Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0722040	08/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Laboratory Poplar Bluff	225 Physicians' Park Drive Suite 104, Poplar Bluff, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of quality assessment procedures, 2019, 2020 and to date August 11, 2021 quality control (QC) and interview with the laboratory manager, the laboratory failed to follow written procedures for review of QC for 31 of 31 months. Findings: 1. Review of quality assessment procedures revealed "Quality Control" procedure states "All quality control records should be reviewed and assessed at least monthly by the appropriate staff". 2. Review of Tosoh AIA 900 analyzer QC, Dimension EXL analyzer QC, Cobas 6000 analyzer QC, Stago Sta Compact Max analyzer QC, Sysmex X1000i analyzer QC and Biosite Alere Triage analyzer QC showed no review for 2019, 2020 and to date August 11, 2021. 3. Interview with the laboratory manager on August 11, 2021 at 11:30 AM confirmed the laboratory failed to follow written procedures for review of QC.
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 urine centrifuge, microscopic procedures, hematology procedures, freezer temperature logs, manual differential stain, chemistry reagents, pipettes, protector hood, Tosoh AIA 900 chemistry analyzer quality control (QC) logs, package inserts, Sysmex X1000i and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to follow written procedures and ensure procedures were provided for all testing personnel (Refer to 5401); failed to ensure freezer was within acceptable criteria (Refer to D5413); failed to ensure stain was labeled with expiration date (Refer to D5415); failed to ensure chemistry reagents are not used when they have exceeded their expiration dates (Refer to D5417); failed to ensure pipettes and protector hood was maintained (Refer to D5435); failed to include two control materials of different concentrations each day of patient testing (Refer to D5447); failed to establish or verify the criteria for acceptability of chemistry QC (Refer to D5469); failed to document stain quality (Refer to D5473); and failed to define a relationship between automated differentials and manual differentials (Refer to 5775).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of hematology procedures and interview with the laboratory manager the laboratory failed to have written procedures for fecal white blood cell, white blood cell (WBC) manual differential and use of an alternative anti-coagulant for hematology testing. Findings: 1. Review of hematology procedures showed no written procedure for fecal white blood cell, WBC manual differential and use of an alternative anti-coagulant for hematology testing. 2. Interview with the laboratory manager on August 11, 2021 at 11:30 AM confirmed the laboratory failed to have written procedures for fecal white blood cell, WBC manual differential and use of an alternative anti-coagulant for hematology testing. 44735 Based on review of urinalysis microscopic procedure, centrifuge maintenance, and interview with the technical consultant (TC) #2, the laboratory failed to follow written procedures for "Urinalysis Microscopic Guidelines". Findings: 1. Review of procedure "Urinalysis Microscopic Guidelines" states "Centrifuge at 1500 rpm for 5 minutes." 2. Review of centrifuge maintenance showed the Quest Diagnostics VanGuard V6500 centrifuge was checked at 3400 RPM's. 3. Interview with TC #2 on August 11, 2021 at 10:00 AM confirmed the laboratory failed to follow written procedures for "Urinalysis Microscopic Guidelines".
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 manufacturer's instructions, documentation of freezer temperatures, observation of quality control (QC) material stored in the freezer, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for storage of control materials for 211 of 214 testing days from January 1, 2021 through August 11, 2021. Findings: 1. Review of the manufacturer's instructions for Bio-Rad liquichek cardiac markers control, Bio-Rad specialty immunoassay liquichek control, and Bio-Rad liquid assayed multiqual control showed controls must be stored at minus 20 degrees Celsius (C) to minus 70 degrees C. 2. Review of the laboratory's temperature chart showed a defined acceptable range of minus 15 degrees C to minus 20 degrees C. For 211 of 214 testing days the laboratory failed to meet the manufacturer's required minus 20 degrees C to minus 70 degree C temperature range. 3. Observation of the laboratory freezer showed 1 box of Bio-Rad liquichek cardiac markers control level 1, 1 box of Bio-Rad specialty immunoassay liquichek control level 2, and 2 boxes of Bio-Rad liquid assayed multiqual level 3 controls currently in use. 4. Interview with the laboratory manager on August 11, 2021 at 11:30 AM confirmed the laboratory failed to properly monitor the freezer and store QC materials and supplies per manufacturer's instructions.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of fecal white blood cell stain, white blood cell (WBC) manual differential stain and interview with the laboratory manager, the laboratory failed to label stain with expiration dates. Findings: 1. Observation of Quicklink III fixative, Quicklink III solution 1 and Quicklink III solution II used for staining fecal white blood cells and WBC manual differentials showed no expiration date. 2. Interview with the laboratory manager on August 11, 2021 at 11:30 AM confirmed the laboratory failed to label stain with expiration dates.
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 chemistry reagents and interview with the laboratory manager, the laboratory failed to ensure chemistry reagents are not used when they have exceeded their expiration date. Findings: 1. Review of chemistry reagents still in use showed: 3 cobas e multi lot #267636-01 expiration 5/20. 1 cobas e multi lot #360917-01 expiration 6/30/20. 2 cobas e multi lot #233508-01 expiration 12/19. 1 cobas e multi lot #292350-01 expiration 8/31/20. 4 traige cardiac lot #101020 expiration 6/22/21. 2. Interview with the laboratory manager on August 11, 2021 at 11:30 AM confirmed the laboratory failed to ensure chemistry reagents are not used when they have exceeded their expiration date.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of maintenance documentation and interview with the technical consultant (TC) #2, the laboratory failed to perform and document function checks for one Fisherbrand Elite pipette, one DiamondPro pipette and the Labconco Protector Laboratory Hood for 2019, 2020 and to date August 11, 2021. Findings: 1. Review of pipette calibration documentation showed the last calibration for the Fisherbrand Elite 100-1000 microliter multichannel pipette serial number LU08908 was November 20, 2018 and the last pipette calibration for the DiamondPro 10-100 microliter multichannel pipette serial number LD623321 was November 20, 2018. 2. Review of the Labconco Protector Laboratory Hood serial number 110947689 showed the last inspection was completed in July 2018. 3. Interview with the TC #2 on August 11, 2021 at 9:30 AM confirmed, the laboratory failed to perform and document function checks for one Fisherbrand Elite pipette, one DiamondPro pipette and the Labconco Protector Laboratory Hood for 2019, 2020 and to date August 11, 2021.
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 2021 Tosoh AIA- 900 chemistry analyzer quality control (QC) logs for vitamin B12, and interview with the technical consultant (TC) #2, the

	laboratory failed to include two control materials of different concentrations each day of patient testing for 15 of 114 patient testing days. Findings: 1. Review of 2021 vitamin B12 chemistry QC logs showed no documentation of acceptable level 1 QC for April 20, April 21, April 23, April 26, April 27, May 4, May 24, May 27, June 7, June 8, July 8, July 12, July 13, July 19, and August 10. 2. The laboratory reported 277 vitamin B12 patient results during the timeframe that there was no acceptable vitamin B12 QC. 3. Interview with the TC #2 on August 11, 2021 at 10:30 AM confirmed the laboratory failed to include two control materials of different concentrations each day of patient testing.
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 the Liquichek Immunoassay Plus Control package insert, LIS Total Quality Control (QC) module for the Tosoh AIA- 900 chemistry analyzer and interview with the technical consultant (TC) #2, the laboratory failed to ensure the established criteria for acceptability of controls was followed by the laboratory personnel for 15 of 114 patient testing days. Findings: 1. Review of the Liquichek Immunoassay Plus Control package insert showed QC ranges for vitamin B12 level one, lot number 85331 as 163 - 303 pg/mL. 2. Interview with testing personnel #1 confirmed that the laboratory uses Liquichek Immunoassay Plus Control package insert QC ranges for vitamin B12. 3. Review of the LIS Total QC module for the Tosoh AIA- 900 chemistry analyzer showed QC ranges for vitamin B12 level one, lot number 85331 as 153.2 - 376.4 pg/mL. 4. Interview with the TC #2 on August 11, 2021 at 10:30 AM confirmed the laboratory failed to ensure the established criteria for acceptability of controls was followed by the laboratory personnel.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on lack of hematology records and interview with the technical consultant (TC) #2, the laboratory failed to document the quality of staining materials each day of use for manual differentials for 2019, 2020 and to date August 11, 2021. Findings: 1. Lack of hematology records showed the laboratory failed to document the quality of staining materials each day of use for manual differentials. 2. Interview with TC #2 on August 11, 2021 at 9:00 AM confirmed the laboratory failed to document the quality of the manual differential stain each day of use.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of laboratory procedures, review of laboratory records and interview with the laboratory manager, the laboratory failed to develop a procedure to monitor, evaluate and define acceptable limits for white blood cell counts (WBC) using two different methodologies two times a year. Findings: 1. Observation of the laboratory revealed a Sysmex X1000i for performing automatic WBC differentials and an area for staining, counting and performing WBC manual differentials. 2. Review of the proficiency results showed a lack of enrollment for the secondary method for WBC manual differentials. Review of the laboratory records revealed a lack of documentation to define and evaluate the relationship between automatic and manual WBC differentials two times a year. 3. Interview with the laboratory manager on August 11, 2021 at 11:30 AM, confirmed testing personnel perform manual differentials. Interview also confirmed the laboratory is not enrolled in proficiency testing for manual WBC differentials and failed to define a relationship between the primary method of automatic differentials and the secondary method of manual WBC differential counts two times a year.
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 review of personnel records, the laboratory's policy "Responsibilities of Laboratory Medical Director", competency evaluations, quality control (QC) records and interview with the laboratory manager, the laboratory director (LD) failed to

	delegate the responsibilities of the technical consultant to personnel meeting the qualifications of technical consultant from April 2019 to May 2021. Findings: 1. Review of personnel records showed that the laboratory did not have a qualified technical consultant on staff from April 2019 to May 2021. 2. Review of the policy "Responsibilities of Laboratory Medical Director" states "Personnel- Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory." 3. Review of competency evaluations showed the laboratory failed to have a qualified technical consultant perform competency evaluations for nine of eleven testing personnel in 2019, 2020 and to May 2021. 4. Review of QC records showed the the laboratory failed to have a qualified technical consultant to review, monitor, and address QC problems from April 2019 to May 2021. 5. Interview with the laboratory manager on August 11, 2021 at 10:30 AM confirmed the laboratory director (LD) failed to delegate the responsibilities of the technical consultant to personnel meeting the qualifications of technical consultant from April 2019 to May 2021.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy "Responsibilities of Laboratory Medical Director", and interview with the laboratory manager, the laboratory director failed to specify, in writing, the responsibilities and duties of the technical consultant engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing and failed to specifically delegate to qualified staff the competency evaluation responsibility. Findings: 1. Review of the laboratory's policy "Responsibilities of Laboratory Medical Director" showed that there was no delegation of competency evaluation to the technical consultants. 2. Interview with the laboratory manager on August 11, 2021 at 10:00 A.M. confirmed that the laboratory director failed to specifically delegate to qualified staff the competency evaluation responsibility.
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 personnel records and interview with the laboratory manager, the

	laboratory did not have academic credentials required to qualify one of two technical consultants that provides technical oversight for moderate complexity testing. (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 personnel records and interview with the laboratory manager, the laboratory failed to have documentation of academic credentials to qualify one of two technical consultants that provide technical oversight for moderate complexity testing from April 2019 to date August 11, 2021. Findings: 1. Review of the personnel records for technical consultant #1 showed no academic credentials to qualify the technical consultant. 2. Interview with the laboratory manager on August 11, 2021 at 10:30 AM confirmed, the laboratory failed to have the required documentation to qualify technical consultant #1.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413

	The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the "Form CMS-209" and interview with the laboratory manager, the laboratory failed to ensure a technical consultant (TC) was responsible for technical and scientific oversight of the laboratory for 21 of 26 months. Findings: 1. Review of the "CMS-209" showed no qualified TC from April 2019 to May 2021. 2. Interview with the laboratory manager on August 11, 2021 at 11:30 AM confirmed the laboratory failed to ensure a TC was responsible for the technical and scientific oversight of the laboratory.
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 review of "Quality Control" procedure, Tosoh AIA 900 quality control (QC), Tosoh AIA 900 Unity peer review, Dimension EXL Unity peer review, and interview with the laboratory manager, the technical consultant (TC) failed to ensure acceptable levels of analytic performance were maintained. Findings: 1. Review of "Quality Control" procedure states "All quality control records should be reviewed and assessed at least monthly by the appropriate personnel". 2. Review of Tosoh AIA 900 QC showed vitamin B12 QC level 1 was not within acceptable limits for 14 days in 2021, 277 patient test results were reported with no documentation of TC review. 3. Review of Tosoh AIA 900 Unity peer review showed no documentation of TC review for: November 2020 Unity report stated ferritin level 1 and level 3 "Warning: Acceptable values are above -2 below 2". December 2020 Unity report stated ferritin level 1 and level 3 "Warning : Acceptable values are above -2 below 2". December 2020 Unity report stated vitamin B12 level 3 "Data exclusion lab CV=65.46%. Acceptable values are 0-23%". 4. Review of Siemens Dimension EXL Unity peer review showed no documentation of TC review for: November 2020 Unity report stated creatinine level 3 "Warning: Acceptable values are above -2 and below 2". June 2021 Unity report stated "ALT level 3 Data exclusion: Lab CV=18.55%. Acceptable values are 0 to 18%". 5. Interview with the laboratory manager on August 11, 2021 at 11:30 AM confirmed the TC failed to ensure acceptable levels of analytic performance were maintained.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.

	This CONDITION is not met as evidenced by: Based on review of personnel records, and interview with the laboratory manager, the laboratory failed to provide academic qualifications required to perform moderate complexity testing for two of eleven testing personnel. (Refer to D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of academic credentials and interview with the laboratory manager, the laboratory failed to provide academic credentials to qualify two of eleven testing personnel (TP). Findings: 1. The laboratory could not provide academic credentials to show TP #6 and TP #9 were qualified to perform moderate complexity testing. 2. Interview with the laboratory manager on August 11, 2021 at 10:00 AM confirmed the laboratory failed to provide academic credentials for two TP.