Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0057925	09/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Little Colorado Medical Center	1501 N Williamson Avenue, Winslow, AZ	

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
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 Proficiency Testing (PT) reports for 2022 sent to the State Agency by the PT provider and interview with the Technical Consultant (TC-1), the laboratory failed to successfully participate in a PT program for the regulated analyte, Fibrinogen, resulting in subsequent unsuccessful PT performance. Findings include: 1. The laboratory's PT performance was unsatisfactory for the first event of 2022 for the regulated analyte, Fibrinogen, with a score of 40%. 2. The laboratory's PT performance was unsatisfactory for the second event of 2022 for the regulated analyte, Fibrinogen, with a score of 60%. 3. The laboratory's PT performance was unsatisfactory for the third event of 2022 for the regulated analyte, Fibrinogen, with a

	score of 60%. 4. *Unsatisfactory participation in the first and second events of 2022 (two consecutive testing events) for the regulated analyte, Fibrinogen, constitutes an initial unsuccessful PT performance. 5. **Unsatisfactory participation in the second and third events of 2022 (two consecutive testing events) for the regulated analyte, Fibrinogen, constitutes an unsuccessful PT performance and a subsequent unsuccessful PT performance to the initial unsuccessful PT as outlined above in #4. 6. The TC-1 interviewed on June 12, 2023 at 11:50 AM confirmed the laboratory received unsuccessful PT results for Fibrinogen during each testing event of 2022, resulting in subsequent unsuccessful PT performance.
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 lack of analytic records for review and interview with the Technical Consultant (TC-1), (A) the laboratory failed to retain quality control records and patient test records for Blood Gas testing for at least two years; and (B) failed to retain the manufacturer's package inserts for reagents used for Coagulation testing for at least two years. Findings include: A1. The laboratory performs Arterial Blood Gas (ABG) testing on the i-Stat analyzer under the specialty of Chemistry, with an approximate annual test volume of 6. It is the policy of the laboratory to perform two levels of external quality control material each day of patient testing. A2. No documentation was presented for review to indicate the laboratory retained instrument printouts showing quality control results from the i-Stat analyzer from 2021 through the date of the survey conducted on June 12, 2023. A4. No documentation was presented for review to indicate the laboratory retained instrument printouts showing patient test results from the i-Stat analyzer from 2021 through the date of the survey conducted on June 12, 2023. A4. The TC-1 interviewed on June 12, 2023 at 3:50 PM confirmed the laboratory failed to retain instrument printouts from the i-Stat analyzer showing quality control results and patient test results for at least 2 years. B1. The laboratory performs Prothrombin Time (PT/INR) testing on the Sysmex CA660 analyzer, using the 'Dade Innovin' reagent. B2. No documentation was presented for review to indicate the laboratory retained the manufacturer's package insert for each lot of Dade Innovin reagent used on the analyzer, for at least two years. The package insert contains lot specific values for the International Sensitivity Index (ISI) which is used in the INR calculation. B3. The TC-1 interviewed on June 12, 2023 at 5:05 PM confirmed the laboratory failed to retain the manufacturer's package inserts for Dade Innovin for at least two years.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by:

	Based on the number and severity of deficiencies identified during the survey conducted on June 12, 2023, it was determined that the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299 for patient testing performed in the specialty of Hematology. See D5411, D5437, D5545 and D5791 for findings.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of i-Stat instrument printouts, i-Stat test procedures and interview with the Technical Consultant (TC-1), the laboratory failed to establish written policies and procedures to ensure positive identification of the patient's specimen from the time of collection through completion of testing and reporting of results. Findings include: 1. The laboratory performs Arterial Blood Gas (ABG) testing on the i-Stat analyzer, with an approximate annual test volume of 6. It is the practice of the laboratory to manually enter the patient's accession number into the i-Stat analyzer prior to testing the sample. 2. The laboratory failed to provide evidence of a written policy and procedure to ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results, for testing performed on the i-Stat analyzer. 3. The TC-1 interviewed on June 12, 2023 at 3:15 PM confirmed the laboratory failed to establish policies and procedures to ensure positive identification and optimum integrity of a patient's specimen throughout the entire testing process, for testing performed on the i-Stat analyzer.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results from the second event of 2022 and interview with the Technical Consultant (TC-1), the laboratory failed to verify the accuracy of analytes assigned a proficiency testing score that does not reflect laboratory test performance. Findings include: 1. The laboratory performs testing for Blood Culture Identification (BCID2) Resistance Genes (15 total) on the BioFire Torch analyzer in the subspecialty of Bacteriology, with an approximate annual test volume of 1,455. 2. The laboratory is enrolled in PT with American Proficiency Institute (API) for the test panel titled, 'Molecular Resist. Genes - Blood', which includes testing for 15 gene resistance markers: CTX-M, IMP, KPC, mcr-1, mecA, mecA/C, mecA/C & MREJ, mecC, NDM, OXA, OXA-48 like, vanA, vanA/B, vanB,

	and VIM. 3. PT records reviewed from the second event of 2022 for 'Molecular Resist. Genes - Blood' indicated the laboratory received a result of "Not Graded [11]" for the 15 tests listed above. API's PT report lists code [11] as 'No Appropriate Peer Group'. 4. The laboratory failed to verify the accuracy of each gene resistance marker included in the "Molecular Resist. Genes - Blood" PT event during the second event of 2022. 5. No written documentation was presented for review to indicate the laboratory evaluated the reported results against the expected results for the PT samples which were given the result of "Not Graded [11]". 6. The TC-1 interviewed on June 12, 2023 at 12:00PM confirmed the laboratory failed to verify the accuracy of the PT samples indicated above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of coagulation test records, direct inspection of the coagulation analyzer, review of the manufacturer's package insert for test reagents and interview with the Technical Consultant (TC-1), the laboratory failed to use the correct International Sensitivity Index (ISI) value for each lot of Innovin reagent used on the analyzer. Findings include: 1. The laboratory performs Prothrombin Time (PT/INR) testing on the Sysmex CA660 coagulation analyzer. The analyzer uses a reagent called "Dade Innovin" in conjunction with PT/INR testing. 2. The ISI value contained in the manufacturer's package insert from the Dade Innovin reagent must be correctly programmed into the analyzer with each new lot of reagent used on the analyzer, to ensure the correct ISI value is used in the calculation of the International Normalized Ratio (INR). The ISI value varies with each new lot of Innovin reagent. 3. Direct inspection of the Dade Innovin reagent data entered in the analyzer at the time of the survey conducted on June 12, 2023 revealed the following: Lot# 549786, expiration date 09-24-2023, ISI = 1.06. 4. Direct inspection of the manufacturer's package insert for the Dade Innovin reagent (Lot# 549786) used on the analyzer at the time of the survey listed an ISI value of 1.05. 5. The laboratory failed to document the exact date in which the Dade Innovin reagent (Lot# 549786, exp. date 09-24-2023, ISI = 1.05) was put into use for patient testing on the Sysmex CA660 analyzer. 6. The number of inaccurate PT/INR test results (using the incorrect ISI value) reported by the laboratory could not be determined at the time of the survey. 7. The TC-1 interviewed on June 12, 2023 at 4:50 PM confirmed the laboratory failed to enter the correct ISI value in the analyzer for the current lot of Dade Innovin reagent used at the time of the survey, and failed to document the exact date the current lot of Dade Innovin reagent was put into use for patient testing
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on review of test records for the i-Stat analyzer and interview with the Technical Consultant (TC-1), the laboratory failed to perform and document the electronic simulator check performed on the i-Stat analyzer each day prior to patient testing. Findings include: 1. The laboratory performs Arterial Blood Gas (ABG) testing on the i-Stat analyzer, with an approximate annual test volume of 6. 2. No documentation was presented for review during the survey to indicate the laboratory performed and documented the electronic simulator check on the i-Stat analyzer prior to testing patients during 2021, 2022 and 2023 (through the date of the survey). 3. The manufacturer requires a passing result for the electronic simulator check prior to testing patient samples each day of testing. 4. The TC-1 interviewed on June 12, 2023 at 3:30 PM confirmed the laboratory failed to provide documentation of the electronic simulator check for the date range indicated above.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration records from 2022 for the Sysmex XS 1000i and Medonic CDSM series hematology analyzers and interview with the Technical Consultant (TC-1), the laboratory failed to perform and document calibration procedures with at least the frequency recommended by the manufacturer's. Findings include: 1. The laboratory utilizes the Sysmex XS 1000i and Medonic CDSM hematology analyzers to perform patient testing, with an approximate annual test volume of 58,824. 2. No documentation was presented for review during the survey conducted on June 12, 2023 to indicate the laboratory performed and documented calibration procedures every 6 months as indicated by the manufacturer's for each analyzer indicated above. 3. Calibration records reviewed for the Sysmex XS 1000i indicated calibration procedures were not performed during 2022. A calibration was performed on 10/29/2021 and not again until 2/17/2023. 4. Calibration records reviewed for the Medonic CDSM indicated calibration procedures were not performed during 2022. A calibration was performed on 7/01/2021 and not again until 3/20/2023. 5. The TC-1 interviewed on June 12, 2023 at 1:40 PM confirmed the laboratory failed to perform calibration procedures in 2022 on the hematology analyzers indicated above.
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 lack of calibration verification documentation for the Siemens Dimension EXL 200 chemistry analyzers and interview with the Technical Consultant (TC-1), the laboratory failed to perform and document calibration verification procedures at least once every 6 months during 2022 and 2023. Findings include: 1. The laboratory utilizes two Siemens Dimension EXL 200 chemistry analyzers (instrument A and instrument B) to conduct patient testing in the subspecialties of Routine Chemistry and Endocrinology, with an approximate annual test volume of 129,807. 2. No documentation was presented for review to indicate the laboratory performed a calibration verification on each chemistry analyzer at least once every six months during 2022 and 2023, 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. 3. Review of calibration verification records for each chemistry analyzer revealed the laboratory performed a calibration verification on each analyzer on 7/29/2021. 4. The TC-1 interviewed on June 12, 2023 at 1:35 PM confirmed the laboratory failed to perform a calibration verification on each chemistry analyzer since 7/29/2021.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of Quality Control (QC) documentation, laboratory policies and procedures and interview with the Technical Supervisor (TS-1), the laboratory failed to perform and document Body Fluid control procedures using the number and frequency established by the laboratory. Findings include: 1. The laboratory performs Body Fluid testing on patient specimens under the specialty of Hematology, with an approximate annual test volume of 11. 2. Review of the laboratory's established QC procedure included in the policy titled, "Body Fluid - Manual Method" states, "If cells are present perform count on Cell-Chex Level 1 and differential of Cell-Chex Level 2 (see Body Fluid Worksheet)". 3. The Body Fluid Worksheet presented for review for patient #471151 from 11-13-2022 failed to include QC results from two separate levels of QC material. Cell-Chex Level 2 QC was not performed. 4. The Body Fluid Worksheet used by the laboratory to document patient results and QC results failed to include an area to document QC information for Cell-Chex Level 2 (lot#, Expiration Date, expected range and QC results). 5. The TS-1 interviewed on June 12, 2023 at 4: 20 PM confirmed that the laboratory failed to perform and document two levels of Cell-Chex control material each day of patient testing.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) documentation for Bactec Blood Culture media and interview with the Technical Supervisor (TS-1), the laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms. Findings include: 1. The laboratory uses the Bactec test system and culture media for blood culture incubation and preliminary identification. The media used in the Bactec may include Aerobic, Anaerobic and/or Pediatric blood culture bottles. 2. No documentation was presented for review during the survey to indicate the laboratory checked each batch of Bactec blood culture media using at least one gram negative organism to confirm its ability to support growth and, as appropriate, select or inhibit specific organisms. 3. The TS-1 interviewed on June 12, 2023 at 4:00 PM stated the laboratory was checking each batch of blood culture media with a gram positive organism, Staphylococcus aureus, to demonstrate its ability to support growth, but failed to check each batch of blood culture media using a gram negative organism. 4. The laboratory's approximate annual test volume for Blood Culture testing in the Bactec is 1,176.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on review of coagulation Quality Control (QC) records requested by the State Agency as the result of a complaint investigation, the laboratory failed to perform and document two levels of control material each 8 hours of operation for Coagulation testing performed in the specialty of Hematology. Findings include: 1. The State Agency received an anonymous complaint on June 13, 2023 related to the laboratory's quality control performance for Coagulation testing. 2. The laboratory performs Protime/INR (PT/INR) and Activated Partial Thromboplastin Clotting Time (APTT) testing on the Sysmex CA660 coagulation analyzer in the specialty of Hematology. The laboratory's hours of operation are reported as 24 hours per day, 7 days a week. 3. Review of the laboratory's QC records indicated the laboratory failed to perform two levels of control material for PT/INR testing each 8 hours of operation for the following dates during 2022: January 11, January 14, January 17, January 21, February 4 and March 20. 4. Review of the laboratory's QC records indicated the laboratory failed to perform two levels of control material for APTT testing each 8 hours of operation for the following dates: December 15, 2021, January 17, 2022 and March 27, 2022. 5. The laboratory reports an annual test volume of 2,027 PT/INR tests and 1,766 APTT tests.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) documentation and interview with the Technical Supervisor (TS-1), the laboratory's established QA policies and procedures failed to monitor, assess and, when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory utilizes a form titled, "Laboratory Quality Assessment Review" to document QA activities for each specific laboratory systems (general, pre-analytic, analytic and post-analytic). The form includes an area to document the reason of completing the form as "Routine review", "Review of Identified problem" or "Follow-up review", with check boxes next to each reason. 2. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with using the incorrect ISI value for PT/INR testing on patient specimens. See D5411 for findings. 3. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of function check records for the i-Stat analyzer. See D5431 for findings. 4. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of calibration and calibration verification performance for testing performed in the specialties of Hematology and Chemistry. See D5437 and D5439 for findings. 5. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of quality control records for cell counts performed on Body Fluid

	specimens and a lack of quality control records for testing performed under the specialties of Microbiology and Hematology. See D5445, D5477 and D5545 for findings. 6. The TS-1 interviewed on June 12, 2023 at 5:30 PM confirmed that the laboratory's QA processes at the time of the survey were not effective at monitoring, identifying and correcting problems associated with the analytic laboratory systems.
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 the number and severity of the deficiency cited herein, the Condition: Laboratories Performing Moderate Complexity Testing - Technical Consultant was not met. The technical consultant failed to ensure that Quality Control programs are maintained and failed to ensure that acceptable levels of analytic performance are maintained throughout the entire testing process. See D6042.
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 lack of quality control documentation and errors identified with the ISI value used in the calculation of PT/INR test results, the technical consultant failed to maintain the laboratory's quality control programs and failed to ensure that the parameters for acceptable levels of analytic performance are maintained throughout the entire testing process. See D5411, D5431, D5445, D5477 and D5545 for findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: Laboratories Performing High Complexity Testing - Laboratory Director was not met. The laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H of this part (see D2016 and D6089).
D6089	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, it was determined the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a PT program for the regulated analyte, Fibrinogen. See D6076 for findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation of a semi-annual competency evaluation for two testing personnel and interview with the Technical Supervisor (TS-1), the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings include: 1. No evidence of a semi-annual competency evaluation was presented for review for two out of four testing personnel who began testing in May and September 2022. 2. The TS-1 interviewed on June 12, 2023 at 10:42 AM confirmed the technical supervisor failed to document a semi-annual competency evaluation for the testing personnel indicated above.