Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0710715	11/02/2023
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	An unannounced revisit survey was performed on 12/29/2023. The laboratory remains out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The condition not met was: D5400- 42 C.F.R. 493.1250 Condition: Analytic Systems ********** An announced survey of the laboratory was conducted from 11/01/2023 through 11/02/2023. In addition, a complaint investigation was conducted alongside the recertification survey starting on 11/02/2023. The complaint was substantiated. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D5400- 42 C.F.R. 493.1250 Condition: Analytic Systems D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records, policies/procedures and staff interview the laboratory failed to document required attestation signatures for 1 of 24 PT records reviewed. Findings included: 1. Review of laboratory's PT records revealed the laboratory used College of American Pathologists (CAP) as its PT provider. CAP instructions included: "Attestation/Use of Other Form ... The laboratory director or designee and the testing personnel must sign on the result form. You must use the attestation form provided..." 2. Further review of the PT records for 2022 and 2023 revealed the laboratory director did not sign the attestation form for 1 of 24 reviewed PT events: Chemistry event C-C 2022 3. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place addressing

	PT attestation requirements. 4. In an interview on 11/01/2023 at 1500 hours in the office, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor's observations in the facility, review of policies/procedures and staff interview, the laboratory failed to ensure safety procedures were established and observed to ensure protection from physical and chemical hazards for three of three safety concerns observed, storage and disposal of chemicals, obsolete/discontinued equipment and/or patient related paperwork. Findings included: 1. Surveyors observations on 11/01/2023 at 0940 hours in the warehouse revealed 22 large 19-20L (Liter) canisters containing highly flammable materials (methanol [lot 23A1561008], acetone [lot unspecified], poured over into a methanol canister), hexanes [lot 165046]), stacked up to 4 high in an open area, propped up against a flammable cabinet, next to cardboard boxes and plastic bags strewn on the floor. Opened/empty canisters (some unstoppered) were intermixed with full ones. The canisters were not labeled full/empty. Upon investigation, the flammable cabinet behind the stacked canisters was found to be full of boxes containing various expired chemicals. Examples of found chemicals included ergocalciferol (no exp.[expiration], marked as poison), concanavalin A (exp.2009), magnesium sulfate (exp. 2015), L-methionine (exp. 2014), iron (II) sulfate heptahydrate (exp. 2014), thymidine (exp. 2017), bovine serum albumin (exp. 2016). Along with the boxes of expired chemicals gallon containers of vacuum pump oil and descaler were observed. In a separate area of the warehouse another two 19L canisters of methanol were found sitting on the floor in front of another flammable cabinet. A 1L bottle of denatured ethanol (lot FC 08053EC) was sitting on top of the cabinet. The cabinet was half empty. 2. Surveyor's observations on 11/01/2023 at 1010 hours in the Lipoprotein Particle Profile (LPP) centrifuge room revealed two tables next to the ultracentrifuges piled up with open cardboard boxes with patient requisitions from 2020 and 2021, closed cardboard boxes containing more paperwork, plastic crates filled with dusty unused paper holders and centrifuge parts, along open and closed dusty Styrofoam containers and old/unused reagent containers. A chemical spill kit was also found on top of the table. It was unclear if the kit was current or expired. Next to all this were found two new boxes of Eppendorf pipette tips currently used in LPP testing. Under the table an old, decommissioned Siemens analyzer was sitting on the floor. Disintegrating reagent boxes, still containing reagent contents, were attached to the instrument via tubing. Next to the instrument, spare parts, paper and reagent cardboard boxes were on the floor. The boxes had stains and tears on the bottom due to unknown cause. 3. Review of laboratory's policies and procedures revealed there were no safety protocols in place for storage and disposal of large quantities of flammable materials, expired chemicals/reagents, or decommissioned equipment. Laboratory's policies did not address separation of old versus in-use reagents or equipment to prevent cross contamination. Laboratory's policies did not address maintaining a clean environment, free of tripping, slipping or falling objects' hazards. Laboratory's policies did not address requirements for storage of patient related paperwork. 4. In an interview on 11

	/01/2023 at 1050 hours in the office, the laboratory's General supervisor and Technical Supervisor (as indicated on submitted form CMS 209), after touring the laboratory and warehouse, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
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 a review of the laboratory's quality control records for CBC (Complete Blood Count) testing on the Coulter ACT diff 2 hematology analyzers and staff interview, the laboratory failed to retain the following records: a) analyzer results for the daily quality control material analyzed from January 1, 2022 to April 27, 2022 for the two Coulter ACT diff 2 hematology analyzers b) Levy Jennings charts, evaluating quality control values over time, for the daily quality control material analyzed from January 1, 2023 to March 29, 2023 for the two Coulter ACT diff 2 hematology analyzers. Findings include: 1. A review of the laboratory's quality control records for CBC testing on the Coulter ACT diff 2 analyzers (serial numbers AU20394 and AW21329) revealed the laboratory failed to retain the following records: a) analyzer results for the daily quality control material analyzed from January 1, 2022 to April 27, 2022 for the two Coulter ACT diff 2 hematology analyzers b) Levy Jennings charts, evaluating quality control values over time, for the daily quality control material analyzed from January 1, 2023 to March 29, 2023 for the two Coulter ACT diff 2 hematology analyzers. 2. An interview with the general supervisor on 11/1/23 at 1355 hours in the conference room, after review of the records, confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 12/29/2023. D5209 - remains uncorrected. Based on review of the laboratory plans of correction with a completion date of 12/29 /2023, laboratory's personnel records, and staff interview the laboratory failed to follow its own plan of correction and document competency assessment for one of 15 personnel employed by the facility, the employee holding the title of General Supervisor (GS) and Technical Supervisor (TS). Findings included: 1. Review of the laboratory plans of correction with a completion date of 12/29/2023 revealed: "The LD /GS/QC will establish a Competency Assessment Policy for positions such as Technical Supervisor, General Supervisor, Clinical Consultant, and Technical Consultant. A spreadsheet will be created to keep track of the annual competency assessments ." And, "The LD will conduct yearly competency assessments to ensure that the laboratory stays in compliance." 2. Review of laboratory's personnel recoreds

	reveled the laboratory did not have documentation of annual competency assessment for the employee holding the title of GS and TS. 3. In an interview on 12/29/2023 at 1020 hours in the conference room, the laboratory's TS/GS (as indicated on submitted Form CMS 209), stated that the competency assessments for the TS and GS positions have not been completed, confirming the findings ********** Based on review of laboratory's personnel records, policies/procedures and staff interview, the laboratory failed to document competency assessment for 2 of 15 personnel employed by the facility, General Supervisor and Technical Supervisor. Findings included: 1. Review of laboratory's personnel records revealed the General Supervisor and Technical Supervisor did not have competency assessment documented prior to starting their respective duties. 2. Review of laboratory's policies revealed the laboratory did not have protocols in place for competency assessment of positions such as Clinical Consultant, Technical Consultant, General Supervisor or Technical Supervisor. 3. In an interview on 11/01/2023 at 1500 hours in the office, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, laboratory's twice annual test accuracy verification records, policies/procedures and staff interview, the laboratory failed to document twice annual test accuracy verification for one of four laboratory developed tests performed by the facility, Telomere testing. Findings included: 1. Review of laboratory's submitted test menu revealed the laboratory performed Telomere testing. 2. Review of laboratory's twice annual test accuracy verification records for 2022 and 2023 revealed there was no documentation of twice annual test accuracy verification for the Telomere test. 3. Review of laboratory's policies/procedures revealed there were no protocols in place addressing twice annual test accuracy verification for the Telomere test. 4. In an interview on 11/01/2023 at 1500 hours in the office, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: A. Based on review of laboratory's proficiency testing (PT) records, policies /procedures and staff interview the laboratory failed to document required PT evaluation for one of 24 PT records reviewed. Findings included: 1. Review of laboratory's PT records for 2022 and 2023 revealed one of 24 reviewed PT events did not have documentation of PT result review by laboratory director or designated personnel: Hematology Auto Differentials FH2-A 2022 2. Review of laboratory's

	policies/procedures revealed there was no protocol in place delineating PT evaluation requirements, or designated personnel authorized to perform PT evaluation. 3. In an interview on 11/01/2023 at 1500 hours in the office, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. B. Based on review of laboratory's twice annual test accuracy verification records, policies/procedures and staff interview, the laboratory failed to document evaluation and corrective action for discrepant accuracy verification results for two of four laboratory developed tests, Micronutrient testing and Lipoprotein Particle Profile (LPP). Findings included: 1. Review of laboratory's twice annual test accuracy verification records for 2022 and 2023 revealed the laboratory performed test accuracy verification for Micronutrient and LPP testing by split sample testing through Isolation Comparison. 2. Review of the Isolation Comparison results of samples involved in twice annual test accuracy verification revealed there was no evaluation of discrepancies or corrective action documentation for the discrepant split sample results. The discrepant results lacking evaluation or corrective action included: Isolation Comparison from 02/02/2023 Micronutrient: Pantothenate Result 1: 10 Result 2: 13 Micronutrient: Choline Result 1:19 Result 2: 73 No documentation of evaluation of discrepant results or corrective action taken. Isolation Comparison from 03/29/2023 Micronutrient: Micronutrient: Folate Result 1: 33 Result 2: 44 Micronutrient: Choline Result 1: 65 Result 2: 37 Micronutrient: Oleic Acid Result 1: 160 Result 2: 117 Micronutrient: CoQ10 Result 1: 85 Result 2: 97 Micronutrient: Selenium Result 1: 115 Result 2: 135 Micronutrient: Vit D3 Result 1: 55 Result 2: 73 No documentation of evaluation of discrepant results or corrective action taken. Isolation Comparison from 05/23//2023 LPP: Total LLD Result 1: 898; Interpretation: Borderline Result 2: 925; Interpretation: Out of range No documentation of evaluation of discrepant results or corrective action taken. 3. Review of laboratory's policies /procedures revealed there were no protocols addressing evaluation or corrective action requirements for discrepant results of split samples involved in twice annual test accuracy verification. 4. In an interview on 11/01/2023 at 1500 hours in the office, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's Directory of Services and staff interview, the laboratory failed to provide collection instructions for the MTHFR (Methylenetetrahydrofolate reductase) test using one of two specimen collection tubes to their clients for testing performed in 2023. Findings include: 1. A review of the laboratory's Directory of Services (REV 09/23) titled 'Specimen Collection & Handling Procedures' revealed the following: "MTHFR: Collection Tubes: Blue Top (Sodium Citrate) Whole Blood - No fasting is required -Collect 1 FULL tube - Invert 6 times immediately after drawing; DO NOT centrifuge nor freeze - Not temperature sensitive" 2. An interview with the general supervisor on 9/2/23 at 1600 hours in the conference room revealed the laboratory also accepted patient specimens collected in lavender top EDTA (Ethylenediaminetetraacetic Acid) tubes for the MTHFR test. 3. Further review of the Directory of Services revealed the laboratory failed to provide

	collection instructions for the MTHFR test using EDTA tubes. 4. An interview with the general supervisor on 11/2/23 at 1600 hours in the conference room, after review of the records, confirmed the above findings. B. Based on a review of the laboratory's Directory of Services and staff interview, the laboratory failed to define the acceptability criteria for patient specimens listed as "Not temperature sensitive" in the Directory of Services for two of four tests performed by the laboratory in 2023. Findings include: 1. A review of the laboratory's Directory of Services (REV 09/23) revealed the laboratory performed four tests: - Micronutrient Test - LPP (Lipoprotein Particle Profile) Plus Test - MTHFR (Methylenetetrahydrofolate reductase) Test - Telomere test 2. Further review of the laboratory's Directory of Services revealed the following collection and shipping instructions for the MTHFR and Telomere tests: "- MTHFR Instructions: No fasting is required, Collect 1 FULL tube, Invert 6 times immediately after drawing: DO NOT centrifuge nor freeze, Not temperature sensitive - Telomere Instructions: No fasting is required, Collect 1 FULL tube, Invert 6 times immediately after drawing: DO NOT centrifuge nor freeze, Not temperature sensitive" 3. The laboratory failed to define 'Not temperature sensitive' and provide acceptability criteria for patient samples sent to the laboratory for MTHFR and Telomere testing. 4. An interview with the general supervisor on 11/2/23 at 1600 hours 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: An unannounced revisit was performed on 12/29/2023. D5400 - Condition remains uncorrected. Based on review of the laboratory plans of correction with a completion date of 12/29/2023, laboratory's records, and staff interview, the laboratory failed to follow its own plan of correction and meet analytic systems requirements for three of six laboratory's test platforms. Findings included: 1. Laboratory failed to follow own plan of correction and document laboratory director's approval of policies/procedures. Refer to D5407. 2. Laboratory failed to follow own plan of correction and document determination of potential patient harm as a result of failure to establish performance specifications for laboratory developed DNA (Deoxyribonucleic acid) extraction process. Refer to D5423B. 3. Laboratory failed to follow its own plan of correction and document determination of potential patient harm as a result of failure to establish and document maintenance for one of one Breadbox Camara ensemble/imaging system used in Lipid Particle Panel (LLP) testing. Refer to D5435. 4. Laboratory failed to follow its own plan of correction to ensure one of one policy was established by the completion date, the "Coulter ACT diff 2 Comparison" Policy. Refer to D5775. ********** Based on review of laboratory's records, manufacturer instructions for use, FDA CLIA data base and staff interview, the laboratory failed to meet analytic systems requirements for six of six laboratory's test platforms. Findings included: 1. Laboratory failed to define protocols for performance, evaluation/acceptability criteria and corrective action requirements for twice annual test accuracy verification of laboratory developed tests. Refer to

	D5401A. 2. Laboratory failed to document weekly performance of Isolation Comparison as per its own policy. Refer to D5401B. 3. Laboratory failed to have documentation of performing one End of the Day Clean Up procedure, as required by the laboratory's policies. Refer to D5401C. 4. Laboratory failed to update two policies in 2019 when the use of Cell Preparation Tubes (CPT) for micronutrient testing were discontinued. Refer to D5403. 5. Laboratory failed to have documentation of the current laboratory director signing and approving two laboratory procedures. Refer to D5407. 6. Laboratory failed to document room temperature monitoring for Lipoprotein Particle Profile ultracentrifuge operation. Refer to D5413A. 7. Laboratory failed to document monitoring of temperature to ensure reagent stability. Refer to D5413B. 8. Laboratory failed to document the open dates and the revised expiration dates on three Strek Para 12 Extend control vials. Refer to D5415A. 9. Laboratory failed to label 23 bottles of autoclaved water and 87 aliquot tubes of media with the contents' identity, preparation dates, and expiration dates for patient micronutrient testing. Refer to D5415B. 10. Laboratory failed to ensure 25 of 25 vitamins and amino acids had not exceeded their expiration dates prior to using them for micronutrient testing. Refer to D5417. 11. Laboratory failed to document establishment of performance specifications for laboratory modified testing protocols. Refer to D5423A. 12. Laboratory failed to document establishment of performance specifications for laboratory developed DNA (Deoxyribonucleic acid) extraction process. Refer to D5423B. 13. Laboratory failed to have documentation of performing establishment studies in 2019 when the use of the Cell Preparation Tube (CPT) for micronutrient testing was discontinued. Refer to D5423C. 14. Laboratory failed to establish and document maintenance for Breadbox Camara ensemble/imaging system. Refer to D5435. 15. Laboratory failed to have documentation of performing calibration procedures on the two Coulter ACT diff 2 hematology analyzers. Refer to D5437. 16. Laboratory failed to ensure accuracy of the Daily Harvest QC when results were entered into the Excel program incorrectly. Refer to D5441A. 17. Laboratory failed to ensure the Media Test results were calculated accurately to determine acceptable media for micronutrient testing. Refer to D5441B. 18. Laboratory failed to have a mechanism in place to be able to determine the lot numbers of QC material used for the daily QC run on the Coulter ACT diff 2 hematology analyzers. Refer to D5441C. 19. Laboratory failed to ensure that comparison studies were performed on the two Coulter ACT diff 2 hematology analyzers performing CBC (Complete Blood Count) testing. Refer to D5775. 20. Laboratory failed to have documentation of performing corrective action when the average percent growth activity for certain nutrients failed to meet the laboratory's acceptability criteria for media used for micronutrient testing. Refer to D5779. 21. Laboratory failed to document corrective actions for out-of-range temperatures. Refer to D5785. 22. Laboratory's Quality Assurance failed to identify and correct issues in laboratory's analytic systems. 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: A. Based on review of laboratory's test menu, policies/procedures and staff interview,

	the laboratory failed to define protocols for performance, evaluation/acceptability criteria and corrective action requirements for twice annual test accuracy verification of four of four laboratory developed tests, Telomere, Lipid Particle Profile, Methylenetetrahydrofolate Reductase (MTFHR) and Micronutrient testing. Findings included: 1. Review of laboratory's test menu revealed the laboratory performed the following laboratory developed tests: Telomere Lipid Particle Profile Methylenetetrahydrofolate Reductase (MTFHR) Micronutrient testing. 2. Review of laboratory's policies/procedures revealed there were no protocols in place for performance, evaluation/acceptability criteria and corrective action requirements for twice annual test accuracy verification of the above laboratory developed tests. 3. In an interview on 11/01/2023 at 1500 hours in the office, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. B. Based on review of laboratory's policies/procedures, Isolator Comparison records for January to October 2023 and staff interview, the laboratory failed to document weekly performance of Isolation Comparison as per its own policy for 39 of 42 weeks reviewed. Findings included: 1. Review of laboratory's policy "Cell Isolation and Inoculation" (last revised January 2014) revealed: "V. Quality Control Isolator Comparison is performed at least once per week to monitor assay reproducibility among the technician performing the isolation procedure." 2. Review of the Isolator Comparison records revealed Isolator Comparison was documented for the following 3 of 42 weeks from January to October of 2023: 02/02/2023 03/29/2023 05/04/2023 There was no documentation of Isolator Comparison for the other 39 weeks within the 10-month interval reviewed. 3. In an interview on 11/01/2023 at 1530 hours in the conference room, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid C. Based on a review of the laboratory's polices, the laboratory's records, staff interview, the laboratory failed to have documentation of performing one End of the Day Clean Up procedure, as required by the laboratory's policies, in three different areas of the laboratory for 303 of 303 days from January 1, 2023 to October 31, 2023. Findings include: 1. A review of the laboratory's policy titled 'Micronutrient Test-Janus' revealed the following: "End of the Day Clean Up - Wipe down all counters, hoods, and the Janus instrument with 70% isopropyl" 2. A review of the laboratory's policy titled 'Micronutrient Test- Filter Post Harvest' revealed the following: "End of the Day Clean Up - Wipe all the bench workspaces with 70% Isopropyl." 3. A review of the laboratory's policy titled 'Micronutrient Test- Harvest' revealed the following: "End of the Day Clean Up - Wipe the bench work space with 70% Isopropyl." 4. A review of the laboratory's records revealed the laboratory failed to have documentation of wiping down workspaces in the three areas of the laboratory (Janus room, Harvest area, Post Harvest area) for the 303 days from January 1, 2023 to October 31, 2023. 5. An interview with the general supervisor on 11/2/23 at 1520 hours in the conference room, after review of the records, confirmed the above findings.
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 a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to update two of two policies in 2019 when the use of Cell Preparation Tubes (CPT) for micronutrient testing were discontinued. Finding include: 1. A review of the laboratory's policy titled 'Processing & Receiving Samples' revealed the following: "Micronutrient Test (MNT) Rejection Criteria - Reject MNT if wrong sample received: Only a Cell Preparation tube (CPT) containing whole blood in sodium citrate or Acid Citrate Dextrose tube (ACD) tube is acceptable." 2. A review of the laboratory's policy titled 'Procedure for Cell Isolation and Inoculation' revealed the following: "Cell Isolation: - ACD or Heparin tubes must be poured into properly labeled and numbered CPT tubes (after disposing of the citrate liquid from above the separator gel surface)." 3. A review of the laboratory's records revealed the laboratory discontinued the use of the CPT tube as part of the procedure for micronutrient testing in 2019. 4. An interview with the general supervisor on 11/2/23 at 915 hours in the conference room, after review of the records, confirmed the policies had not been updated.
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 procedure manual, the laboratory's records, and staff interview, the laboratory failed to have documentation of the current laboratory director signing and approving two of two laboratory procedures used by laboratory personnel for testing in 2022 and 2023. Findings include: 1. A review of the laboratory's procedure manual revealed the laboratory director failed to sign and approve the following 2 procedures: - Processing and Receiving of Samples - Micronutrient Test Media Preparation 2. A review of the laboratory's records revealed the current laboratory director was employed by the laboratory in September 2021. 3. An interview with the laboratory director on 11/2/23 at 1600 hours in the conference room, after review of the records, confirmed the above findings.
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:
A. Based on surveyor's observations, review of manufacturer's user manual, review of laboratory's temperature records and staff interview, the laboratory failed to document room temperature monitoring for ultracentrifuge operation for one of one room where centrifugation of Lipoprotein Particle Profile (LPP) samples was performed. Findings included: 1. Surveyor's observations on 11/02/2023 at 1000 hours in the laboratory revealed the following ultracentrifuges used in centrifugation of samples for LPP testing were in operation: Thermo Scientific Seroval Discovery M120 Ultracentrifuges Serial Numbers: S09T-659914-ST S13T-659916-ST V22R-650538-VR Y25T-423093-ZT Y25T-423094-ZT Z13S-657794-ZS 2. Further observations revealed no temperature monitoring device in the room where the above ultracentrifuges were operating. 3. Review of manufacturer's user manual for the Thermo Scientific Seroval Discovery M120 ultracentrifuge revealed the following operating conditions: Ambient (operating) Temperature: 5 to 25C (Degrees Celsius) 4. Review of laboratory's temperature records revealed no documentation of ambient temperature monitoring for the room where the ultracentrifuges were operating. 5. In an interview on 11/02/2023 at 1000 hours in the laboratory, the laboratory's General Supervisor (as indicated on submitted form CMS 209) confirmed the findings. B. Based on review of laboratory's temperature logs, manufacturer instructions for reagent storage, laboratory's policies/procedures and staff interview, the laboratory failed to document monitoring of temperature to ensure reagent stability for 12 of 12 required temperature monitoring instances. Findings included: 1. Review of laboratory's temperature logs from June 2022 to June 2023 revealed the following gaps in temperature records for refrigerators and freezers: a. LPP Refrigerator Acceptable Temperature range: 2-8C (Degrees Celsius) No temperature recorded for: 06/22/2022 Examples of currently stored reagents: K-Assay Insulin reagent (lot WC270) K-Assay hsCRP reagent (lot 1230) Sekure N-geneous LDL-ST Cholesterol Calibrator (lot 62633) b. Walk-in Refrigerator Acceptable Temperature range: 2-8C No temperature recorded for: 06/25/2022 10/21/2022 11/15/2022 04/29/2023 05/20 /2023 06/28/2023 06/29/2023 Examples of currently stored reagents: Laboratory prepared media for Micronutrient testing Prepared: 10/11/2023 c. Freezer B Acceptable Temperature range: -17 to -23C No temperature recorded for: 09/22/2023 Acceptable Temperature range changed January 2023: -15 to -25C No temperature recorded for: 04/29/2023 06/28/2023 06/29/2023 Examples of stored reagents: LightCycler 480 SYBR Green I Master Note: No corrective action was documented addressing verification of reagent stability for days where the temperature was not monitored. 2. Review of manufacturer instructions for reagent storage and laboratory's policies/procedures revealed the following reagent storage requirements: a. Manufacturer requirements for storage temperature for the K-Assay Insulin reagent, K-Assay hsCRP reagent, and Sekure N-geneous LDL-ST Cholesterol Calibrator were 2-8C. b. Laboratory defined storage temperature for laboratory prepared media was 2-8C. c. Manufacturer requirements for storage of LightCycler 480 SYBR Green I Master were -15 to -25C. 3. In an interview on 11/02/2023 at 1540 hours in the conference room, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

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: A. Based on a review of the Strek Para 12 Extend Multi-Parameter Assayed Hematology Control Instructions for Use, surveyor observation, and staff interview, the laboratory failed to document the open dates and the revised expiration dates on three of three Strek Para 12 Extend control vials used on the Coulter ACT diff 2 hematology analyzers in October and November 2023. Findings include: 1. A review of the Strek Para 12 Extend Multi-Parameter Assayed Hematology Control Instructions for Use (350307-43, 2023-01) revealed the following: "Open-vial stability: 30 days" 2. Surveyor observation of the walk in refrigerator on 11/1/23 at 1420 hours revealed the following 3 Strek Para 12 Extend controls currently in use for the Coulter ACT diff 2 hematology analyzer with no documentation of an open date or revised expiration date: Strek Para 12 Extend Low Control Lot number: 31560422 Strek Para 12 Extend Normal Control Lot number: 31560423 Strek Para 12 Extend High Control Lot number: 31560424 3. An interview with the general supervisor on 11 /2/23 at 1600 hours in the conference room, after review of the records, confirmed the above findings. B. Based on surveyor observation and staff interview, the laboratory failed to label 23 of 23 bottles of autoclaved water and 87 of 87 aliquot tubes of media, used for the laboratory's micronutrient testing, with the contents' identity, preparation dates, and expiration dates for patient micronutrient testing performed in November 2023. Findings include: 1. Surveyor observation of room B128 on 11/2/23 at 1155 hours revealed 23 bottles of autoclaved water and 87 aliquot tubes of media, used for micronutrient testing, that the laboratory failed to label with the contents' identity, preparation dates and expiration dates. 2. An interview with the general supervisor on 11/2/23 at 1155 hours in room B128, confirmed the above findings.
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 a review of the laboratory's policies, surveyor's observation, a review of the laboratory's submitted CMS 116 form, and staff interview, the laboratory failed to ensure 25 of 25 vitamins and amino acids had not exceeded their expiration dates prior to using them for micronutrient testing in 2022 and 2023. Findings include: 1. A review of the laboratory's policy titled 'Micro Nutrient Test Media Preparation' revealed the following: "The internal shelf life of all vitamins and amino acids will be six (6) months." 2. Surveyor observation of room B125 on 11/2/23 at 1240 hours revealed the following 25 vitamins and amino acids used for micronutrient testing had exceeded their expiration date: Myo-Inositol Lot: SLCF2797 Opened: 12/5/22

	Expired: 6/5/23 L-Methionine Lot: 1003454128 Opened: 8/30/22 Expired: 3/1/23 Glycine Lot: 1003531349 Opened: 1/4/23 Expired: 7/4/23 Manganese(II) sulfate monohydrate Lot: SLCJ4601 Opened: 10/13/21 Expired: 4/13/22 L-Lysine monohydrochloride Lot: 1003467163 Opened: 8/29/23 Expired: 3/1/23 L-Leucine Lot: 1002447643 Opened: 8/29/22 Expired: 3/1/23 Iron(II) sulfate hepta-hydrate Lot: 1003341772 Opened: 3/15/22 Expired: 9/15/22 L-Histidine monohydro-chloride monohydrate Lot: 1003422740 Opened: 1/4/23 Expired: 7/4/23 Ethylenediaminetetraacetic Acid Lot: SLCG2340 Opened: 3/15/22 Expired: 9/15/22 Chromium(III) chloride hexahydrate Lot: STBK2363 Opened: 12/30/21 Expired: 7/3 /22 Adenine hydrochloride hydrate Lot: A9795-5G Opened: 3/13/23 Expired: 9/13/23 L-Phenylalanine Lot: 102476803 Opened: 8/30/22 Expired: 3/1/23 L-Serine Lot: 1003410472 Opened: 10/11/22 Expired: 4/11/23 L-Threonine Lot: 1003431517 Opened: 8/29/22 Expired: 3/1/23 Thymidine Lot: SLCG7664 Opened: 7/15/22 Expired: 1/15/23 L-Tryptophan Lot: T0254-5G Opened: 8/29/22 Expired: 3/1/23 L-Tyrosine Lot: T3754-50G Opened: 8/29/22 Expired: 3/1/23 L-Valine Lot: 1003466550 Opened: 8/29/22 Expired: 2/29/23 Thiamine hydrochloride Lot: 102504213 Opened: 9/19/22 Expired: 3/19/23 (-)Riboflavin Lot: 102423233 Opened: 9/20/22 Expired: 3/20/23 Nicotinamide Lot: 1003480109 Opened: 9/19/22 Expired: 3 /19/23 Calcium chloride Lot: 1003533019 Opened: 3/23/23 Expired: 9/23/23 Bovine Serum Albumin Lot: SLCB8822 Opened: 1/16/23 Expired: 7/16/23 Vitamin B12a hydrochloride Lot: MKCL8213 Opened: 9/20/22 Expired: 3/20/23 L-Dehydroascorbic acid Lot: BCCG1102 Opened: 5/10/22 Expired: 11/10/22 3. A review of the laboratory's submitted CMS 116 form revealed the laboratory estimated performing 509,972 micronutrient tests annually. 4. An interview with the general supervisor on 11/2/23 at 1240 hours in the laboratory, after review of the records, confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 12/29/2023. D5423B - remains uncorrected. Based on review of the laboratory plans of correction with a completion date of 12/29/2023, laboratory's records, and staff interview, the laboratory failed to follow its own plan of correction and document determination of potential patient harm as a result of failure to establish performance specifications for one of one laboratory developed process, DNA (Deoxyribonucleic acid) extraction. Findings included: 1. Review of the laboratory plans of correction with a completion date of 12 /29/2023 revealed: "The LD determined that no patient harm occurred." 2. Review of laboratory's records revealed there was no documentation of LD's determination of potential patient harm as a result of failure to document establishment of performance

specifications for laboratory developed DNA (Deoxyribonucleic acid) extraction process. 3. In an interview on 12/29/2023 at 1035 hours in the conference room, the laboratory's General Supervisor (as indicated on submitted Form CMS 209), confirmed the findings. ********** A. Based on surveyor's observations, review of FDA's CLIA data base, laboratory's establishment studies, laboratory's test volumes and staff interview, the laboratory failed to document establishment of performance specifications for laboratory modified testing protocols for one of one chemistry analyzers, the Beckman Coulter AU680. Findings included: 1. Surveyor's observations on 11/01/2023 at 1035 hours in the laboratory revealed the laboratory used one Beckman Coulter AU680 chemistry analyzer for testing of lipid panel, apolipoprotein, high-sensitivity C-reactive protein(hsCPR), homocysteine and insulin. 2. Surveyor's observations on 11/02/2023 at 1100 hours in the laboratory revealed the following reagents stored in the "LPP Refrigerator": K-Assay Insulin reagent (lot WC270, expiration 2024-05-14) Diazyme Lipoprotein(a) Assay reagent (lot LT001220-01-01, expiration 2024-03-07) 3. In an interview on 11 /02/2023 at 1100 hours in the laboratory, Testing Person number 13 (as indicated on submitted form CMS 209), when queried, stated the above reagents were for use on the Beckman Coulter AU680 chemistry analyzer. 4. Review of the FDA's CLIA data base (accessdata.fda.gov) revealed the above reagents were not approved for the Beckman Coulter AU680 chemistry analyzer (Note: there are no reagents approved for insulin testing on the AU680 instrument). This change in reagents/analyte amended testing of these analytes on the AU680 to a Laboratory Developed Test (LDT) classification, requiring full establishment studies to include accuracy, precision, analytical sensitivity and specificity, establishment of reportable range and reference intervals as well as evaluation of possible interfering substances and/or other parameters. 5. The laboratory was asked to provide establishment studies for the above reagents, and no such studies were available for review prior to survey exit. 6. Review of laboratory's submitted test volumes revealed the laboratory performed 33,970 tests annually on the Beckman Coulter AU680 chemistry analyzer. 7. In an interview on 11/02/2023 at 1155 hours in the conference room, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209), confirmed the findings. B. Based on surveyor's observations, review of manufacturer's instructions, FDA's CLIA data base, laboratory's establishment studies and staff interview, the laboratory failed to document establishment of performance specifications for one of one laboratory developed DNA (Deoxyribonucleic acid) extraction process used in Telomere testing. Findings included: 1. Surveyor's observations on 11/02/2023 at 1230 hours in the laboratory revealed one BioTeke Corporation (Wuxi) AU1001S Automated Nucleic Acid Extraction System and the accompanying BioTeke Nucleic Acid Extraction Kit used in Telomere testing (placed in use in June 2023). 2. Review of manufacture instructions manual for the AU1001S Automated Nucleic Acid Extraction System revealed there were no instructions for establishment of performance specifications for this instrument, or protocols addressing calibration /quality control requirements. 3. Review of the User Instruction for the BioTeke Nucleic Acid Extraction Kit (edition A1.1, Revision date: 8 Nov. 2022) revealed there were no instructions for establishment of performance specifications for this kit, or protocols addressing calibration/quality control requirements. 4. Review of the FDA's CLIA data base (accessdata.fda.gov) revealed the BioTeke AU1001S instrument and the BioTeke Nucleic Acid Extraction Kit were not approved by the FDA for use in the United States, making the use of this instrument/kit combination a laboratory developed process, requiring full establishment studies to include accuracy, precision, analytical sensitivity and specificity, establishment of reportable range and reference intervals as well as evaluation of possible interfering substances and/or establishment of calibration and quality control requirements. 5. The laboratory was asked to

	provide establishment studies for the BioTeke instrument and kit. The laboratory provided a 13-sample method comparison spreadsheet comparing laboratory's manual extraction method to the instrument/kit extraction process. No summary of the evaluation of data, or other parameters' studies were documented. There were no protocols in place addressing calibration or quality control requirements. 6. Review of laboratory's submitted test volumes revealed the laboratory performed 654 Telomere tests annually. At the time of the survey the laboratory could not provide the total number of patient tests performed using the new BioTeke extraction instrument and kit. 7. In an interview on 11/02/2023 at 1400 hours in the conference room, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. Key: CLIA - Clinical Laboratory Improvement Amendments FDA - United States Food and Drug Administration CMS - Centers for Medicare and Medicaid C. Based on a review of the laboratory's policies, the laboratory's records, the laboratory's test records, and staff interview, the laboratory failed to have documentation of performing establishment studies in 2019 when the use of one of one Cell Preparation Tube (CPT) for micronutrient testing was discontinued. Findings include: 1. A review of the laboratory's policy titled 'Procedure for Cell Isolation and Inoculation' revealed the following step in the Cell Isolation procedure for the laboratory's micronutrient testing: "Cell Isolation: - ACD or Heparin tubes must be poured into properly labeled and numbered CPT tubes (after disposing of the citrate liquid from above the separator gel surface)." 2. A review of the laboratory's records revealed the laboratory discontinued the use of the CPT tube in 2019. 3. Further review of the laboratory's records revealed the laboratory failed to have documentation of performing establishment studies in 2019 when the laboratory discontinued the use of the CPT tube as part of the procedure. 4. A review of the laboratory's test records revealed the laboratory performed an estimated 500,000 micronutrient tests in 2022. 5. An interview with the general supervisor on 11/1/23 at 930 hours in the conference room, after review of the records, confirmed the above findings.
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: An unannounced revisit was performed on 12/29/2023. D5435 - remains uncorrected. Based on review of the laboratory plans of correction with a completion date of 12/29 /2023, laboratory's records, and staff interview, the laboratory failed to follow its own plan of correction and document determination of potential patient harm as a result of failure to establish and document maintenance for one of one Breadbox Camara ensemble/imaging system used in Lipid Particle Panel (LLP) testing. Findings included: 1. Review of the laboratory plans of correction with a completion date of 12 /29/2023 revealed: "LD determined that no patient results were affected." 2. Review of laboratory's records revealed there was no documentation of LD's determination of

	potential patient harm as a result of failure to establish and document maintenance for the Breadbox Camara ensemble/imaging system used in Lipid Particle Panel (LLP) testing. 3. In an interview on 12/29/2023 at 1050 hours in the conference room, the laboratory's TS/GS (as indicated on submitted Form CMS 209), confirmed the findings. ********** Based on surveyor's observations, review of manufacturer instructions for use, laboratory's equipment maintenance records, policies/procedures, laboratory's submitted test volumes and staff interview, the laboratory failed to establish and document maintenance for one of one Breadbox Camara ensemble/imaging system used in Lipid Particle Panel (LLP) testing. Findings included: 1. Surveyor's observations on 11/01/2023 at 1020 hours in the laboratory revealed one in-use Breadbox Camara ensemble/imaging system utilized in LLP testing. 2. Review of manufacturer instructions for use for the Breadbox Camara ensemble revealed there were no specific instructions for frequency and/or performance of maintenance, bulb change specifications/requirements, or light source collimation verification requirements. 3. Review of the laboratory's equipment maintenance records for 2022 and 2023 revealed the Breadbox Camara ensemble did not have any maintenance documented for 2022 and 2023. 4. Review of laboratory's policies/procedures revealed there were no protocols in place regarding Breadbox Camara ensemble maintenance requirements. 5. Review of laboratory's submitted test volumes revealed the laboratory performed 30,573 LPP tests annually using the Breadbox Camara ensemble. 6. In an interview on 11/02/2023 at 1500 hours in the conference room, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
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 a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to have documentation of performing six of six calibration procedures on the two Coulter ACT diff 2 hematology analyzers from January 2022 to October 2023. Findings include: 1. A review of the laboratory's policy titled 'Procedure for Cell Isolation and Inoculation' revealed the following: "Calibrating the Coulter Cell Counters: - Note: We perform the Calibration and Linearity check every six months or whenever a major component inside the instrument is changed, such as a syringe or valve that might affect the volume of sample or reagent." 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing calibration procedures every six months on the two Coulter ACT diff 2 hematology analyzers (serial numbers AU20394 and AW21329) from January 2022 to October 2023. 3. An interview with the general

	supervisor on 11/2/23 at 915 hours in the laboratory, after review of the records, confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on a random review of the laboratory's Daily Harvest QC (Quality Control) reports and staff interview, the laboratory failed to ensure accuracy of the Daily Harvest QC when results were entered into the Excel program incorrectly for nine of nine days reviewed from March 2023 to September 2023. Findings include: 1. An interview with the general supervisor on 11/2/23 at 1000 hours in the laboratory revealed there were 2 harvesters (number 4 and number 5) in use from March 2023 to September 2023. Two testing personnel would perform a quality check daily by running two patient samples on each harvester. The results were then entered into an Excel program for analysis. A CV% (coefficient of variation) of less than or equal to 20 meant the QC was acceptable. 2. A random review of the Daily Harvest QC reports from March 2023 to September 2023 revealed the following 9 days when a) the patient's accession number, pipette number, and TC Recount number from harvester number 4 were entered under the column for harvester number 1 (this harvester was not in use) b) the CPM, CV%, TC Recount CV, and Recount CPM from harvester number 4 were entered under an unlabeled column: - 3/27/23 - 4/6/23 - 4/12/23 - 4/19 /23 - 5/4/23 - 6/26/23 - 7/17/23 - 8/16/23 - 9/4/23 *NOTE: The laboratory failed to have a policy outlining the steps for performing the Daily Harvest QC and entering the results into the Excel program. 3. An interview with the general supervisor on 11/2 /23 at 1020 hours in the laboratory, after review of the records, revealed the laboratory personnel copied and pasted the results into the wrong columns of the Excel program. B. Based on a review of the laboratory's Media Test Validation Sheets, the media testing logs, and staff interview, the laboratory failed to ensure the Media Test results were calculated accurately to determine acceptable media for micronutrient testing for four of four Media Test Validations reviewed from May 2023 to August 2023. Findings include: 1. A review of the laboratory's Media Test Validation Sheets revealed the following: "To determine acceptable media, calculate the percent cell growth activity using the following formula (% new media/ % current media) x 100 for each nutrient." 2. Further review of the Media Test Validation Sheets revealed the percent cell growth activity for each nutrient tested was not calculating results using the formula listed above (see 2 examples from each batch of media below) for the following batch numbers of media prepared: a) Batch number: 230525 -Choline run on plate #5 % New media = 21 % Old media = 31 Calculation on Validation sheet = 68.4% Manual calculation of formula = 67.7% -Calcium run on plate #4 % New media = 110 % Old media = 89 Calculation on Validation sheet = 124.5% Manual

	calculation of formula = 123.5% b) Batch number: 230608 -Glutamine run on plate #2 % New media = 84 % Old media = 78 Calculation on Validation sheet = 108.4% Manual calculation of formula = 107.6% -Zinc run on plate #1 % New media = 107 % Old media = 109 Calculation on Validation sheet = 98.0% Manual calculation of formula = 98.2% c) Batch number: 230714 -Asparagine run on plate #5 % New media = 97 % Old media = 77 Calculation on Validation sheet = 126.7% Manual calculation of formula = 125.9% -Fructose run on plate #4 % New media = 78 % Old media = 92 Calculation on Validation sheet = 84.2% Manual calculation of formula = 84.7% d) Batch number: 230831 -Folate run on plate #3 % New media = 244 % Old media = 248 Calculation on Validation sheet = 98.5% Manual calculation of formula = 98.3% -Biotin run on plate #2 % New media = 74 % Old media = 95 Calculation on Validation sheet = 78.4% Manual calculation of formula = 77.8% 3. A review of the media testing logs revealed the dates the batch numbers of media were put into use and how many plates were set up using those batch numbers of media: a) Batch number: 230525 First used on 6/29/23 401 patient test plates were set up using this batch number of media b) Batch number: 230608 First used on 7/11/23 535 patient test plates were set up using this batch number of media c) Batch number: 230714 First used on 8/17/23 441 patient test plates were set up using this batch number of media d) Batch number: 230831 First used on 10/5/23 468 patient test plates were set up using this batch number of media 4. An interview with the general supervisor on 11 /2/23 at 1549 hours in the conference room, after review of the records, confirmed the above findings. C. Based on a review of the laboratory's quality control (QC) records for the Coulter ACT diff 2 hematology analyzer and staff interview, the laboratory failed to have a mechanism to determine the lot numbers of QC material used for the daily QC run on the Coulter ACT diff 2 hematology analyzers for 21 of 21 months from January 2022 to October 2023. Findings include: 1. A review of the laboratory's quality control records for the Coulter ACT diff 2 hematology analyzer from January 2022 to October 2023 revealed the laboratory ran three levels of Strek Para 12 Extend QC material each day of patient testing. The laboratory used a patient ID for each level. Patient IDs consisted of the year, month, day, and a unique three digit number (for example: the first patient run on 1/24/23 would be 230124001). 2. Further review of the laboratory's QC records for the Coulter ACT diff 2 hematology analyzers revealed the laboratory failed to have a mechanism to determine the lot numbers of the QC material used. 3. An interview with the general supervisor on 11/2/23 at 920 hours in the laboratory, after review of the records, confirmed the above findings.
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 a review of the laboratory's records and staff interview, the laboratory failed to ensure that two of two comparison studies were performed as required in 2022 on the two Coulter ACT diff 2 hematology analyzers performing CBC (Complete Blood Count) testing. Findings include: 1. A review of the laboratory's records revealed the laboratory used the following 2 hematology analyzers for CBC testing in 2022: - Coulter ACT diff 2 Serial number: AU20394 - Coulter ACT diff 2 Serial number:

	AW21329 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of performing 2 comparison studies in 2022 on the Coulter ACT diff 2 hematology analyzers. 3. An interview with the general supervisor on 11/1 /23 at 1520 hours in the conference room, after review of the records, confirmed the above findings.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Media Test Validation Sheets, the laboratory's records, the media testing logs, and staff interview, the laboratory failed to have documentation of performing corrective action four of four times from March 2023 to August 2023, when the average percent growth activity for certain nutrients failed to meet the laboratory's acceptability criteria for media used for micronutrient testing. Findings include: 1. A review of the laboratory's Media Test Validation Sheets revealed the following: "To determine acceptable media, calculate the percent cell growth activity using the following formula (% new media/ % current media) x 100 for each nutrient. Using any 3 or more %-cell growth results from acceptable plates, calculate the average for each component nutrient. The average must exhibit plus or minus 12.5% cell growth activity of the previous lot # media (87.5% - 112.5%.)" 2. Further review of the Media Test Validation Sheets from four batch numbers from March 2023 to August 2023 revealed the average percent growth activity values for the following nutrients failed to meet the laboratory's acceptability criteria of 87.5% - 112.5%: a) Batch number: 230525 Vitamin B2 = 134.3% Vitamin B3 = 119.9% "Comments: Remake Vit B2& Vit B3" b) Batch number: 230608 Choline = 67.4% "Comments: Remake Choline" c) Batch number: 230714 Choline = 115.8% "Comments: Remake Choline" d) Batch number: 230831 Serine = 60.3% Glutamine = 71.7% Oleic Acid = 163.6% "Comments: Remake Serine, Glutamine, Oleic Acid" Note: The laboratory included corrective action steps in the comment section of the Media Test Validation Sheets. 3. Review of the laboratory's records revealed the laboratory failed to have documentation of performing corrective action (remaking the nutrients) when the average percent growth activity values for the nutrients failed to meet the laboratory's acceptability criteria. 4. A review of the media testing logs revealed the dates the batch numbers of media were put into use and how many plates were set up using those batch numbers of media: a) Batch number: 230525 First used on 6/29/23 401 patient test plates were set up using this batch number of media b) Batch number: 230608 First used on 7/11/23 535 patient test plates were set up using this batch number of media c) Batch number: 230714 First used on 8/17/23 441 patient test plates were set up using this batch number of media d) Batch number: 230831 First used on 10/5/23 468 patient test plates were set up using this batch number of media 5. An interview with the general supervisor on 11/2/23 at 1550 hours in the conference room, after review of the records, confirmed the above 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 review of laboratory's temperature logs, policies/procedures and staff interview, the laboratory failed to document corrective actions for five of five out-of-range temperatures noted. Findings included: 1. Review of laboratory's temperature logs for 2022 and 2023 revealed the following out-of-range temperatures did not have corrective action documented: LPP Refrigerator Acceptable temperature range: 2-8C (Degrees Celsius) Date: Temperature: 03/22/2022 1.5C 05/23/2023 1C 06/02/2023 9C No corrective action was documented. Freezer B Acceptable temperature range: -17C to -23C Date: Temperature: 03/07/2023 -27C 03/17/2023 -24C No corrective action was documented. 2. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place addressing corrective actions for out-of-range temperatures. 3. In an interview on 11/02/2023 at 1540 hours in the office, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
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: An unannounced revisit was performed on 12/29/2023. D5791 - remains uncorrected. Based on review of the laboratory's plan of correction with a completion date of 12/29/2023, laboratory's records, and staff interview, the laboratory failed to establish and follow overall Quality Assurance protocols and follow its own plan of correction for laboratory director's approval of policies/procedures and test comparison evaluation, two of two unaddressed components of laboratory's plans of correction. Refer to D5407 and D5775. ********** Based on review of laboratory's records, policies/procedures and staff interview, the laboratory's Quality Assurance failed to identify and correct issues with Laboratory Developed Tests' establishment studies, maintenance of equipment, reagents preparation/storage/disposal, quality control and corrective actions for six of six laboratory's test platforms. Refer to D5413 A and B, D5423 A and B, D5435, D5441 and D5785.
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 review of manufacturer instructions, laboratory's records, policies /procedures and staff interview, the laboratory director failed to provide overall management and direction for one of one laboratory surveyed. Findings included: 1. Laboratory director failed to ensure safety procedures were established and observed. Refer to D6084. 2. Laboratory director failed to ensure establishment studies were adequate. Refer to D6086. 3. Laboratory director failed to ensure evaluation and corrective action for Proficiency Testing were documented. Refer to D6091. 4. Laboratory director failed to ensure laboratory's Quality Assurance was established and maintained. Refer to D6094. 5. Laboratory director failed to ensure that personnel retraining/competency reassessment was documented upon rehire. refer to D6102A. 6. Laboratory director failed to ensure laboratory's technical supervisor and general supervisor had appropriate training and experience to oversee all of the facility's laboratory developed tests. Refer to D6102B.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on surveyor's observations in the facility, review of policies/procedures and staff interview, the laboratory director failed to ensure safety procedures were established and observed to ensure staff protection from physical and chemical hazards for three of three safety concerns observed. Refer to D3011.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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's new test/equipment establishment studies, policies /procedures and staff interview, the laboratory director failed to ensure establishment studies were adequate for three of four laboratory developed tests. Refer to D5423 A, B, and C.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records, laboratory's twice annual test accuracy verification records, policies/procedures and staff interview, the

	laboratory director failed to ensure evaluation and corrective action were documented for 3 of 3 PT and /or accuracy verification events. Refer to D5219 and D5221 A, B.
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: An unannounced revisit was performed on 12/29/2023. D6094 - remains uncorrected. Based on review of the laboratory's policies/procedures, laboratory's records, and staff interview, the laboratory director failed to ensure laboratory's overall Quality Assurance was established, maintained and documented for one of one surveyed laboratory. Findings included: 1. Review of laboratory's policies/procedures revealed the laboratory addressed quality assurance through documentation of individual tests' quality control (QC) and instrument's maintenance records but did not have a policy in place addressing overall laboratory's preanalytic, analytic and post analytic aspects of Quality Assurance (QA), QA review or its frequency, how issues are to be monitored and corrected, or how corrective actions were to be assessed for effectiveness. 2. Review of laboratory's records revealed there was no documentation of oveall assessment of laboratory's QA. 3. In an interview on 12/29/2023 at 1120 hours in the conference room, the laboratory's TS/GS (as indicated on submitted Form CMS 209), confirmed the findings. ********** Based on review of laboratory's records and staff interview, the laboratory director failed to ensure laboratory's Quality Assurance was established and maintained for six of six laboratory's test platforms. Refer to D5791.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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: An unannounced revisit was performed on 12/29/2023. D6102B - remains uncorrected. Based on review of the laboratory's plans of correction with a completion date of 12/29/2023, laboratory's records, and staff interview, the laboratory director failed to follow laboratory's own plan of correction for ensuring personnel holding the Technical Supervisor (TS) and General Supervisor GS) positions had documentation of training for two of four laboratory developed test for which TS/GS was responsible. Findings included: 1. Review of the laboratory's plans of correction with a completion date of 12/29/2023 revealed: "The GS will develop a log to help manage training and competency assessments." And, "The GS/QC will monitor the training log to ensure that the policy is being followed and that the laboratory is in compliance." 2. Review of laboratory's personnel records revealed the TS/GS did not have documentation of training/experience for the Lipoprotein Particle Profile (LPP) or

	Methylenetetrahydrofolate Reductase (MTHFR) testing, two of four laboratory developed tests. 3. In an interview on 12/29/2023 at 1145 hours in the conference room, the laboratory's TS/GS (as indicated on submitted Form CMS 209), confirmed the findings. ********** A. Based on review of provided Listing of Laboratory Personnel, laboratory's personnel records, policies /procedures and staff interview, the laboratory director failed to ensure that personnel retraining/competency reassessment was documented upon rehire for two of two testing personnel with intermittent work history. Findings included: 1. Review of provided Listing of Laboratory Personnel and personnel records revealed two personnel with intermittent work history: Listing's Testing Person number 8: Hired: 05 /13/2021 Terminated: 08/01/2022 Rehired: 08/12/2022 Listing's Testing Person number 15 Hired: 02/14/2011 Terminated: 12/31/2021 Rehired: 03/13/2023 Terminated: 10/02/2023 2. Further review of laboratory's personnel records revealed the two personnel with intermittent work history did not have documentation of retraining and/or competency reassessment upon rehire. 3. Review of the laboratory's policies/procedures revealed there was no protocol in place regarding retraining and /or competency reassessment for rehired personnel prior to restarting patient testing. 4. In an interview on 11/01/2023 at 1355 hours in the conference room, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. B. Based on review of provided Listing of Laboratory Personnel, laboratory's personnel records, policies/procedures and staff interview, the laboratory director failed to ensure laboratory's Technical Supervisor and General Supervisor had appropriate training and experience to oversee all four of four facility's laboratory developed tests. Findings included: 1. Review of laboratory's personnel records and interview with the Technical Supervisor on 11/01/2023 at 1100 hours revealed the Technical Supervisor did not have training/experience documented in laboratory developed Micronutrient, Lipoprotein Particle Profile (LPP) or Methylenetetrahydrofolate Reductase (MTHFR) testing. 2. Review of provided Listing of Laboratory Personnel and personnel records revealed the laboratory's General Supervisor had training and experience in only one of four laboratory developed tests, Micronutrient testing. The General Supervisor did not have training /experience documented in LPP, Telomere or MTHFR testing. 3. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place regarding required training and experience for the positions of Technical Supervisor and General Supervisor. 4. In an interview on 11/01/2023 at 1355 hours in the conference room, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of laboratory's personnel competency assessments and staff interview, the laboratory's Technical Supervisor failed to document performance of annual competency assessment for 4 of 14 testing personnel (TP) employed by the

	laboratory. Findings included: 1. Review of laboratory's personnel competency assessments for 2022 and 2023 revealed personnel did not have documentation of personnel's competency assessments as follows: TP number 7* Testing: Micronutrient data analysis/interpretation No documentation of competency assessment for 2022 or 2023 TP number 10* Testing: Micronutrient data analysis/interpretation No documentation of competency assessment for 2022 or 2023 TP number 13* Testing: Chemistry and Lipoprotein Particle (LPP) No documentation of competency assessment for 2022 2. Further review of the 2022-2023 personnel competency assessments revealed the following personnel had competency assessments performed by another testing person (TP) instead of the Technical Supervisor: TP number 2* Competency assessment performed on: 10/05/2022. Competency assessment performed by: TP number 7* 3. In an interview on 11/01/2023 at 1310 hours in the office, the laboratory's Technical Supervisor* confirmed the findings. Key: * - As indicated on submitted form CMS (Centers for Medicare and Medicaid) 209