Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2149001	11/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Fernandez Community Center	8376 Six Forks Road, Suite 104, Raleigh, NC	

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	A scheduled initial survey was conducted 11/13/20 at Fernandez Community Center. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Clinical Laboratories. The laboratory performs urine drug screen testing on the ThermoFisher Indiko Plus analyzer for the following 10 analytes: Heroin Metabolite, Amphetamine, Benzodiazepine, Buprenorphine, Cocaine, Ethanol, Hydrocodone, Methadone, Oxycodone and Cannabinoids (THC). The laboratory's estimated annual test volume per year is 10,400, as stated on the Center for Medicare & Medicaid Services (CMS)-116 form submitted at time of survey. Total number of patients tested since June 2018 until time of survey is approximately 3,510. Based on survey findings, an Immediate Jeopardy situation was identified. The laboratory was notified at approximately 1:30 p.m. 11/13/20. The laboratory director/technical consultant failed to provide overall management and direction to the laboratory for the toxicology testing performed. The following Conditions were not met: D5022-Toxicology 493.1213 D6000-Laboratories performing moderate complexity testing; laboratory director 493.1403 D6063-Laboratories performing moderate complexity testing; testing personnel 493.1421
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory performance specification records and interview with testing personnel (TP) #1 11/13/20, the laboratory failed to retain the raw data used to determine the validation of performance specifications for the Indiko Plus analyzer. Findings: Review of performance specification records revealed EP Evaluator Graphs were used to demonstrate precision, accuracy and linearity for each of the analytes

	tested on the Indiko Plus analyzer. The records failed to include the raw data used to create the EP Evaluator Graphs. Interview with TP #1 at approximately 12:00 p.m. confirmed the laboratory had not retained the raw data. He stated the performance specification testing was performed by the ThermoFisher representative and he was unsure where it would be.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records, and interviews with TP #1 11/13/20, the laboratory failed to meet all specified requirements for the performance of toxicology testing on the Indiko Plus analyzer. Findings: 1. The laboratory failed to verify the accuracy of all testing performed on the Indiko Plus toxicology analyzer at least twice annually since June 2018, a period of approximately 29 months in which verification of accuracy was not performed. See D5217. 2. The laboratory failed to have complete and current procedures for the testing performed on the Indiko Plus analyzer. See D5403. 3. The laboratory failed to monitor and document the conditions essential for proper storage of reagents, calibrators, controls and patient specimens and failed to monitor and document conditions essential for accurate and reliable testing on the Indiko Plus analyzer since June 2018, a period of approximately 29 months in which patient testing was performed. See D5413. 4. The laboratory failed to verify the precision of the Indiko Plus analyzer and failed to verify the LIS LabTrak accurately receives and transmits data as established by the manufacturer before beginning patient testing in June of 2018. See D5421. 5. The laboratory failed to document required maintenance for the Indiko Plus analyzer and failed to perform maintenance of the LIS LabTrak since June 2018, a period of approximately 29 months in which patient testing was performed. See D5429.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, lack of verification of accuracy records and interview with TP #1 11/13/20, the laboratory failed to verify the accuracy of all testing performed on the Indiko Plus toxicology analyzer at least twice annually since June 2018, a period of approximately 29 months in which verification of accuracy was not performed. Findings: Review of laboratory procedure, "External Monitoring Program", revealed "External quality assurance procedures are used to compare the performance between different laboratories and are important for maintaining the long-term accuracy of analytical methods...If available, the laboratory must participate in external programs..." The procedure then explains how results should be processed and evaluated. Review of laboratory procedure, "Quality Assessment Program", under section "Proficiency Proformance Evaluations" revealed "The laboratory tests that are

	not CLIA regulated for PT purposes and therefore are tested twice per year by a scientifically defensible means to verify accuracy." Review of laboratory procedure, "Quality Improvement Plan", under section "Department Specific Process: Toxicology" revealed "2. API Quality Improvement Programs: The Toxicology department participates in the API PT program and inter-laboratory blind sample comparison with a CLIA/COLA accredited laboratory." Review of laboratory records revealed no documentation the laboratory participated in an "external monitoring program", the API PT program or an "inter-laboratory blind sample comparison" to verify the accuracy of testing performed on the Indiko Plus analyzer. Interview with TP #1 at approximately 1:00 p.m. confirmed the laboratory had not participated in any "external monitoring program" to verify the accuracy of testing performed. He stated he did not realize the laboratory needed to do this.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of laboratory records and interview with TP#1 11/13/20, the laboratory failed to have complete and current procedures for the testing performed on the Indkio Plus analyzer. Findings: 1. The laboratory has multiple verification of accuracy procedures and it is unclear which method the laboratory will use to determine the accuracy of testing performed. For example: The laboratory procedure "External Monitoring Program" states, "External quality assurance procedures are used to compare the performance between different laboratories and are important for maintaining the long-term accuracy of analytical methods...If available, the laboratory must participate in external programs..." The procedure fails to state what "external program" the laboratory has determined to participate in. The laboratory procedure "Quality Assessment Program" under section "Proficiency Proformance Evaluations" states, "The laboratory tests that are not CLIA regulated for PT purposes and therefore are tested twice per year by a scientifically defensible means to verify accuracy." The procedure fails to state what "scientifically defensible means" the laboratory has determined to use for accuracy verification. The laboratory procedure, "Quality Improvement Plan" under section "Department Specific Process: Toxicology" states "2. API Quality Improvement Programs: The

	Toxicology department participates in the API PT program and inter-laboratory blind sample comparison with a CLIA/COLA accredited laboratory." Review of laboratory records revealed the laboratory has not performed a verification of accuracy since testing began in June 2018. See D5217. 2. The laboratory procedures for quality control (QC) are incomplete and fail to include the type and level of QC reagents used for each analyte tested on the Indiko Plus analyzer. For example: The laboratory procedure "Quality Control" under section "Scope" states "This procedure will outline the content of the QC monitoring system that are to be written specifically for each test system." The procedure than explains how a laboratory QC monitoring system should be developed. The laboratory procedure for analyte Ethyl Alcohol states "Refer to Indiko Plus laboratory procedures provided for Quality Control". The laboratory procedure for analyte Amphetamine states "For Calibration, QC and Patient testing refer to Indiko Plus Calibration, QC and Patient Testing Protocol." The laboratory procedure "Indiko Start-Up, Calibration and QC Procedure" includes the frequency of QC and the criteria used to determine if QC is acceptable, but fails to include the type and level of QC reagents used. 3. The laboratory procedures for calibration are incomplete and fail to include the type and level of calibration reagents used for each analyte tested on the Indiko Plus analyzer. For example: The laboratory procedure for analyte Ethyl Alcohol states "Refer to Indiko Plus laboratory procedures provided for Calibration and Calibration verification of each analyte." The laboratory procedure for analyte Amphetamine states "For Calibration, QC and Patient testing refer to Indiko Plus Calibration, QC and Patient Testing Protocol." The laboratory procedure "Indiko Start-Up, Calibration and QC Procedure" includes the frequency of calibration and the criteria used to determine if calibration is acceptable, but fails to include the type and level of calibration reagents used.
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 laboratory procedure manual, surveyor observation, lack of temperature and humidity records and interview with TP #1 11/13/20, the laboratory failed to monitor and document the conditions essential for proper storage of reagents, calibrators, controls and patient specimens and failed to monitor and document conditions essential for accurate and reliable testing on the Indiko Plus analyzer since June 2018, a period of approximately 29 months in which patient testing was performed. Findings: Review of laboratory procedure "Temperature/Humidity Monitoring and Refrigerator/Freezer Maintenance" revealed "Monitor temperatures on a regular basis to ensure the integrity of reagents, calibrators, controls and patient samples and maintain temperature and humidity control in the laboratory...A. Use: Place electronic traceable thermometer on refrigerator and place ends in refrigerator and freezer. Place Room Temperature Thermometer with Humidity reader in the laboratory to be monitored....B. Refrigerator and Freezers: a. Monitor the temperatures of refrigerators and freezers daily or when samples are processed....C.

	Room Temperature and Humidity: Room temperature and humidity is monitored daily or on the days specimens are processed...Document on log sheet in Maintenance Log Binder." During laboratory tour at approximately 10:30 a.m., the surveyor observed analyzer reagents, including quality control reagents and calibration reagents stored in a white refrigerator in the testing area of the laboratory. The surveyor also observed no thermometer was present in the refrigerator and no thermometer was present in the testing area of the laboratory. Review of laboratory records revealed no documentation of refrigerator and freezer temperature recordings and no documentation of room temperature and humidity recordings since patient testing began in June of 2018. Interview with TP #1 at approximately 10:30 a.m. confirmed the laboratory did not have thermometers in the refrigerator, freezer and testing room area. He also confirmed the laboratory had not been monitoring and documenting the refrigerator, freezer or room temperature and room humidity since testing began in June of 2018. He stated he did not realize they needed to be monitoring and documenting the temperatures and humidity. When asked if patient specimens were stored in the refrigerator he stated that sometimes they are because he usually runs the analyzer only once a week.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory performance verification records for the Indiko Plus analyzer, lack of performance verification records for the Laboratory Information System (LIS) LabTrak and interview with TP #1 11/13/20, the laboratory failed to verify the precision of the Indiko Plus analyzer and failed to verify the LIS LabTrak accurately receives and transmits data as established by the manufacturer before beginning patient testing in June of 2018. 1. The laboratory failed to verify the precision of the testing performed on the Indiko Plus analyzer by demonstrating an assessment of day-to-day, run-to-run, and within-run variations, as well as operator variance. Findings: Review of laboratory performance verification records for the analyzer revealed all precision verification runs were completed by the ThermoFisher representative and failed to demonstrate operator variance. It was unclear, due to missing raw data, if the assessment included day-to-day, run-to-run, and within-run variations. Interview with TP #1 at approximately 1:00 p.m. confirmed the performance verification was performed by the ThermoFisher representative only. He was unsure if it included all the variations needed to demonstrate precision. 2. The laboratory failed to verify the LIS LabTrak accurately receives and transmits data as established by manufacturer. Findings: Review of laboratory records revealed no documentation to verify the LIS LabTrak accurately received and transmitted data as established by the manufacturer. Interview with TP#1 at approximately 1:00 p.m. confirmed the laboratory had not verified the accuracy of the LIS LabTrak. He stated he was not aware it needed to be done.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, lack of laboratory maintenance records and interview with TP #1 11/13/20, the laboratory failed to document required maintenance for the Indiko Plus analyzer and failed to perform maintenance of the LIS LabTrak since June 2018, a period of approximately 29 months in which patient testing was performed. 1. The laboratory failed to document required maintenance for the Indiko Plus analyzer. Review of laboratory procedure, "Indiko Daily, Weekly, Monthly Maintenance", revealed "Scope...Regular Daily, Weekly and Monthly maintenance is required by manufacturer. Procedure...each task is marked off on the Indiko Plus Maintenance Checklist." Review of laboratory records revealed one blank copy of the "Indiko Plus Maintenance Checklist", there was no documentation that maintenance had been performed as required since June of 2018. Interview with TP #1 at approximately 12:30 p.m. confirmed the laboratory had not documented the required maintenance for the analyzer. He stated he performs the maintenance, but did not realize he had to document it. 2. The laboratory failed to perform required maintenance of the LIS LabTrak. Review of laboratory procedure, "Laboratory Information Semi-Annual Accuracy Review", revealed "2. Procedure...a. Review five patient orders, tests and results and complete the following items on the WORKSHEET...2. All No responses require remedial corrective actions...". Review of laboratory records revealed one blank copy of the "LIS WORKSHEET", there was no documentation that maintenance had been performed semi-annually as required since June 2018. Interview with TP #1 at approximately 12:30 p.m. confirmed the laboratory had not performed a semi-annual accuracy of the LIS. He stated he did not realize they needed to do this.
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 review of laboratory procedures, review of laboratory records and interview with TP #1 11/13/20, the laboratory director (LD) failed to provide overall management and direction for the laboratory services provided. Findings: The laboratory performs urine drug screen testing for the following 10 analytes: Heroin Metabolite, Amphetamine, Benzodiazepine, Buprenorphine, Cocaine, Ethanol, Hydrocodone, Methadone, Oxycodone and Cannabinoid (THC), on the Thermo Fisher Indiko Plus analyzer. The laboratory's estimated annual test volume per year is 10,400, as stated on the CMS-116 submitted at time of survey. Total number of patients tested since June 2018 until time of survey is approximately 3,510. 1. The LD failed to ensure verification procedures were established and adequate to verify the accuracy of testing performed on the Indiko Plus toxicology analyzer. See D6013. 2.

	The LD failed to implement and maintain the laboratory's QA program to ensure the quality of the laboratory services provided. See D6021. 3. The LD failed to ensure the maintenance of acceptable levels of analytical performance for the testing performed on the Indiko Plus analyzer and the LIS LabTrak. See D6023. 4. The LD failed to review and approve the laboratory procedure manual before patient testing began in June 2018. See D6031. 5. The LD failed to evaluate the competency of 1 of 1 testing personnel at least semi-annually during the first year and at least annually thereafter since June of 2018. See D6046. 6. The LD failed to verify that TP#1 met the minimum education requirements for moderate complexity testing. See D6065.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with TP #1 11/13/20, the LD failed to ensure verification procedures were established and adequate to verify the accuracy of testing performed on the Indiko Plus toxicology analyzer. Findings: The LD failed to establish a performance verification procedure required to determine the biannual accuracy of the testing performed on the Indiko Plus analyzer by either defining the performance verification procedure or by enrolling in a proficiency testing program. See D5217.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) procedures, lack of QA records, review of quality control (QC) and calibration records and interview with TP#1 11/13/20, the LD failed to implement and maintain the laboratory's QA program to ensure the quality of the laboratory services provided. Findings: Review of procedure "Quality Assessment Program" revealed under section "Procedure...The quality assessment (QA) program monitors and evaluates the quality of services the Laboratory provides. The laboratory director oversees the implementation of our plan and helps identify, then correct problems as they occur..." Under section "QUALITY ASSESSMENT ACTIVITIES...The laboratory director is responsible for the overall operation of the laboratory..." Under section "QUALITY CONTROL...For tests that produce a

	qualitative result, QC results are routinely reviewed by the Technical Supervisor and /or Director to identify failures and unacceptable results...Calibrations are reviewed to ensure they were performed at the appropriate frequencies and are acceptable." Under section "RECORD RETENTION...All monthly QC reviews are performed by the Technical Supervisor or Laboratory Director and include initials or signatures to verify the review. Reviews are performed in a timely manner....QA is monitored monthly: Please see QA calendar" Review of QA records revealed monthly QA checklists. The checklists included various QA tasks, for example: "Quality Assurance...Laboratory Director and staff have signed off on last month's QA review... Quality control...Required controls, calibrations and maintenance have been performed...Controls, calibrations and maintenance documents have been reviewed...". No monthly QC checklist had been completed or signed off by the LD or the staff since testing began in June 2018. Review of QC and calibration records revealed no signatures or dates to indicate routine review by the LD as stated in the "Quality Assessment Program" procedure. Interview with TP #1 at approximately 1: 30 confirmed QA had not been performed and also confirmed the LD had not reviewed QC and calibration records since patient testing began in June 2018. He stated he (TP#1), reviews the QC and calibrations when he performs the testing. He also stated he was unaware of the QA program and did not realize the LD need to perform reviews.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with TP #1 11/13/20, the LD failed to ensure the maintenance of acceptable levels of analytical performance for the testing performed on the Indiko Plus analyzer and the LIS LabTrak. Findings: 1. The LD failed to ensure biannual verifications were performed to verify the accuracy of the testing performed on the Indiko Plus analyzer. See D5217. 2. The LD failed to ensure acceptable temperature and humidity ranges were monitored and documented for the performance of testing on the Indiko Plus analyzer. See D5413. 3. The LD failed to ensure the precision verification of the Indiko Plus analyzer was adequate before performing patient testing. See D5421. 4. The LD failed to ensure the LIS LabTrak accurately received and transmitted data before performing patient testing. See D5421. 5. The LD failed to ensure the maintenance of the Indiko Plus anaylzer and the LIS LabTrak were performed and documented as required. See D5429.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of quality assessment procedure, review of laboratory procedure manual, and interview with TP #1 11/13/20, the LD failed to review and approve the laboratory procedure manual before patient testing began in June 2018. Findings: Review of procedure "Quality Assessment Program" revealed under section "Quality Control", "A director approved procedure manual is readily available at all times of testing to the laboratory staff." Review of laboratory procedure manual revealed all procedures included the "Document Author" signature, but failed to include the LD's signature indicating his review and approval of the procedures. Interview with TP #1 at approximately 1:00 p.m. confirmed the LD had not signed the procedures. He stated he thought they had been reviewed by the LD, and that he must have forgotten to sign them.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of personnel records and interview with TP #1 11/13/20, the technical consultant (laboratory director) failed to evaluate the competency of 1 of 1 testing personnel at least semi-annually during the first year and at least annually thereafter since June of 2018, a period of approximately 29 months. Findings: Review of laboratory procedure "Competency Assessment" revealed under section "Responsible Personnel:...Ultimately, it is the Laboratory Directors responsibility to ensure that all testing personnel are competent and maintain their competency in order to perform and report accurate and reliable test results." Review of laboratory procedure "Competency Assessment" revealed under section "How often should competency assessment be performed?...Evaluating and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual tests patient specimens. Thereafter, competency assessment must be performed at least annually." Review of personnel records for TP #1 revealed a training certificate from Thermo Scientific for the Indkio Plus analyzer. There was no documentation of competency assessments since TP#1 began testing in June of 2018. Interview with TP #1 at approximately 11:00 a.m. confirmed no competency assessments were completed since he began testing. He stated he was unaware that competency assessments were required.
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 TP #1 11/13/20, the laboratory failed to verify that 1 of 1 testing personnel met the minimum education requirements for moderate complexity testing. Findings: See 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 personnel records, and interview with TP #1 11/13/20, the laboratory failed to verify that TP#1 met the minimum education requirements for moderate complexity testing. Findings: Review of personnel records for TP #1 revealed a diploma that was obtained outside the United States. The personnel records did not include an evaluation by a nationally recognized organization to determine equivalency of the education to education obtained in the United States. During interview with TP #1 at approximately 11:00 a.m. he confirmed that he did not have an equivalency evaluation for the diploma and asked to be given names of organizations in which to obtain one.