Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0691515	03/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Stover Diagnostics Laboratories, Inc	1776 Crosswinds Dr, Wentzville, MO	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation of the Beckman Coulter LH500 hematology analyzer and lack of chemistry, hematology, and coagulation quality control (QC) assay information, and interviews, the laboratory failed to meet the requirements for condition of facility administration. The laboratory failed to maintain adequate space and ventilation for the proper operation of the Beckman Coulter LH500 hematology analyzer (Refer to D3001); failed to retain QC assay information for at least two years to verify acceptability of control materials (Refer to D3031).
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by:

	Based on observation, review of manufacturer's guidelines, and interview with the laboratory director (LD), the laboratory failed to maintain adequate space and ventilation for the proper operation of the Beckman Coulter LH500 hematology analyzer. Findings: 1. Observation of the Beckman Coulter LH500 hematology analyzer showed it was located in the same room directly across from the furnace and hot water heater with a distance of approximately two and one-half feet. 2. The laboratory failed to monitor and document the room temperature and humidity to ensure proper operational temperature. 3. Review of the Beckman Coulter LH 500 manufacturer's operating manual revealed "Operate the system in a room with a temperature of 15.5 to 32 degrees C (60 to 90 degrees F) and humidity up to 95% without condensation. If the average room ambient temperature changes more than 5.5 degrees C, from the calibrating temperature, verify calibration and recalibrate if necessary to ensure conformance to specifications." 4. Interview with the LD on March 2, 2020 at 3:00 PM stated "I have asked the owner to move the hematology analyzer out of the furnace room for the past three months." Interview confirmed the laboratory failed to ensure proper space and ventilation for operation of the Beckman Coulter LH500 hematology analyzer.
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 review of quality control (QC) records for 2018 and to date March 2, 2020 and interview with testing personnel (TP) #1, the laboratory failed to retain QC assay information for at least two years to verify acceptability of control materials. Findings: 1. The laboratory did not have documentation to show it retained chemistry, hematology, and coagulation QC assay information for at least two years to verify acceptability of QC results. 2. Interview with TP #1 on March 2, 2020 at 2:30 PM confirmed the laboratory failed to retain QC assay information for at least two years.
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 review of quality control (QC) procedures, QC and laboratory records for 2018 and to date March 2, 2020, and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to ensure the laboratory director approved, signed, and dated chemistry, hematology, and coagulation procedures (Refer to D5407); failed to document the room temperature and humidity in the laboratory where the chemistry, hematology, and coagulation analyzers were in

	operation (Refer to D5413); failed to ensure chemistry calibrators and QC have not exceeded their expiration date (Refer to D5417); failed to ensure chemistry verification procedures were performed and approved before reporting patient results (Refer to D5421); failed to perform calibration verification at least every 6 months in 2018 and 2019 (Refer to D5439); failed to perform two control materials of different concentrations (Refer to D5447); failed to verify the criteria for acceptability of control materials for chemistry, hematology, and coagulation testing (Refer to D5469), and failed to ensure test results and patient specific data were reliably sent from the Beckman Coulter LH 500 hematology analyzer, the Siemens Dimension EXL 200 chemistry analyzer, and the Sysmex CA 600 coagulation analyzer to the laboratory information system (Refer to D5801).
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 review of laboratory procedures and interview with the laboratory director (LD), the laboratory failed to ensure procedures and changes to procedures be approved, signed, and dated by the current laboratory director before use. Findings: 1. Review of hematology, chemistry, and coagulation procedures revealed the current LD did not approve, sign, and date the procedures. 2. Interview with the LD on March 2, 2020 at 2:30 PM confirmed, the current LD did not approve, sign, and date laboratory procedures. The current LD assumed responsibilities July 2019.
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 review of the manufacturer's operating manuals and interview with testing personnel (TP) #1, the laboratory failed to monitor and document the temperature and humidity of the laboratory where the hematology, coagulation, and chemistry analyzers were in operation. Findings: 1. Review of the Beckman Coulter LH 500 manufacturer's operating manual revealed "Operate the system in a room with a temperature of 15.5 to 32 degrees C (60 to 90 degrees F) and humidity up to 95% without condensation. If the average room ambient temperature changes more than 5.5 degrees C, from the calibrating temperature, verify calibration and recalibrate if necessary to ensure conformance to specifications." 2. Review of the Siemens Dimension EXL 200 manual showed "to operate in a temperature of 18-30 degrees C (64-86 degrees F)." 3. Review of the Sysmex CA 600 coagulation analyzer manual showed "to operate in a temperature of 15-35 degrees C with a humidity of 30-85 %."

	4. No documentation of room temperature or humidity was available for review. 5. Interview with TP#1 on March 2, 2020 at 12:00 PM confirmed the laboratory failed to document the room temperature and humidity in the laboratory where the chemistry, hematology, and coagulation analyzers were in operation.
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 review of Siemens Dimension EXL 200 chemistry calibrators and quality control (QC) and interview with testing personnel (TP)#1, the laboratory failed to ensure chemistry calibrators and QC have not exceeded their expiration date. Findings: 1. Review of Siemens Dimension EXL 200 calibrators showed 1 set of Siemens Vitamin D calibrators lot # 8HD037 expired 9/1/19, and 2 sets of total iron binding capacity IBCT calibrators lot #8KD062 expired 11/1/19, still in use. 2. Review of Siemens Dimension EXL 200 Bio-rad QC lot # 45781, expired 10/31/2019 and Bio-rad QC lot # 45783 expired 10/31/2019 still in use for the following analytes: sodium, potassium, chloride, glucose, blood urea nitrogen, creatinine, calcium, carbon dioxide, total protein, albumin, aspartate aminotransferase, alanine aminotransaminase, alkaline phosphatase, total bilirubin, direct bilirubin, total protein, albumin, cholesterol, triglycerides, high density lipoprotein cholesterol, phosphorus, magnesium, and uric acid. 3. Interview with TP #1 on March 2, 2020 at 2:15 PM confirmed the laboratory failed to ensure chemistry calibrators and QC have not exceeded their expiration date.
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 review of verification procedures, laboratory policy, patient records for January 2019 through February 2020, and interview with the laboratory director (LD), the laboratory failed to demonstrate it obtained performance specifications comparable to those established by the manufacturer for the Dimension EXL 200 chemistry analyzer before reporting iron, total iron binding capacity, magnesium, uric acid, sodium, potassium, chloride, carbon dioxide, glucose, blood urea nitrogen, creatinine, calcium, phosphorus, albumin, aspartate aminotransferase, alanine aminotransaminase, alkaline phosphatase, total bilirubin, direct bilirubin, total protein, albumin, cholesterol, triglycerides and high density lipoprotein cholesterol. Findings: 1. No documentation was available to show the laboratory performed verification

	procedures for iron, total iron binding capacity, magnesium, uric acid, sodium, potassium, chloride, carbon dioxide, glucose, blood urea nitrogen, creatinine, calcium, phosphorus, albumin, aspartate aminotransferase, alanine aminotransaminase, alkaline phosphatase, total bilirubin, direct bilirubin, total protein, albumin, cholesterol, triglycerides and high density lipoprotein cholesterol on the Dimension EXL 200 to demonstrate it obtained performance specifications comparable to those of the manufacturer for the following performance characteristics: a) Accuracy b) Precision c) Reportable range of test results for the test system. d) Verify the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population. 2. The laboratory policy states,"Stover must document all of the verification and establishment activities and maintain these documents so that they can be provided to CLIA when requested." 3. January 2019 through February 2020 showed the laboratory reported 24,301 patient results to the provider(s). 4. Interview with the LD on March 2, 2020 at 2:30 PM confirmed the laboratory failed to ensure verification procedures were performed and approved before reporting patient results.
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 review of chemistry calibration records and interview with testing personnel (TP) #1, the laboratory failed to perform calibration verification at least once every 6 months for 24 of 24 analytes in 2018 and 2019. Findings: 1. Review of calibration records showed no documentation of calibration every 6 months for iron, total iron binding capacity, magnesium, uric acid, sodium, potassium, chloride, carbon dioxide, glucose, blood urea nitrogen, creatinine, calcium, phosphorus, albumin, aspartate aminotransferase, alanine aminotransaminase, alkaline phosphatase, total bilirubin, direct bilirubin, total protein, albumin, cholesterol, triglycerides and high density lipoprotein cholesterol in 2018 and 2019. 2. Interview with TP #1 on March 2, 2020 at 2:45 PM confirmed the laboratory failed to perform calibration verification at least every 6 months in 2018 and 2019.

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: Based on review of the quality assurance procedure, calcium quality control (QC), patient test volumes, and interview with testing personnel (TP) #1, the laboratory failed to perform two control materials of different concentrations. Findings: 1. Review of "Quality Assurance Procedure" states "for each quantitative and qualitative procedure: 2 levels of control materials must be used prior to testing each day and for each 8 hour interval that he analyzers are in use." 2. Review of Levey-Jennings calcium QC from January 2019 through March 2019 showed no level 3 QC performed. 3. Review of patient volumes from January 2019 to March 2019 showed 4948 calcium test results were reported to the ordering provider(s) by the laboratory. 4. Interview with TP #1 on March 2, 2020 at 2:30 PM confirmed the laboratory failed to perform two control materials of different concentrations each day of testing for calcium.
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 review of quality control (QC) procedures, chemistry and coagulation QC records for December 2018 and to date March 2, 2020, lack of QC assay information and interview with the laboratory director (LD), the laboratory failed to verify the criteria for acceptability of four of four control materials in use for chemistry and coagulation testing. Findings: 1. The QC procedure states, "For quantitative procedures the laboratory must have all quality controls within 2 standard deviations of the mean prior to accepting patient results." 2. The laboratory did not record and retain assay (sheets) information/statistical parameters (standard deviations, mean values) to verify acceptability for the following control materials in use: a) Multi-Qual chemistry QC lot number 45781 Level 1 b) Multi-Qual chemistry QC lot number 45783 Level 3 c) Coagulation QC lot number 548063 Level 1 d) Coagulation QC lot

	number 548491 Level 3 3. Review of QC records (Levy-Jennings graphs) showed the laboratory could not provide verifiable limits of QC acceptability for lot numbers of QC materials in use and previously in use for 2018 to date March 2, 2020. 4. Interview with the LD on March 2, 2020 at 2:30 PM confirmed, the laboratory failed to ensure statistical parameters for each lot number of chemistry and coagulation control material in use and previously in use were defined and available. The LD said he "shared the same concerns."
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on lack of documentation, patient test volumes from December 19, 2018 through March 2, 2020, and interview with testing personnel (TP) #1, the laboratory failed to ensure test results and patient specific data were reliably sent from the Beckman Coulter LH 500 hematology analyzer, Siemens Dimension EXL 200 chemistry analyzer, and the Sysmex CA 600 coagulation analyzer to the laboratory information system(LIS). Findings: 1. The laboratory moved to a new location in November 2018. 2. Review of documentation revealed the laboratory failed to check patient data and test results sent from the Beckman Coulter LH 500 hematology analyzer, the Siemens Dimension EXL 200 chemistry analyzer, and the Sysmex CA 600 coagulation analyzer to the LIS. 3. Review of patient test volumes sent from the analyzers to the LIS from December 2018 to March 2, 2020 was approximately 53,200 reports. 4. Interview with the TP #1 on March 2, 2020 at 2:30 PM confirmed the laboratory failed to check patient test results and patient specific data electronically transmitted from the Beckman Coulter LH 500 hematology analyzer, the Siemens Dimension EXL 200 chemistry analyzer, and the Sysmex CA 600 coagulation analyzer to the LIS for accuracy.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation, review of quality control (QC) plan, quality assessment plan (QAP), laboratory records for 2018, 2019 and to date March 2, 2020 and interviews, the laboratory director failed to provide overall management and direction. The laboratory director failed to provide a safe environment to ensure employees are protected from physical, chemical, and biological hazards (Refer to D6011); failed to

	ensure coagulation verification procedures were adequate before introducing a new lot number of prothrombin time (innovin) reagent (Refer to 6013); failed to establish and maintain the QC program (Refer to D6020); failed to establish and maintain the QA program (Refer to D6021), failed to ensure all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance specifications (Refer to D6024), and failed to ensure an approved coagulation procedure manual was available to personnel for any aspect of testing (Refer to 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: Based on observation of cabinets in the laboratory and interview with testing personnel (TP) #1, the laboratory director (LD) failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards. Findings: 1. Review of cabinets under the Sysmex CA 600 analyzer showed food for employee consumption. 2. Interview with TP #1 on March 2, 2020 at 2:00 PM confirmed the LD failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards.
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 review of laboratory policy, coagulation verification procedures for 2019 and to date March 2, 2020, and interview with testing personnel (TP) #1, the laboratory director (LD) failed to ensure coagulation verification procedures were adequate before introducing a new lot number of prothrombin time (innovin) reagent. Findings: 1. The laboratory policy states, "The new lot number of reagent and new ISI must be validated by performing 20 normal PT/INR assays with both the old and new lot for comparison. This data must be reviewed by the medical director prior to the new reagent lot being put into place." 2. The laboratory did not have documentation to show the LD reviewed and approved the verification procedures for innovin reagent lot #549750 introduced in 2019. The laboratory was unable to provide date the innovin reagent was put into use. 3. Interview with TP #1 on March 2, 2020 at 2:30

	PM confirmed the laboratory could not provide documentation to show the LD approved the verification procedures for innovin reagent change prior to reporting patients in 2019.
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 review of the quality control (QC) program and interview with the laboratory director (LD), the LD failed to establish and maintain the QC program. Findings: 1. Review of the QC program revealed no documentation to show the current LD reviewed and approved the written QC program. 2. Interview on March 2, 2020 at 2:30 PM, the LD said the laboratory did not send policies and procedures for LD review. The LD indicated he assumed responsibilities July 2019. Interview confirmed the LD failed to establish and maintain the written QC program. 38475 Based on review of Quality Assurance procedure, Siemens Dimension EXL 200 chemistry analyzer quality control (QC), and interview with testing personnel (TP) #1, the laboratory director (LD) failed to ensure the QC program is maintained. Findings: 1. Review of "Quality Assurance Procedure" states "for each quantitative and qualitative procedure: 2 levels of control materials must be used prior to testing each day and for each 8 hour interval that he analyzers are in use." 2. Review of monthly Levey-Jennings QC showed no documentation of QC performed in December 2019 for iron, total iron binding capacity, magnesium, uric acid, sodium, potassium, chloride, carbon dioxide, glucose, blood urea nitrogen, creatinine, calcium, phosphorus, albumin, aspartate aminotransferase, alanine aminotransaminase, alkaline phosphatase, total bilirubin, direct bilirubin, total protein, albumin, cholesterol, triglycerides and high density lipoprotein cholesterol. The laboratory reported 355 basic metabolic panels, 251 comprehensive metabolic panels, 9 hepatic panels, 355 electrolyte panels, 48 renal panels, 1 aspartate aminotransferase and 119 lipid panels to the ordering provider(s) during December 2019. 3. Interview with TP #1 on March 2, 2020 at 2:15 PM confirmed the LD failed to ensure the chemistry QC program is maintained.
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 review of the quality assessment (QA) program and interview with the laboratory director (LD), the LD failed to establish and maintain the QA program. Findings: 1. Review of the QA program revealed no documentation to show the current LD reviewed and approved the written QA program. 2. Interview on March 2, 2020 at 2:30 PM, the LD said the laboratory did not send policies and procedures to the LD for review. The LD indicated he assumed responsibilities July 2019. Interview confirmed the LD failed to establish and maintain a written QA program for laboratory services.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) and interview with laboratory director (LD), the LD failed to ensure all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance specifications occur. Findings: 1. Review of Siemens Dimension EXL 200 QC from December 19, 2018 to February 17, 2020 showed the analytes: iron, total iron binding capacity, magnesium, uric acid, sodium, potassium, chloride, carbon dioxide, glucose, blood urea nitrogen, creatinine, calcium, phosphorus, albumin, aspartate aminotransferase, alanine aminotransaminase, alkaline phosphatase, total bilirubin, direct bilirubin, total protein, albumin, cholesterol, triglycerides and high density lipoprotein cholesterol results were not within 2 standard deviations for 166 events and no remedial action was taken. 2. Review of monthly QC showed no documentation of QC performed in December 2019 for iron, total iron binding capacity, magnesium, uric acid, sodium, potassium, chloride, carbon dioxide, glucose, blood urea nitrogen, creatinine, calcium, phosphorus, albumin, aspartate aminotransferase, alanine aminotransaminase, alkaline phosphatase, total bilirubin, direct bilirubin, total protein, albumin, cholesterol, triglycerides, high density lipoprotein cholesterol. A total of 6945 patient results were reported to the provider(s) with no remedial action. 3. No calcium QC level 3 was performed from January 14, 2019 through March 21, 2019. The laboratory reported 4948 calcium patient results to the provider(s) with no remedial action. 4. Interview with the LD on March 2, 2020 at 1:30 PM confirmed the laboratory director failed to ensure all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance specifications occur.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) program, the lack of a coagulation procedure manual, and interview with the testing personnel (TP) #1, the laboratory director (LD) failed to ensure an approved coagulation procedure was available to TP responsible for every aspect of the coagulation testing process. Findings: 1. The QA program states, "Stover must have a procedure manual for the step by step performance of all tests performed. This includes all steps in the pre-analytic, analytic, and post analytic phases of testing, literature references and the laboratory's system for reporting results." 2. The laboratory could not provide a procedure manual for coagulation testing on day of survey. 3. Interview with TP # 1 on March 2, 2020 at 2: 30 PM confirmed the LD failed to ensure an approved coagulation procedure manual was available.
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 review of quality control and quality assessment policies and procedures, personnel policies, and interviews, the technical consultant failed to establish the parameters for acceptable levels of analytic performance and ensure these levels are maintained throughout the entire testing process (Refer to D6042); failed to resolve technical problems and ensure remedial actions were taken whenever test systems deviate from the laboratory's established performance specifications (Refer to D6043), and failed to evaluate the competency of all testing personnel (Refer to D6046).
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 a lack of the Beckman Coulter LH500 hematology analyzer quality control (QC) assay information for complete blood cell counts (CBC), review of one of one patient CBC report dated 8/7/2019 which includes the following reported values: white blood cell (WBC), red blood cell (RBC), hemoglobin (HGB), hematocrit (HCT), platelet (PLT), mean cell volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red cell distribution width (RDW), neutrophil percentage and absolute value (N%, N#), lymphocyte percentage and absolute value (L% L#), basophil percentage and absolute value

(BASO%, BASO#), eosinophil percentage and absolute value (EOS%, EOS#), monocyte percentage and absolute value (MONO%, MONO#), mean platelet volume (MPV), daily QC reports, review of CBC patient report volumes, review of Levey Jennings QC for CBC for December 19, 2018 through November 25, 2019, review of quality assurance procedure, and interview with testing personnel (TP)#1 and the technical consultant (TC), the TC failed to verify acceptable levels of analytic performance and ensure the levels were maintained throughout the entire testing procedure for CBC testing. Findings: 1. No hematology QC assay information/lot number information was available for review. The laboratory temporarily suspended complete blood cell (CBC) testing December 2019. No daily CBC QC reports were available for review. 2. The laboratory is open Monday through Friday for an approximate total of 243 testing days from December 19, 2018 to November 25, 2019. 3. Review of "Quality Assurance Procedure" states "For quantitative procedures, the laboratory must have all quality controls within 2 standard deviations of the mean prior to accepting patients results." 4. Review of Beckman Coulter LH500 Levey Jennings QC from December 19, 2018 to November 25, 2019 showed QC was performed and not within 2 standard deviations (SD): WBC low level >2SD for 9 testing days and >3SD for 4 testing days. WBC normal level >2SD for 4 testing days and >3SD for 3 testing days. WBC high level >2SD for 3 testing days and >3SD for 6 testing days. RBC low level >2SD for 3 testing days and >3SD for 3 testing days. RBC normal level >2SD for 8 testing days and >3SD for 1 testing day. RBC high level >2SD for 8 testing days and >3SD for 1 testing day. HGB low level >2SD for 1 testing day and >3SD for 3 testing days. HGB normal level >2SD for 8 testing days and >3SD for 4 testing days. HGB high level >2SD for 4 testing days and >3SD for 1 testing day. HCT low level >2SD for 1 testing day and >3SD for 3 testing days. HCT normal level >2SD for 1 testing day and >3SD for 2 testing days. HCT high level >2SD for 9 testing days and >3SD for 3 testing days. PLT low level >2SD for 15 testing days and >3SD for 5 testing days. PLT normal level >2SD for 8 testing days and >3SD for 3 testing days. PLT high level >2SD for 5 testing days and >3SD for 18 testing days. MCV low level >2SD for 15 testing days and >3SD for 3 testing days. MCV normal level >2SD for 10 testing days and >3SD for 1 testing day. MCV high level >2SD for 4 testing days and >3SD for 3 testing days. MCH low level >2SD for 9 testing days and >3SD for 5 testing days. MCH normal level > 2SD for 2 testing days and >3SD for 5 testing days. MCH high level >2SD for 8 testing days and >3SD for 10 testing days. MCHC low level >2SD for 7 testing days and >3SD for 2 testing days. MCHC normal level >3SD for 2 testing days. MCHC high level >2SD for 2 testing days and >3SD for 1 testing day. RDW low level >3SD for 2 testing days. RDW normal level >2SD for 2 testing days and >3SD for 1 testing day. N % low level > 2SD for 3 testing days. N% normal level >2SD for 2 testing days. N% high level >2SD for 2 testing days. L% low level >2SD for 77 testing days. L% normal level >2SD for 1 testing day. L% high level >2SD for 59 testing days and >3SD for 2 testing days. MONO% low level >2SD for 51 testing days and >3SD for 13 testing days. MONO% normal level >2SD for 18 testing days. MONO% high level >2SD for 1 testing day. BASO% low level > 2SD for 1 testing day. BASO% high level > 2SD for 2 testing days. BASO% and # values had a consistent negative bias at the 2SD value. MPV low level >2SD for 3 testing days. MPV normal level >2SD for 1 testing day and >3SD for 1 testing day. MPV high level >2SD for 1 testing day. N# low level > 2SD for 5 testing days and > 3SD for 1 testing day. N# normal level >3SD for 2 testing days. N# high level > 2SD for 5 testing days. L# low level >3SD for 3 testing days. L# normal level >2SD for 2 testing days and >3SD for 1 testing day. L# high level >2SD for 3 testing days. MONO# low level >3SD for 1 testing day. MONO# normal level >3SD for 1 testing day. MONO# high level >2SD for 1 testing day and >3SD for 1 testing day. EOS# low level >2SD for 1 testing day. EOS# normal level

	>2SD for 5 testing days. EOS# high level >2SD for 16 testing days and >3SD for 9 testing days. 5. Review of CBC patient test results reported to the provider from January 1, 2019-March 2, 2020 showed: CBC with auto differential = 7334 patient reports CBC with no differential = 9772 patient reports 6 Interview with TP #1 and TC on March 2, 2020 at 2:00 PM confirmed the TC failed to verify acceptable levels of analytic performance and ensure the levels were maintained throughout the entire testing procedure for CBC testing. 38475 Based on review of Siemens Dimension EXL 200 chemistry analyzer quality control (QC) assay information, observation of chemistry QC, review of quality assurance procedure, review of chemistry QC, and interview with testing personnel (TP) #1, the technical consultant failed ensure acceptable levels of analytic performance were maintained throughout the entire testing process. Findings: 1. Review of Bio-rad QC for the Siemens Dimension EXL 200 chemistry analyzer from December 19, 2018 to February 28, 2020 showed no assay information for Bio-rad level 1 QC lot #45781 and Bio-rad level 2 QC lot #45783, in use during that time. 2. Review of Bio-rad QC for the Siemens Dimension EXL 200 chemistry analyzer showed Bio-rad level 1 QC lot # 45781 expired 10/31 /19, still in use until 2/28/20 and Bio-rad level 3 lot # 45783 expired 10/31/19, still in use until 2/28/20. 3895 patient results were reported to the provider(s) from October 31, 2019 to February 28, 2020. 3. Review of "Quality Assurance Procedure" states "For quantitative procedures, the laboratory must have all quality controls within 2 standard deviations of the mean prior to accepting patients results." 4. Review of Levey-Jennings graphs for Siemens Dimension EXL 200 chemistry QC from December 19, 2018 to February 17, 2020 showed QC performed and not within acceptable limits for: Sodium QC Level 1 >2SD, 2 days of testing. Sodium QC Level 3 >2SD, 10 days of testing. Potassium QC level 1 >2SD, 5 days of testing. Potassium QC level 3 >2SD, 7 days of testing. Chloride QC Level 1 >2SD, 3 days of testing. Chloride QC Level 3 >2SD, 3 days of testing. Carbon Dioxide level 3 >2SD, 2 days of testing. Glucose level 3 >2SD, 2 days of testing. BUN level 3 >2SD, 1 day of testing. Creatinine level 3 >2SD, 4 days of testing. Calcium level 1 >2SD, 16 days of testing. Calcium level 3 >2SD, 3 days of testing. Magnesium level 1 >2SD, 19 days of testing. Magnesium level 3 >2SD, 12 days of testing. Phosphorus level 3 >2SD, 3 days of testing. Total Protein level 3 >2SD, 1 day of testing. Albumin level 1 >2SD, 1 day of testing. AST level 3 >2SD, 23 days of testing. Triglycerides level 1 >2SD, 2 days of testing. Alkaline Phosphatase level 3 >2SD, 33 days of testing. HDL level 3 >2SD, 14 days of testing. 5. Review of Siemens Dimension EXL 200 chemistry QC showed the laboratory could not provide a daily printout of QC only Levey Jennings graphs. 6. Interview with TP #1 on March 2, 2020 at 2;00 PM confirmed the technical consultant failed to ensure acceptable levels of analytic performance were maintained throughout the entire testing process.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of Levey-Jennings (LJ) charts for 243 testing days for complete blood cell counts (CBC) for December 19, 2018 to November 25, 2019, review of one of one patient CBC report which includes the following reported values: white blood cell (WBC), red blood cell (RBC), hemoglobin (HGB), hematocrit (HCT), platelet

(PLT), mean cell volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red cell distribution width (RDW), neutrophil percentage and absolute value (N%, N#), lymphocyte percentage and absolute value (L% L#), basophil percentage and absolute value (BASO%, BASO#), eosinophil percentage and absolute value (EOS%, EOS#), monocyte percentage and absolute value (MONO%, MONO#), mean platelet volume (MPV), review of CBC patient report volumes, review of quality assurance procedure, review of the Corrective Action Policy, review of the monthly laboratory director and technical consultant (TC) review, and interview with the TC, the TC failed to resolve technical problems and ensure actions were taken when the test system deviated from the laboratory's established specifications. Findings: 1. The laboratory is open Monday through Friday for a total of 243 testing days from December 19, 2018 to November 25, 2019. 2. Review of "Quality Assurance Procedure" states "For quantitative procedures, the laboratory must have all quality controls within 2 standard deviations of the mean prior to accepting patients results." 3. The TC failed to resolve negative bias trends in BASO#, BASO%. 4. Review of the "Corrective Action" policy showed, "If results of control or calibration materials, or both, fail to meet the criteria of acceptability, all patient test results obtained in the unacceptable test runs since the last acceptable test run must be evaluated to determine if the patient test results have been adversely affected. The lab must document any corrective action taken necessary to ensure the reporting of accurate and reliable patient test results." 5. Review of CBC QC for December 19, 2019 through January 2, 2019 revealed the following unacceptable QC results for the following analytes; HCT normal level >2SD for one day. HCT high level >2SD for three testing days. L % low level > 2SD for seven testing days. L% high level >2SD for nine testing days. MONO% low level >2SD for six testing days. No monthly LD/TC review for this timeframe was available. The LJ charts were signed by the LD with no comments of remedial action. Review of CBC QC for January 3-11, 2019 revealed the following unacceptable QC results for the following analytes: HCT high level >2SD for one day. MCV high level >2SD for one day. RDW low level >2SD for one day. PLT low level >2SD for one testing days and >3SD for one testing day. M# high level >3SD for one testing day. L% low level >2SD for six testing days and >3SD for one testing day. L% high level >2SD for six testing days. MONO% low level >2SD for four testing days and >3SD for four testing days. MONO% normal level >2SD for five testing days N% high level >2SD for two testing day. Review of the monthly LD/TC review on January 14, 2019 showed the following notations: "re-examine CBC QC from Dec with proper SD. Dec-Jan. New lot OK." No comments of remedial action. Review of CBC QC for January 14 through April 25, 2019 revealed the following unacceptable QC results for the following analytes: WBC low level >2SD for six testing days and >3SD for three testing day. WBC normal level >2SD for four testing days and >3SD for one testing day. WBC high level >2SD for two testing day. RBC low level >3SD for one testing day. RBC normal level >2SD for seven testing days and >3SD for one testing day. RBC high level >2SD for ten testing days and >3SD for one testing day. HGB low level >3SD for one testing day. HGB normal level >2SD for seven testing days and >3SD for two testing day. HGB high level >2SD for four testing days. HCT normal level >3SD for one testing day. HCT high level >2SD for eight testing day and >3SD for one testing day. MCV low level >2SD for ten testing days. MCV normal level >2SD for ten testing days. MCV high level >2SD for four testing days and >3SD for one testing day. MCHC lo level >2SD for one testing day. MCHC normal level >2SD for one testing day. MCHC high level >2SD for one testing day. RDW normal level >2SD for one testing day. RDW high >2SD for one testing day. PLT low level >2SD for seven testing days and >3SD for two testing days. PLT normal level >2SD for six testing days and >3SD for one testing day. PLT high level >2SD for four testing days

and >3SD for two testing day. MPV low level >2SD for two testing days. MPV normal level >2SD for one testing day. L% low level >2SD for 65 testing days L% normal level >2SD for one testing day. L% high level >2SD for 48 testing days and > 3SD for one testing day. L# normal level >2SD for two testing days. L# high level >2SD for two testing days. MONO% low level >2SD for 35 testing days and >3SD for 15 testing days. MONO% normal level >2SD for 13 testing days. MONO% high level >2SD for one testing day. MONO# high level >2SD for one testing day. N% low level >2SD for one testing day, N% normal level >2SD for two testing days. N% high level >2SD for one testing day. N# low level >2SD for six testing days. N# high level >2SD for one testing day. EOS% high level >2SD for one testing day, EOS# low level >2SD for one testing day. BASO% low level >2SD for one testing day, BASO% high level >2SD for two testing days. BASO# normal level >2SD for one testing day. No monthly LD/TC review for this timeframe was available. The LJ charts were signed by the LD with no comments of remedial action. Review of CBC QC for May 24 through June 21, 2019 revealed the following unacceptable QC results for the following analytes: WBC high level >2SD for five testing days and >3SD for five testing days. MCH low >2SD eight days and >3SD for three testing days. MCH normal >2SD one testing day and >3SD for 1 testing day. MCH high level >2SD for nine testing days and >3 SD for six testing days. MCHC low >2SD for one testing day. PLT normal >3SD for three testing days. PLT high level >2SD for two testing days. N# high level >2SD for three testing days. Review of the monthly LD/TC review showed no comments for hematology except on the LJ charts it was noted "WBC II and MCH II watch?" the LD/TC signed off on the LJ charts with the notation "deterioration". No comments of remedial action. Review of CBC QC for June 24 through July 26, 2019 revealed the following unacceptable QC results for the following analytes: PLT high level >3SD for 15 testing days. EOS# high level >2SD for two testing days. Review of the monthly LD/TC report for hematology showed "performed and issues discussed." the LJ chart had no comments of remedial action. Review of CBC QC for July 29 through August 23, 2019 revealed the following unacceptable QC results for the following analytes: WBC normal level >3SD for one testing day. RBC low level >3SD for two testing. RBC normal >3SD for one testing day HGB low level >3SD for two testing day HGB normal level >3SD one testing day HCT low level >3SD for two testing days HCT normal level >3SD for one testing day MCV low level >3SD for two testing days MCV normal level >3SD for one testing day. MCH low level >3SD for two testing days. MCH normal level >3SD for one testing day MCH high level >3SD for one testing day. MCHC low level >3SD for one testing day. RDW low level >3SD for two testing days. RDW normal level >3SD for one testing day. PLT low level >3SD for two testing days. PLT normal level >3SD for one testing day. L# low level >2SD for one testing day and >3SD for one testing day. MONO# normal level >3SD for one testing day. N# normal level >3SD for one testing day. EOS# high level >3SD three testing days. L% low level >2SD for one testing day. Review of LD/TC monthly report showed "discussed" and "end of QC". No comments of remedial action. Review of CBC QC for August 26 through September 27, 2019 revealed the following unacceptable QC results for the following analytes: WBC high level >3SD for one testing day. L# high level >2SD for one testing day N# high level >2SD for one testing day. EOS # high level >3SD for four testing days. Review of the LD/TC monthly report showed the TC noted "discussed". No comments of remedial action. Review of CBC QC for October 1 through November 18, 2019 revealed the following unacceptable QC results for the following analytes: WBC low level >3SD for one day. WBC normal level >3SD for one day. RBC low level >3SD for one day. HGB low level >3SD for one day. HGB normal level >3SD for one day. HCT low level >3SD for one day. HCT high level >2SD for two days. MCV low level >2SD for four days and > 3SD for one day. MCH low level

	>2SD for two days and > 3SD for one day. MCH normal level >3SD for one day. MCHC low level >2SD for six days, MCHC normal level >2SD for one day PLT low level >2SD for 5 days and > 3SD for four days. PLT normal level >3SD for one day. MPV low level >2SD for one day. MPV normal level >3SD for one day. L# low level >3SD for one day. MONO# low level >3SD for one day. N# low level >3SD for one day, N# normal level >3SD for one day. EOS# normal level >2SD for five days. EOS# high level > 3SD for 13 days. Review of monthly LD/TC report showed the TC signed and initialed the report with no comments or remedial action. Review of CBC QC for November 19-26, 2019 revealed the following unacceptable QC results for the following analytes: HGB normal level >2SD for one day. HGB high level >3SD for one day. HCT low level >3SD for one day. HCT high level >2SD for one day. MCH low level >3SD for one day. MCH normal level >3SD for one day. MCH high level >3SD for one day. MCHC low level >3SD for one day. MCHC normal level >2SD for one day. MCHC high level > 2 SD for one day. PLT low level > 2SD for two days. EOS# high level >3SD for two days. Review of monthly LD/TC report showed no the TC signed the LJ charts with no comments or remedial action. 6. Interview with the LD/TC on March 2, 2020 at 2:00 PM confirmed "I have addressed my concerns with the owner and testing staff with no corrective outcome." "I have concerns with the testing." Interview confirmed the TC failed to resolve technical problems and ensure remedial actions were taken whenever test systems deviate from the laboratory's established performance specifications.
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 a lack of personnel documentation and interview with the technical (TC), the TC failed to perform 1 of 1 competency evaluations for 2019 and to date March 2, 2020. Findings: 1. No documentation of employee competencies were available for review for 1 of 1 TP of moderate complexity testing. 2. Interview with the TC on March 2, 2020 at 3:00PM confirmed the TC failed to perform annual competencies for 2019 and to date March 2, 2020.