Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0710715	01/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Spectracell Laboratories Inc	6030 North Course Dr, Houston, TX	

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	The laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems. Noted deficiencies and plans of correction were discussed with the laboratory representative (s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists proficiency testing (PT) records from 2020 and 2021 and staff interview it was revealed that the

	laboratory failed to retain all proficiency testing records for the required minimum of two years for 1 of 6 General Chemistry/Therapeutic Drugs events reviewed. Findings included: 1. A review of the laboratory's College of American Pathologists PT records for General Chemistry/Therapeutic Drugs (there are three events per year) from 2020 and 2021 revealed that for 1 of the 6 events (Event C-B 2020) the attestation, original forms and test records were not available for review. 2. In an interview on 01/11/2022 at 1310 hours in the conference room the Technical Supervisor, after his own review of the records, confirmed the findings.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on a review of the manufacturer's instructions, laboratory and patient test records from 2020, 2021, and 2022, and staff interview, it was revealed that the laboratory failed to report 347 positive and negative SARS-CoV-2 antibody test results as required by 42 CFR 493.41 and 493.1100(a) for 15 of 15 months reviewed from 10/1/20 to 1/10/22. Findings include: 1. Review of the Instructions for Use for the Megna Health Rapid COVID-19 IgM/IgG Combo Test Kit (Ver 2.02) and the Healgen COVID-19 IgG/IgM Rapid Test Cassette (B21901-01, 6/2020) revealed the following: "Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities." 2. Review of the laboratory test records from 2020, 2021, and 2022 revealed the laboratory started SARS-CoV-2 IgG/IgM antibody patient testing using the Megna Health Rapid COVID-19 IgM/IgG Combo Test Kit and the Healgen COVID-19 IgG/IgM Rapid Test Cassette on 5/18/20. 3. Review of the laboratory policies available revealed no documentation of a policy/procedure related to SARS-CoV-2 test reporting. 4. Review of the laboratory SARS-CoV-2 IgG/IgM antibody patient test records from 2020, 2021, and 2022 revealed no documentation the laboratory reported 347 of 347 positive and negative patient test records for 15 of 15 months of testing. Refer to Covid Antibody Patient Alias list. 5. An interview with the technical supervisor (as indicated on the CMS 209 form) on 1/10/22 at 1:30 p.m. in his office, confirmed the above findings.
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 surveyor's observations, review of the laboratory's Chemistry Refrigerator temperature logs for 2020 and 2021, review of CMS Form 116 and staff interview it was determined the laboratory failed to retain records of chemistry refrigerator temperature monitoring for 4 of 24 months reviewed. Findings included: 1. Surveyor's observations on 01/11/2022 at 1300 hours in the laboratory revealed the following chemistry reagents were stored in the Chemistry Refrigerator (2-8C): Secure N-geneous LDL-ST Cholesterol Reagent (R2) Lot 56827; Expiration 2022-02-03 Storage requirement: 2-8C Secure N-geneous LDL-ST Cholesterol Calibrator Lot 60663; Expiration 2023-07-25 Storage requirement: 2-8C K-Assay hsCRP Calibrator Lot 1210; Expiration 2022-10-12 Storage requirement: 2-8C K-Assay hsCRP Immunoturbidimetric Assay Lot 1210; Expiration 2022-10-02 Storage requirement: 2-8C MAS Liquimmune Controls (1, 2 and 3) Lot LIA2409 (1A,2A,3A); Expiration 2024-09-30 Storage requirement: 2-8C BIO-RAD Liquicheck Lipids Controls 1 and 2 (opened) Lot 57611 and 67612; Expiration 2023-10-31 Storage requirement: 2-8C K-Assay Apo A1 Immunoturbidimetric Assay Lot K154; Expiration 2023-03-31 Storage requirement: 2-8C K-Assay Insulin (L) Immunoturbidimetric Assay Lot UH300; Expiration 2022-09-15 Storage requirement: 2-8C 2. Review of the laboratory's temperature logs for the Chemistry Refrigerator for 2020 and 2021 revealed there were no records of temperature documentation for the chemistry refrigerator available for review for the following 4 of 24 months reviewed: July 2020 August 2020 September 2020 October 2020 3. Review of the CMS Form 116 submitted by the laboratory at time of the survey revealed the laboratory performed 46,395 chemistry tests annually. 4. In an interview on 01/11/2022 at 13:15 hours in the conference room the Technical Supervisor confirmed the unavailability of the temperature logs for the above months.
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 a review of the laboratory's records from May 2020 to December 2021, and staff interview, it was revealed that the laboratory failed to have documentation of four of four accuracy assessments for 2020 and 2021 for two rapid COVID-19 IgG /IgM antibody testing kits. Findings include: 1. A review of the laboratory's test records revealed the laboratory started COVID-19 IgG/IgM rapid antibody testing using the the two testing kits: Megna Health Rapid COVID-19 IgM/IgG Combo Test Kit and the Healgen COVID-19 IgG/IgM Rapid Test Cassette in May 2020. 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of the twice annual accuracy assessments in 2020 and 2021 for COVID-19 IgG/IgM rapid antibody testing using the two testing kits: Megna Health Rapid COVID-19 IgM/IgG Combo Test Kit and the Healgen COVID-19 IgG/IgM Rapid Test Cassette. 3. An interview with the technical supervisor (as indicated on the CMS 209 form) on 1/10/22 at 1:30 p.m. in the conference room, after review of the records, confirmed the above findings.
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 the manufacturer's instructions, review of patient records, review of instruments' maintenance, quality control (QC) and calibration documents, and staff interview, it was determined the laboratory failed to meet analytic systems requirements. Findings included: 1. The laboratory failed to ensure its policies were followed for Apolipoprotein A1 (APO A1) QC (refer to D5401). 2. The laboratory failed to have documentation of the laboratory director signing and approving one of one procedure for COVID-19 IgG/IgM antibody testing (refer to D5407). 3. The laboratory failed to ensure weekly/quarterly/6 months maintenance for the Beckman Coulter AU680 chemistry analyzer was performed according to requirements (refer to D5429). 4. The laboratory failed to ensure that calibration verification for Cholesterol, Triglycerides, High-density lipoprotein and Low-density lipoprotein was performed on the Beckman Coulter AU680 chemistry analyzer every 6 months (refer to D5439). 5. The laboratory failed to ensure corrective actions for out of limit temperatures for storage of Lipoprotein Particle Profile (LPP) calibrator were documented (refer to D5785). 6. The laboratory failed to ensure Quality Assurance assessments identified and corrected issues with the Beckman Coulter AU680 chemistry analyzer' maintenance, QC and calibration (refer to D5791).
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 the laboratory's policies, review of quality control (QC) records for October to November of 2021, review of random patient's Apolipoprotein results for 11/18/2021 and staff interview it was determined the laboratory failed to follow its own policy for using three levels for Apolipoprotein A1 (APO A1) QC reagents for 15 of 15 days QC was performed. Findings included: 1. Review of the laboratory's policy titled Apolipoprotein A1 (APO A1) - revised 01/10/2018 - under section for Quality Control (page 4) revealed: "Three levels of control material should be analyzed daily." 2. Review of the QC records for APO A1 for October to November of 2021 revealed only 2 levels of controls were documented on the following days QC was performed: 10/05/2021 10/27/2021 10/07/2021 10/28/2021 10/08/2021 11/04/2021 10/12/2021 11/11/2021 10/14/2021 11/17/2021 10/19/2021 11/18/2021 10/20/2021 11/23/2021 10/21/2021 3. Review of random patient results for 11/18/2021 revealed the following patient's samples were tested for Apolipoprotein A1: 2132200082 2132200102 2132200111 2132200093 2132200086 2132300067 2104100093 4. In an interview on

	01/11/2022 at 1030 hours in the conference room the Technical Supervisor stated that the laboratory used only 2 levels of controls for APO A1 QC. This confirmed the findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and staff interview, it was revealed that the laboratory failed to have documentation of the laboratory director signing and approving one of one procedure for COVID-19 IgG/IgM antibody testing. Findings include: 1. A review of the laboratory's policies revealed the laboratory failed to have documentation of the laboratory director signing and approving the COVID-19 IgG /IgM Rapid Test Cassette procedure. 2. An interview with the technical supervisor (as indicated on the CMS 209 form) on 1/10/22 at 1:450 p.m. in the conference room, after review of the records, confirmed the above findings.
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 Beckman Coulter AU680 chemistry analyzer's maintenance logs for 2020 and 2021, review of CMS Form 116 and staff interview it was determined the laboratory failed to document all required weekly, quarterly and every 6 months maintenance. Note: This is a repeat deficiency from the survey conducted on 01/10 /2020. Findings included: 1. Review of Beckman Coulter AU680 chemistry analyzer's maintenance logs for 2020 and 2021 revealed the following maintenance was required to be performed: a. Weekly: Clean the sample bar and mix bars Perform W2 Perform Photocal Clean the pre-dilution bottle b. Quarterly: Clean air filters Inspect and if needed, replace the DI water filter and sample probe filter Replace the wash solution roller pump tubing c. Every 6 months: Replace photometer lamp Clean the cuvettes and the cuvette wheel 2. Review of the Beckman Coulter AU680 analyzer's maintenance logs for 2020 and 2021 revealed: a. None of the weekly maintenance components were documented as performed for the following weeks: Week of 09/29 /2020 to 10/05/2020 Week of 10/27/2020 to 11/02/2020 Week of 11/21/2021 to 11/27 /2021 b. No documentation of quarterly maintenance was found for the last quarter of 2020. Quarterly maintenance was documented on 08/03/2020 with the next documentation on 03/09/2021 (an interval of 7 months). c. Every 6 months maintenance was documented as follows: 02/13/2020 - all components completed 04 /30/2020 - missing documentation of replacement of photometer lamp 08/03/2020 - missing documentation of replacement of photometer lamp 03/09/2021 - all components completed (13 months interval from last complete maintenance documentation) 3. Review of the CMS Form 116 submitted by the laboratory at time of the survey revealed the laboratory performed 46,395 chemistry tests annually. 4. In

	an interview on 01/11/2022 at 1545 hours in the conference room the Technical Supervisor after viewing the analyzer's maintenance logs confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's Beckman Coulter AU680 chemistry analyzer's calibration and calibration verification records for 2020 and 2021, review of a random sampling of patient test results for November of 2021 and staff interview it was determined the laboratory failed to have documentation of performing calibration verification every six months for 4 of 10 analytes tested on the instrument. Note: This is a repeat deficiency from the survey conducted on 01/10/2020. Findings included: 1. Review of the laboratory's Beckman Coulter AU680 chemistry analyzer's quality control and calibration records for 2020 and 2021 revealed the laboratory performed two levels of chemistry controls daily, and calibration was performed using one calibrator for 4 of 10 analytes: Cholesterol, Triglycerides, High-density lipoprotein (HDL) and Low-density lipoprotein (LDL). Therefore, calibration verification was required every six months for those analytes. 2. Review of the Beckman Coulter AU680 analyzer's calibration verification records for 2020 and 2021 for the above analytes revealed calibration verification was documented as follows: Cholesterol: 02 /27/2020 (Lot H392506) 10/06/2020 (Lot H392506) - elapsed time from last calibration verification: 7 months 07/06/2021 (Lot F410606) - elapsed time from last calibration verification: 9 months 12/02/2021 (Lot F410606) - elapsed time from last calibration verification: 6 months Triglycerides: 02/27/2020 (Lot K392206) 10/06 /2020 (Lot K392206) - elapsed time from last calibration verification: 7 months 07/06 /2021 (Lot P402906) - elapsed time from last calibration verification: 9 months 12/02 /2021 (Lot P402906) - elapsed time from last calibration verification: 6 months HDL: 02/27/2020 (Lot A392807) 12/16/2020 (Lot L402807) - elapsed time from last calibration verification: 10 months 12/02/2021 (Lot L402807) - elapsed time from last calibration verification: 12 months LDL: 02/27/2020 (Lot A392807) 12/16/2020 (Lot L402807) - elapsed time from last calibration verification: 10 months 12/02/2021 (Lot

	L402807) - elapsed time from last calibration verification: 12 months 3. Review of a random sampling of patient test results for 11/21/2021 to 11/27/2021 revealed the following patient's samples were tested for HDL and LDL five months beyond the required six months calibration verification period: 2111180111 2111180114 2111180120 2111180138 2111180139 2111180140 2111180149 2111180126 2111180127 2111180128 2111180134 2111180136 4. In an interview on 01/11/2022 at 1415 hours in the conference room the Technical Supervisor stated that calibration verification was not performed on time due to shortage of supplies. This confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of the laboratory's Deep Freezer (-80C) temperature logs for July to December of 2021, review of laboratory's policies, review of test workload for Lipoprotein Particle Profile (LPP) for 2020 and 2021, and staff interview it was determined the laboratory failed to document corrective action for Deep Freezer (-80C) temperature out of laboratory defined range for 4 of 118 days reviewed. Findings included: 1. Surveyor's observations on 01/11/2021 at 1230 hours in the laboratory revealed the following Lipoprotein Particle Profile (LPP) calibrator aliquots stored in the Deep Freezer (-80C): Laboratory prepared LPP Calibrator C11 placed into use 09/18/2019 (no expiration date). 2. Review of the laboratory's Deep Freezer temperature logs revealed: a. The laboratory defined acceptable temperature range for the Deep Freezer (-80C) was -77C to -82C. b. There was no documentation of corrective action for out of range Deep Freezer (-80C) temperatures on the following days: 07/09/2021 - temperature: -72C 09/13/2021 - temperature: -76C 11/09 /2021 - temperature: -73C 12/01/2021 - temperature: -76C 3. Review of the laboratory's Lipoprotein Particle Profile (LPP) - last revised 03/11/2013 - under section Preparation of Calibrators (page 24) revealed: "Once the values are determined to be in proper range the pool should be aliquoted into microtubes of 90uL each. The microtubes should then be frozen and stored at -70C before use and should be treated in the same manner as purchased calibrator." Note: The laboratory did not define temperature acceptability range for deep freezer storage within the policy. 4. Review of the laboratory's test workload for Lipoprotein Particle Profile for 2020 and 2021 revealed the laboratory performed LLP testing as follows: 2020 Workload: LPP Basic - 255 tests LPP Plus - 4755 tests 2021 Workload: LPP Basic - 236 tests LPP Plus - 4089 tests 5. In an interview on 01/11/2022 at 1300 hours in the conference room Technical Supervisor, after reviewing the data, confirmed the findings.
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 the manufacturer's instructions, review of quality control, calibration and maintenance logs and staff interview it was determined the laboratory's Quality Assurance assessment failed to identify and correct issues with quality control, maintenance, calibration verification and corrective action documentation for the laboratory's equipment. Findings included: 1. The laboratory's quality assessment failed to ensure its quality control policies were followed for Apolipoprotein A1 (APO A1) (refer to D5401). 2. The laboratory's quality assessment failed to ensure maintenance for the Beckman Coulter AU680 chemistry analyzer was performed as required (refer to D5429). 3. The laboratory's quality assessment failed to ensure that the Beckman Coulter AU680 chemistry analyzer calibration verification for 4 of 10 analytes (Cholesterol, Triglycerides, High-density lipoprotein and Low-density lipoprotein) was performed every 6 months (refer to D5439). 4. The laboratory's quality assessment failed to ensure corrective actions for out of limit Deep Freezer (-80C) temperatures were documented (refer to D5785).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed that the laboratory director failed to ensure that four of four testing personnel had documentation of training for the rapid COVID-19 IgG/IgM testing (refer to D6066).
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, the laboratory's testing records, and staff interview, it was revealed that four of four testing personnel failed to have documentation of training for two COVID-19 IgG/IgM rapid test kits prior to performing patient testing in 2020. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 1/6/22) revealed the laboratory identified 4 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed that the following testing personnel had no documentation of training for the Megna Health Rapid COVID-19 IgM/IgG Combo Test Kit or the

	Healgen COVID-19 IgG/IgM Rapid Test Cassette: - Testing Person #2 - Testing Person #3 - Testing Person #4 - Testing Person #7 3. A review of the laboratory's testing records revealed the laboratory performed an estimated 347 COVID-19 IgG /IgM rapid tests starting in May 2020. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 1/10/22 at 1:45 p.m. in the conference room, after review of the records, confirmed the above findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quality control, calibration and maintenance logs for the Beckman Coulter AU680 chemistry analyzer and staff interview it was determined the Laboratory Director failed to ensure the laboratory's Quality Assurance assessments identified and corrected issues as they occurred (refer to D5429 and D5439).
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature check records for July to December of 2021 and staff interview it was determined the Laboratory Director failed to ensure all remedial actions for issues were taken and documented (refer to D5785).
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for 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 the laboratory's quality control, maintenance and temperature records and staff interview it was determined the Technical Supervisor failed to ensure laboratory's quality control plan was maintained (refer to D5401, D5429 and D5785).