Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0089209	11/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Roger C Hall Md	89 Hospital Street Po Box 675, Augusta, ME	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA Recertification Survey was completed on November 1, 2021 at the Roger Hall MD Laboratory by the Maine Department of Health and Human Services, Division of Licensing and Certification. The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493. 1 through 493.1780 resulting in the following IMMEDIATELY JEOPARDY finding: 42 C.F.R. 493.1210 Condition: Routine chemistry In addition, the laboratory also had the following CONDITION LEVEL findings: 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

	This CONDITION is not met as evidenced by: Based on review of the Proficiency Testing (PT) data report (Report 155) and graded results from the American Proficiency Institute (APl) and staff interview, the laboratory failed to successfully participate in proficiency testing (PT) for the subspecialty of Routine Chemistry. The laboratory had unsatisfactory PT scores for the 1st and 2nd events of 2020, the 1st and 3rd events of 2021, and the 3rd event 2021. See D2089 and D2096.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the CASPER Proficiency Testing (PT) data report (155), graded results from the American Proficiency Institute (API) and staff interviews, the laboratory failed to successfully participate in PT for Routine Chemistry. Findings include: 1. Record review on 10/27/2021 of the CASPER 155 report revealed: a. Scores of 0% for API 2020 Event 2 and 2021 Event 3, were unsatisfactory due to a failure to participate for the following regulated Chemistry analytes: Cholesterol total, Cholesterol HDL, Creatinine, Glucose (non waived), Potassium and Triglycerides. 2. During interview with testing personnel #1 (TP1) on 10/27/2021 at 11:00 AM, TP1 stated: a. For 2021 event 3 there was a breakdown in communication between the office and TP1. TP1 did not know the event had arrived until it was past the due date. b. For 2020 Event 2 the laboratory was closed due to the PHE. 3. During interview with the laboratory director (LD) on 10/27/2021 at 11:00 AM, the LD confirmed the above findings. 4. Test volume from 01/01/2021 through 10/26/2021 for the above analytes is 1,082.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by:

	Based on lack of documentation, review of the Proficiency Testing (PT) data report (CASPER Report 155), graded results from the proficiency testing organization American Proficiency Institute (API), staff interviews and laboratory PT records, the laboratory failed to document appropriate training and investigation to correct problems with PT testing failures. Findings include: 1. Record review on 10/27/2021 of the CASPER 155 and graded results from API revealed: a. API 2020 Event 1 for Cholesterol, total, the score was 60% and was unsatisfactory. b. API 2021 Event 1 for Cholesterol, total, the Score was 60% and was unsatisfactory. 2. Record review on 10 /27/2021 of the laboratory's PT records revealed: a. API 2020 Event 1 for Cholesterol, total - Samples were repeated and a patient impact study performed. Staff training and investigation to correct problems associated with the failure was not performed. b. API 2021 Event 1 Cholesterol, total - Samples were repeated and daily QC for day of testing was in range. A patient impact study was performed. Staff training and investigation to correct problems associated with the failure was not performed. 3. During interview with testing personnel #1 (TP1) on 10/27/2021 at 10:00 AM, TP1 stated TP1 was unaware the extent corrective action was needed when a PT failure occurs. 4. Record review on 10/27/2021 of the laboratory's 'Proficiency Testing Procedure' Corrective Action section revealed, "Corrective action will include but not be limited to the statistical analysis of the instrument/reagent system, appropriate retraining of personnel, calibration verification, or technical assistance from the technical supervisor or manufacturer's representatives." 5. Record review on 10/27 /2021 of the laboratory's PT Policy Binder revealed: a. 'Policy: Proficiency Testing, Object: Compliance CLIA 88' procedure - "Each analyte where 100% performance was not achieved is documented in our PT data Review Form. A remedial action form will be completed for each analyte or sample from the review form. These forms will be maintained in this binder." b. The binder did not contain any completed remedial action forms. 6. Record review on 10/27/2021 of the laboratory's Quality Assurance Manual revealed: a. 'Quality Assurance Check List' i. "The following elements for QA will be reviewed according to the schedule outlined below. Documentation will be kept using the QA form designed for this purpose." ii. "Six Month Reviews - PT records corrective actions and effectiveness." b. 'Proficiency Testing QA tracking sheet' i. "If any PT reports were received this month, were corrective actions taken and effective?" c. The laboratory did not use the PT QA tracking sheet referenced in b. i. above. 7. During interview with testing personnel #1 (TP1) and the laboratory director (LD) on 10/27/21 at 2:00 PM TP1 and the LD confirmed the above findings. 8. The laboratory performed 269 total Cholesterol tests from 1/1/2021 to 10/26/2021.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the Proficiency Testing (PT) data report (CASPER Report 155), graded results from the proficiency testing organization American Proficiency lnstitute (API) and staff interview, the laboratory failed to successfully participate in Cholesterol, total and sustained a subsequent occurrence of unsuccessful participation in PT. The laboratory had unsatisfactory scores for the 1st event of 2020, the 1st event of 2021 and the 3rd event 2021 for the analyte listed above. Findings include: 1. Record review on 10/27/2021 of the CASPER 155 and graded results from API

	revealed: a. API 2020 Event 1 for Cholesterol, total, the score was 60% and was unsatisfactory. b. API 2020 Event 2 for Cholesterol, total, the Score was 0% (laboratory was closed and not performing testing, but did not inform API). c. API 2020 Event 3 for Cholesterol, total the score was 100% and satisfactory. d. API 2021 Event 1 for Cholesterol, total, the Score was 60% and was unsatisfactory. e. API 2021 Event 2 for Cholesterol, total, the Score was 100% (excused nonparticipation). f. API 2021 Event 3 for Cholesterol, total, the Score was 0% and was unsatisfactory. (Failure to participate). 2. During interview with testing personnel #1 (TP1) on 10/27/2021 at 10:00 AM, TP1 stated the following: a. The laboratory was closed during the timeframe of 2020 Event 2. b. For 2021 event 3 there was a breakdown in communication between the office and TP1. TP1 did not know the event had arrived until it was past the due date. 3. During interview with the laboratory director (LD) on 10/27/2021 at 2:00 PM the laboratory director confirmed the above findings. 4. The laboratory performed 269 total Cholesterol tests from 1/1/2021 to 10/26/2021.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to establish and follow written policies and procedures and the manufacturer's instructions to ensure that specimens were properly collected and stored (refer to D5311); failed to ensure proper storage of controls, calibrators and patient specimens (refer to D5413); failed to perform and document established instrument maintenance (refer to D5433), and failed to document all control procedures (refer to D5481). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. Refer to D5311, D5413, D5433 and D5481.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to establish and follow written policies and procedures and the manufacturer's instructions to ensure that specimens were properly collected and stored. Findings include: 1. Surveyor observation on 10/27/2021 at 2:30 PM of the collection tubes used to collect blood samples for patient testing revealed: a. 1 unopened package of BD Vacutainer red top serum blood collection tubes, lot# 0135434 with an expiration date of 9/30/2021. b. 1 opened package with 1/4 of the tubes remaining of BD

	Vacutainer red top serum blood collection tubes, lot # 0119095 with an expiration date of 8/31/2021. c. 1 unopened package of BD Vacutainer K2 EDTA (K2E) purple top blood collection tubes, lot # 9158891 with an expiration date of 9/30/2020. d. 1 opened package of BD Vacutainer Gel and Lithium Heparin light green top blood collection tubes, lot # 8032761, exp, 2/28/2019. 2. Record review on 10/27/2021 of the laboratory's procedure manual revealed the following: a. Collection requirements: High Density Lipoprotein (HDL): Red top vacutainer tube with serum separator. Cholesterol: Red top vacutainer tube with serum separator. Triglyceride: Red top vacutainer tube with serum separator. Glucose: Red top vacutainer tube with serum separator. Creatinine: Red top vacutainer tube with serum separator. b. Storage requirements when testing is delayed: HDL: 2 - 8 degrees Celsius for up to 7 days and up to 3 months when frozen. Cholesterol: 7 days at 25 degrees Celsius and up to 6 months when frozen. Triglyceride: 2 - 8 degrees Celsius for several days. Glucose - 8 hours at 25 degrees Celsius and up to 24 hours at 2 - 8 degrees Celsius. Creatinine: 2 - 8 degrees Celsius for 24 hours and several months when frozen. 3. Record review on 10/27/2021 of the manufacturer's package inserts revealed following: a. Collection requirements: HDL: Serum, EDTA treated or heparinized plasma. Cholesterol: Fresh, clear, unhemolyzed serum. Triglyceride: Fresh, clear, unhemolyzed serum. Glucose: Fresh, clear, unhemolyzed serum. LDL Direct: Serum, EDTA or Heparinized plasma Creatinine: Fresh, clear, unhemolyzed serum. b. Storage requirements when testing is delayed: HDL: 2 - 8 degrees Celsius for up to 1 week or less than -70 degrees Celsius for up to 3 months. Cholesterol: 2 - 8 degrees Celsius for up to 1 week and at least 4 weeks at -20 degrees Celsius. Triglyceride: 4-8 degrees Celsius for up to 7 days and several weeks at -20 degrees Celsius to 0 degrees Celsius. Glucose - 4 degrees Celsius for up to 3 days. LDL Direct: 2 - 8 degrees Celsius for up to 5 days and frozen at -80 degrees Celsius for longer periods of time. Creatinine: 2 - 8 degrees Celsius for 3 days and -20 degrees Celsius to 0 degrees Celsius for longer periods of time. 4. During interview with the office manager (OM) on 10/27/2021 at 12:25 PM, the OM stated: a. "HDL, Cholesterol, Triglyceride, Glucose, LDL Direct and Creatinine are stored in the refrigerator until testing can be performed. TSH, PSA and Potassium are frozen. We have been doing it that way all along." b. "That was the way I was trained to store the samples." c. "Collection tubes were received from the hospital recently." d. "Prior to TP1's hire date of 12/10/2020, samples were tested at least twice a month." 5. During interview with testing personnel #1 (TP1) on 10/27/2021 at 12:30 PM, TP1 stated: a. Prior to TP1's hire date (12/10/2020), testing was perfromed twice per month. b. Beginning on 12/10/2020 and continuing until inspection date (10/27/2021) testing is performed once a month by TP1. c. "The OM leaves them on the counter for me to test when I arrive." d. Confirmed the tubes indicated above are expired. 6. During interview with the laboratory director (LD) on 10/27/2021 at 12:35 PM, the LD stated, "I thought is was being done correctly. I guess I should have paid more attention." 7. The laboratory performed 1,530 tests in the specialty of Chemistry from 01/01/2021 through 10/26/2021.
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 surveyor observation, lack of documentation and staff interview, the laboratory failed to ensure proper storage of controls, calibrators and patient specimens in the specialty of Chemistry. Findings include: 1. Surveyor observation on 10/27/2021 at 2:00 PM of the refrigerator/freezer unit located in the laboratory revealed: a. Freezer portion - used to store patient specimens for Thyroid Stimulating Hormone (TSH), Prostate Specific Antigen (PSA), Potassium (K) and quality control (QC) materials. b. Refrigerator portion - used to store patient specimens for High Density Lipoprotein (HDL), Cholesterol, Triglycerides, Glucose, Low Density Lipoprotein (LDL) Direct and Creatinine, proficiency testing material, reagents, quality control material and calibrators. 2. Record review on 10/27/2021 of the package inserts for the following analytes revealed the following storage requirements: HDL: 2 - 8 degrees Celsius for up to 1 week or less than -70 degrees Celsius for up to 3 months. Cholesterol: 2 - 8 degrees Celsius for up to 1 week and at least 4 weeks at -20 degrees Celsius. Triglyceride: 4-8 degrees Celsius for up to 7 days and several weeks at -20 degrees Celsius to 0 degrees Celsius. Glucose - 4 degrees Celsius for up to 3 days. LDL Direct: 2 - 8 degrees Celsius for up to 5 days and frozen at -80 degrees Celsius for longer periods of time. Creatinine: 2 - 8 degrees Celsius for 3 days and -20 degrees Celsius to 0 degrees Celsius for longer periods of time. TSH: 2-8 Celsius for up to 6 hours prior to analysis or frozen at -20 C or below for future use. PSA: 2-8 Celsius for up to 6 hours prior to analysis or frozen at -20 C or below for future use. K: Frozen 3. Record review on 10/27/2021 of the laboratory's procedure manual revealed: a. A fillable chart to record daily temperatures of the refrigerator, freezer, room temperature and incubator. b. No documentation was found indicating that temperatures were recorded from 1/1/2019 through 10/27/2021. 4. Record review on 10/27/2021 of the laboratory's 'Quality Assurance Program' procedure "Maintenance, Calibration and Quality Control QA Tracking Sheet' revealed: a. "Are temps. recorded each day for refrigerators, freezers, room temp?" 5. During staff interview on 10/27/2021 at 2:00 PM with testing personnel #1(TP1), TP1 stated, a. "Temperatures are not recorded daily and the QA tracking sheet is not used." b. "There is a thermometer that will beep if the temperature is out of range." 6. Staff interview with the laboratory director (LD) on 10/27/2021 at 2:00 PM confirmed the above findings. 7. The laboratory performed 1,530 tests in the specialty of Chemistry from 01/01/2021 through 10/26/2021.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of documentation, record review and interview with the laboratory director (LD) and testing personnel #1 (TP1), the laboratory failed to perform and document established maintenance protocols for the COBAS MIRA, AVL Electrolyte

	Analyzer and the FREND Immunoassay Analyzer in the specialty of Chemistry. Findings include: 1. Record review on 10/27/2021 of the laboratory's maintenance records revealed: COBAS MIRA: a. Maintenance records showed maintenance was not consistently performed in 2021. b. No maintenance documentation was found for 2020. AVL Electrolyte Analyzer: a. Monthly maintenance was not performed on the AVL in March and April of 2021. b. No maintenance documentation was found for 2020. FREND Immunoassay Analyzer: a. No maintenance documentation was found for 2020. 2. Staff interview with TP1 on 10/27/2021 at 2:00 PM, TP1 stated, a. "I did not consistently document maintenance in 2021 for the COBAS and the AVL and take responsibility for it." b. "I started working in the laboratory in December of 2020. I am unable to locate 2020 maintenance documentation at this time." 3. Staff interview with the LD on 10/27/2021 at 2:00 PM confirmed the above findings. 4. The laboratory performed 1,530 tests in the specialty of Chemistry from 01/01/2021 through 10/26/2021.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation, record review and interview with testing personnel #1 (TP1) and the laboratory director (LD), the laboratory failed to document all control procedures performed in the specialty of Chemistry. Findings include: 1. The 'Maintenance, Calibration, and Quality Control (QC) - QA Tracking Sheet' checklist procedure was reviewed. 2. Quality Control Section has a check box that states "QC done at req. freq. & doc kept?" 3. No documentation was found that QC was performed in 2020 for Thyroid Stimulating Hormone (TSH) and Prostate Specific Antigen (PSA). 4. During interview with TP1 on 10/27/2021 at 2:00 PM, TP1 stated, "I started working in the laboratory in December of 2020. I am unable to locate 2020 QC documentation for TSH and PSA at this time." 5. During interview with the laboratory director (LD) on 10/27/2021 at 2:00 PM, the LD confirmed TP1 and LD are unable to locate 2020 QC documentation for TSH and PSA at this time. 6. The laboratory performed 1,530 tests in the specialty of Chemistry from 01/01/2021 through 10/26/2021.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined that the reference range for Glucose, High Density Lipoprotein (HDL) and Thyroid Stimulating Hormone (TSH) on the laboratory's final patient test report failed to correlate with the reference range in the laboratory's procedure manual. Findings include: 1. Record review on 10 /27/2021 comparing final patient test report's reference range for patient #1 (P1) with

	the laboratory's procedure manual's 'Normal Ranges' (NR) sheet and the individual laboratory procedures (Proc) revealed the following: Test P1 Final Patient Report Glucose 70-110 Mg/dL HDL 35 - 80 Mg/dL TSH 0.32 - 5.00 ulU/mL Test NR Sheet Glucose 70-110 mg/dl HDL 35-80 mg/dl TSH 0.32-5.00 Uil/mL Test Proc Glucose 70-115 mg/dl HDL Male: 29-72 mg/dl, Female: 35-80 mg/dl TSH 0.49-3.82 mIU/L 2. During interview 10/27/2021 at 2:00 PM, testing personnel #1 and the laboratory director confirmed the above reference ranges did not match. 3. The laboratory performed 103 Glucose, 269 HDL and 106 TSH tests in the specialty of Chemistry from 01/01/2021 through 10/26/2021.
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 surveyor observation, record review and staff interviews, the Laboratory Director (LD) failed to ensure the laboratory had a qualified technical consultant (refer to D6004); failed to ensure laboratory staff followed test methods according to established procedures and manufacturer instructions (refer to D6014); failed to ensure the laboratory successfully participated in proficiency testing under the subspecialty of Routine Chemistry (refer to D6016); failed to ensure an approved corrective action plan were followed when any proficiency testing results are found to be unacceptable or unsatisfactory (refer to D6019); failed to ensure all control procedures performed were documented in the specialty of Chemistry (refer to D6020); failed to ensure the accuracy of reference ranges for Glucose, High Density Lipoprotein (HDL) and Thyroid Stimulating Hormone (TSH) appeared on the laboratory's final patient test report (refer to D6021), and failed to document new moderate complexity testing personnel training prior to testing patient samples (D6029). The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure the accuracy and reliability of patient test results in the specialty of Chemistry.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by:

	Based on record review and staff interview the laboratory failed to have a qualified technical consultant who provides technical oversight in the specialty of Chemistry. Refer to D6035.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, lack of documentation, record review and staff interview the laboratory director failed to ensure laboratory staff followed test methods according to established procedures and manufacturer instructions. Refer to D5016 or D5311, D5413, D5433 and D5481.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure the laboratory successfully participated in proficiency testing under the sub specialty of Routine Chemistry. Refer to D2089 and D2096.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director failed to ensure the laboratory documented appropriate training and investigation to correct problems with proficiency testing testing failures for Total Cholesterol. Refer to D2094.

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 documentation and interview with testing personnel #1 and the laboratory director (LD) the LD failed to ensure a quality control program was maintained in the specialty of Chemistry. Refer to D5481.
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 record review and staff interview the laboratory director failed to ensure the accuracy of reference ranges for Glucose, High Density Lipoprotein (HDL) and Thyroid Stimulating Hormone (TSH) appeared on the laboratory's final patient test report. Refer to D5891.
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 lack of documentation, procedure manual review and interview with moderate complexity testing personnel #1 (TP1) and the laboratory director (LD), the LD failed to document new moderate complexity testing personnel training prior to testing patient samples. Findings include: 1. The procedure, 'Quality Assurance Program' was reviewed on 10/27/2021. The procedure stated, "All laboratory personnel must be properly trained to perform assigned duties. All training activities

	must be documented." 2. The procedure, 'Laboratory Director/Clinical Consultant' was reviewed on 10/27/2021. The procedure stated, "Ensure that prior to testing patient samples, all personnel have the appropriate education and experience needed to perform testing operations reliably to provide and report accurate results." 3. TP1 was hired on 12/10/2020. 4. No documentation was found from 12/10/2020 through 10 /27/2021 that TP1 was trained prior to reporting test results on patient samples. 5. During interview on 10/27/2021 at 2:00 PM, TP1 and the LD confirmed that training for TP1 prior to reporting test results on patients was not documented.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to have a qualified technical consultant who provides technical oversight in the specialty of Chemistry. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing

	tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the CMS form 209, Technical Consultant (TC) credentials and interview with the Laboratory Director (LD), the laboratory failed to have a qualified TC in the specialty of Chemistry. Findings include: 1. Record review on 10/27/2021 of the laboratory's CMS form 209 revealed testing personnel #1 (TP1) was designated as the TC. 2. Record review on 10/27/2021 of TP1's credentials revealed TP1 has an Associate's degree. 3. During staff interview with TP1 on 10/27/2021 at 9:00 AM, TP1 stated he/she did not realize an Associate's degree was not enough to qualify as a TC. TC also stated he/she would change the CMS form 209 to designate the LD as TC. 4. During staff interview with the LD on 10/27/2021 at 9:00 AM the LD stated he /she does not have any board certification or the required experience testing patients in the specialty of chemistry and therefore does not qualify. 5. During staff interview with the LD on 11/1/21 at 9:30 AM the LD stated he does not have a qualified TC. 6. The laboratory performs 1,530 tests annually in the specialty of Chemistry.