on the i-STAT analyzer for the PT/INR (prothrombin time International Normalized Ratio) analyte for 3 of 3 days in 2020 (random sampling 09/2020 through 12/2020) and 9 of 9 days in 2021 (random sampling 02/2021 through 11/2021). Refer to D5447, II.
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 the lack of laboratory policies and confirmed in interview, the laboratory failed to have policies in place that included all required components for laboratory tests. (Note: Laboratory testing included - activated clotting times (ACT) and prothrombin time International Normalized Ratio (PT/INR) on the i-STAT analyzer) Findings: 1. The laboratory was asked to provide a copy of their policy manual. No policy manual was provided. The laboratory failed to implement policies for the following components of the services provided by the laboratory for patient testing: a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral, and specimen acceptability and rejection criteria. b. Procedures for interpretation of results and instructions for tests were not established. c. Preparation of controls and reagents for testing on i-STAT analyzer procedures were not established. d. Procedures for establishing/verifying the reportable range for test results on the i-STAT analyzer was not established. e. Control procedures were not established. f. Corrective action or troubleshooting steps to take when QC (quality control) or calibration were unacceptable were not established. g. Verification or establishments of reference intervals (normal range) were not established. h. Protocol for entering and reporting alert or panic values were not established. i. The course of action to take when the laboratory's test systems become inoperable was not established. 2. During an interview on 02/16/2022 at 10:

	15 am, the practice manager stated that the facility did not have a policy manual for laboratory testing, confirming 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: I. Based on direct observation, manufacturer's instructions, the lack of environmental logs, and confirmed in staff interview the laboratory failed to ensure the proper storage conditions of i-STAT analyzer's quality control material and cartridges were maintained according to manufacturer's instructions for 7 of 7 months in 2020 (June-December), 12 of 12 months in 2021 and 2 of 2 months in 2022 (January-February). Findings: 1. During a tour of the laboratory on 02/16/2022 at 10:20 am, the surveyor observed the following stored in a refrigerator in the testing area: 1 box i-STAT Tri Controls; lot #20245; expiration date 12/31/2021 1 box PT/INR cartridges; lot #S21275A; expiration date 03/31/2022 1 box ACT cartridges; lot #R21274; expiration date 03/30/2022 3 boxes i-STAT ACT level 1 control; lot # 261120; expiration date 12 /31/2020 5 boxes i-STAT ACT level 2 control; lot # 271120; expiration date 12/31 /2020 2. Review of i-STAT's user's manual revealed the following: Section 14 "QUALITY CONTROL OVERVIEW The Manufacturer's Quality System Instructions (MQSI) represent information necessary to ensure quality results (accurate, precise, and reliable) based upon the specific characteristics of the i STAT System ... MANUFACTURER'S QUALITY SYSTEM INSTRUCTIONS ... Ensure Proper Cartridge Storage Ensure that refrigerator storage conditions for stored cartridges are between 2-8 C (35-46 F). Ensure that cartridges are not exposed to temperatures exceeding 30 C (86 F) ... i-STAT TRICONTROLS FOR BLOOD GAS /ELECTROLYTE/METABOLITE CARTRIDGES ... Storage Refrigerated storage at 2-8 C (35-46 F) should be maintained until the printed expiration date on the box and ampule labels ... ACT CONTROLS ... Storage i-STAT ACT controls, Levels 1 and 2, are contained in 6 mL vials. Separate 6 mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8 C (35 to 46 F) should be maintained until the printed expiration date on the box and vial labels." 3. The laboratory was asked to provide documentation of temperature logs for the refrigerator. No temperature logs were provided. 4. During an interview on 02/16 /2022 at 10:20 am, Testing Person-2 stated that temperature logs were not kept for the refrigerator. Word key: PT/INR - prothrombin time International Normalized Ratio ACT- activated clotting time II. Based on direct observation, manufacturer's instructions, the lack of environmental logs, and confirmed in staff interview the laboratory failed to ensure the proper storage conditions of i-STAT analyzer was maintained according to manufacturer's instructions for 7 of 7 months in 2020 (June-December), 12 of 12 months in 2021 and 2 of 2 months in 2022 (January-February). Findings: 1. During a tour of the laboratory on 02/16/2022 at 10:20 am, the surveyor observed an i-STAT analyzer (Serial #(21)41688) on the counter in the testing area. 2. Review of the i-STAT's user's manual revealed the following: Section 2 "i-STAT 1

	ANALYZER ... DESCRIPTION Specifications ... OPERATING TEMPERATURE 16-30C (61-86F) for i-STAT cartridge testing ... RELATIVE HUMIDITY 90% (maximum) non-condensing" 3. The laboratory was asked to provide documentation of environmental logs for room temperature and humidity. No environmental logs were provided. 4. During an interview on 02/16/2022 at 10:20 am, Testing Person-2 stated that room temperature and humidity logs were not kept.
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: Based on direct observation and confirmed in interview, the laboratory failed to ensure 9 of 9 boxes of control material did not exceed their expiration date. Findings: 1. During a tour of the laboratory on 02/16/2022 at 10:20 am, the surveyor observed the following stored in a refrigerator in the testing area: 1 box i-STAT Tri Controls; lot #20245; expiration date 12/31/2021 3 boxes i-STAT ACT level 1 control; lot # 261120; expiration date 12/31/2020 5 boxes i-STAT ACT level 2 control; lot # 271120; expiration date 12/31/2020 2. During the exit interview on 02/16/2022 at 12:30 pm, Testing Person-1 confirmed the above findings.
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 the laboratory's CMS 116 form, i-STAT data log, and confirmed in interview, the laboratory failed to perform verification studies for the i-STAT analyzer prior to reporting patient test results. Findings: 1. Review of the laboratory's CMS 116 form submitted on the day of the survey revealed the i-STAT analyzer was used to test PT/INR and ACT analytes. Records further revealed the i-STAT analyzer was put in-use 06/2020. The laboratory was asked to provide verification studies on the i-STAT analyzer prior to reporting 84 patient test results that included: a. Accuracy b. Precision c. Reportable range of test results for PT/INR and ACT analytes. d. Verification of the i-STAT manufacturer's reference intervals for PT/INR and ACT analytes that were appropriate for the laboratory's population. 2. During an interview on 02/16/2022 at 10:15 am, the Practice Manager stated that she could not find any documentation for the initial installation of the i-STAT analyzer. Word key: CMS-Center for Medicare & Medicaid Services PT/INR - prothrombin time International Normalized Ratio ACT- activated clotting time

D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of laboratory policies, lack of quality control records, patient records, and confirmed in staff interview, the laboratory failed to establish a QC program for PT/INR and ACT analytes tested on the i-STAT analyzer for 19 of 19 months from 06 /2020 through 02/2022 to ensure accurate and reliable test results. Findings: 1. The laboratory was asked to provide a policy manual for all tests performed in the laboratory. No policies were provided. The laboratory failed to establish a QC program for all analytes tested on the i-STAT analyzer since it began patient testing in 06/2020. 2. The laboratory was asked to provide QC records for the analytes tested on the i-STAT analyzer. The laboratory was unable to provide QC records or documentation for how QC ranges were established/verified for all analytes tested on the i-STAT analyzer. 3. During an interview on 02/16/2022 at 10:20 am, Testing Person-1 (TP-1) stated there were no written policies for QC procedures, all QC policies were verbal. She also stated that QC was performed every 6 months and believed the last time QC was run was in August or September of 2021. TP-1 also stated that they were instructed not to print out any records from the i-STAT analyzer and they would just verify if QC passed by looking at the screen on the analyzer. 4. The laboratory had an annual volume of 60 ACT tests and 24 PT/INR tests. Word key: QC- quality control PT/INR - prothrombin time International Normalized Ratio ACT- activated clotting time
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on lack of laboratory policies, lack of quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to perform two levels of control each day of patient testing on the i-STAT analyzer for the ACT (activated clotting time) analyte for 4 of 4 days in 2020 (random sampling 09/2020, 10/2020) and 2 of 2 days in 2021 (random sampling 05/2021, 11/2021). Findings: 1. The laboratory was asked to provide a QC policy for the ACT analyte tested on the i-

	STAT analyzer. No policies were provided. 2. The laboratory was asked to provide QC records for the ACT analyte tested on the i-STAT analyzer. The laboratory was unable to provide QC records. 3. A random sampling of patient records from September through October 2020 and May through November 2021, revealed the following dates QC was not performed and patients were tested on the i-STAT analyzer for the ACT analyte: 09/04/2020 Patient ID: 000164 09/09/2020 Patient ID: 000164 10/14/2020 Patient ID: 001449 10/15/2020 Patient IDs: 001449, 000670 05/10/2021 Patient ID: 001188 11/19/2021 Patient ID: 000164 3. During an interview on 02/16/2022 at 10:20 am, Testing Person-1 (TP-1) stated there were no written policies for QC procedures, all QC policies were verbal. She also stated that QC was performed every 6 months and believed the last time QC was run was in August or September of 2021. TP-1 also stated that they were instructed not to print out any records from the i-STAT analyzer and they would just verify if QC passed by looking at the screen on the analyzer. 4. The laboratory had an annual volume of 60 ACT tests. II. Based on lack of laboratory policies, lack of quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to perform two levels of control each day of patient testing on the i-STAT analyzer for the PT/INR (prothrombin time International Normalized Ratio) analyte for 3 of 3 days in 2020 (random sampling 09/2020 through 12/2020) and 9 of 9 days in 2021 (random sampling 02/2021 through 11/2021). Findings: 1. The laboratory was asked to provide a QC policy for PT/INR analyte tested on the i-STAT analyzer. No policies were provided. 2. The laboratory was asked to provide QC records for the PT/INR analyte tested on the i-STAT analyzer. The laboratory was unable to provide QC records. 3. A random sampling of patient records from September through December 2020 and February through November 2021, revealed the following dates QC was not performed and patients were tested on the i-STAT analyzer for the PT/INR analyte: 09/17/2020 Patient ID: 000302 10/02/2020 Patient ID: 000302 12/14/2020 Patient ID: 001564 02/01/2021 Patient ID: 000842 04/02/2021 Patient ID: 000302 04/26/2021 Patient IDs: 002095, 002036 05/07/2021 Patient ID: 001564 05/10/2021 Patient IDs: 001184, 000670 05/24/2021 Patient ID: 000842 05/27/2021 Patient ID: 002220 07/20/2021 Patient ID: 000474 11/19/2021 Patient ID: 000164 3. During an interview on 02/16/2022 at 10:20 am, Testing Person-1 (TP-1) stated there were no written policies for QC procedures, all QC policies were verbal. She also stated that QC was performed every 6 months and believed the last time QC was run was in August or September of 2021. TP-1 also stated that they were instructed not to print out any records from the i-STAT analyzer and they would just verify if QC passed by looking at the screen on the analyzer. 4. The laboratory had an annual volume of 24 PT/INR tests.
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 the lack of laboratory policies, manufacturer's instructions, the lack of quality control (QC) records, the lack of environmental logs, CMS (Center for Medicare & Medicaid Services) form, personnel records, patient records, direct observation, and confirmed in interview, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed

	to ensure analytic systems provided quality results. Refer to D6007. 2. The laboratory director failed to perform establishment/verification studies for the i-STAT analyzer prior to reporting patient test results. Refer to D6013. 3. The laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for each specialty (hematology) for which it seeks certification. Refer to D6015. 4. The laboratory director failed to ensure a quality control program was developed and followed to provide quality laboratory services. Refer to D6020. 5. The laboratory director failed to ensure that 3 of 3 Testing Persons (TP-1, TP-2, TP-3) received the appropriate training in moderate complexity testing (hematology) prior to patient testing. Refer to D6029. 6. The laboratory director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 3 of 3 Testing Persons (TP-1, TP-2, TP-3) performing moderate complexity testing. Refer to D6030. 7. The laboratory director failed to establish a procedure manual available for all testing procedures. Refer to D6031. 8. The laboratory director failed to specify in writing the responsibilities and duties 3 of 3 Testing Persons (TP-1, TP-2, TP-3) of performing moderate complexity testing. Refer to D6032
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the lack of laboratory policies, manufacturer's instructions, the lack of quality control (QC) records, the lack of environmental logs, patient records, direct observation, and confirmed in interview, the laboratory director failed to ensure analytic systems provided quality results as evidenced by: 1. The laboratory director failed to ensure the proper storage conditions of i-STAT analyzer's quality control material and cartridges were maintained according to manufacturer's instructions for 7 of 7 months in 2020 (June-December), 12 of 12 months in 2021 and 2 of 2 months in 2022 (January-February). Refer to D5413, I. 2. The laboratory director failed to ensure the proper storage conditions of i-STAT analyzer was maintained according to manufacturer's instructions for 7 of 7 months in 2020 (June-December), 12 of 12 months in 2021 and 2 of 2 months in 2022 (January-February). Refer to D5413, II. 3. The laboratory director failed to ensure control material did not exceed their expiration date. Refer to D5417.
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: Based on the laboratory's CMS 116 form, i-STAT data log, and confirmed in interview, the laboratory director failed to perform verification studies for the i-STAT analyzer prior to reporting patient test results. Refer to D5421.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the CMS 116 form, CMS 155 report, and confirmed in staff interview, the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for each specialty (hematology) for which it seeks certification. Refer to D2000.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of laboratory policies, lack of quality control (QC) records, patient records, and confirmed in interview, the laboratory director failed to ensure a quality control program was developed and followed to provide quality laboratory services as evidenced by: 1. The laboratory failed to establish a QC program for PT/INR and ACT analytes tested on the i-STAT analyzer to ensure accurate and reliable test results. Refer to D5441. 2. The laboratory failed to perform two levels of control each day of patient testing on the i-STAT analyzer for the ACT (activated clotting time) analyte for 4 of 4 days in 2020 (random sampling 09/2020, 10/2020) and 2 of 2 days in 2021 (random sampling 05/2021, 11/2021). Refer to D5447, I. 3. The laboratory failed to perform two levels of control each day of patient testing on the i-STAT analyzer for the PT/INR (prothrombin time International Normalized Ratio) analyte for 3 of 3 days in 2020 (random sampling 09/2020 through 12/2020) and 9 of 9 days in 2021 (random sampling 02/2021 through 11/2021). Refer to D5447, II.
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 review of Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records and staff interview, the laboratory director failed to ensure that 3 of 3 Testing Persons (TP-1, TP-2, TP-3) received the appropriate training in moderate complexity testing (hematology) prior to patient testing. Findings: 1. Review of the Centers for Medicare & Medicaid (CMS) 209 form revealed TP-1, TP-2, TP-3 as testing persons performing moderately complex laboratory testing. 2. Review of personnel records revealed the following hire dates: TP-1: 05/18/2020 TP-2: 12/27/2021 TP-3: 01/31/2022 3. The laboratory was asked to provide documented training for all testing persons performing activated clotting time (ACT) and prothrombin time International Normalized Ratio (PT/INR) analyte testing on the i-STAT analyzer. No documentation of training was provided. 4. During an interview on 02/16/2022 at 10:15 am, the Practice Manager stated that there was no documented training for any of the testing persons, confirming the findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, lack of laboratory policy, and confirmed in interview, the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 3 of 3 Testing Persons (TP-1, TP-2, TP-3) performing moderate complexity testing. Findings: 1. Review of the CMS 209 form revealed 3 Testing Persons (TP-1, TP-2, TP-3) performing moderate complexity testing. 2. The laboratory was asked to provide a policy for personnel performing moderate complexity testing. No policy was provided. 3. During an interview on 02/16/2022 at 10:15 am, the Practice Manager stated that there were no laboratory policies for training or competency assessments for testing personnel. Word key: CMS: Centers for Medicare and Medicaid Services

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 the lack of laboratory's policy manual and confirmed in interview, the laboratory director failed to establish a written procedure manual available for all testing procedures as evidenced by: 1. The laboratory director failed to have policies in place that included all required components for laboratory tests. Refer to D5403.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records and staff interview, the laboratory director failed to specify in writing the responsibilities and duties for 3 of 3 Testing Persons (TP-1, TP-2, TP-3) performing moderate complexity testing. Findings: 1. Review of the Centers for Medicare & Medicaid (CMS) 209 form revealed TP-1, TP-2, TP-3 as testing persons performing moderately complex laboratory testing in the specialty of hematology. 2. The laboratory was asked to provide documentation of the delegation of responsibilities by the laboratory director for each testing person. No documentation was provided. 3. During an interview on 02/16/2022 at 10:15 am, the Practice Manager stated that there was no documentation of the delegation of responsibilities by the laboratory director for each testing person, confirming the findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records and staff interview, the technical consultant failed to evaluate and document competency assessments for 1 of 3 Testing Persons (TP-1) in 2020 and 2021. Findings: 1. Review of the Centers for Medicare & Medicaid (CMS) 209 form revealed TP-1 as a testing person performing moderately complex laboratory testing. 2. Review of personnel records revealed a hire date for TP-1 as 05 /18/2020. 3. The laboratory was asked to provide documentation for competency assessments for TP-1. No documentation of competency assessments was provided. 4. During an interview on 02/16/2022 at 10:15 am, the Practice Manager stated that there were no documented competency assessments for any of the testing persons, confirming the above findings.
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 review of Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records and staff interview, the technical consultant failed to evaluate and document the performance for 1 of 3 Testing Persons (TP-1) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of the Centers for Medicare & Medicaid (CMS) 209 form revealed TP-1 as a testing person performing moderately complex laboratory testing. 2. Review of personnel records revealed a hire date for TP-1 as 05/18/2020. 3. The laboratory was asked to provide documentation for competency assessments for TP-1. No documentation of competency assessments was provided. 4. During an interview on 02/16/2022 at 10:15 am, the Practice Manager stated that there were no documented competency assessments for any of the testing persons, confirming the above findings.