Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0710715	07/11/2025
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	As part of the recertification process in combination with a complaint investigation, an unannounced survey of the laboratory was conducted 07/08/2025 through 07/11 /2025. 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 D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel The complaint has been substantiated.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 a review of the College of American Pathologist (CAP) attestation forms, the laboratory's CAP proficiency testing records from 2025, and staff interview, the laboratory failed to have documentation of the laboratory director and/or testing personnel's signatures on three of six attestation statements in 2025. Findings include: 1. A review of the CAP attestation form revealed the following: "As stated in the February 28, 1992 United States Federal Register under Subpart H 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 work load using the laboratory's routine methods." The laboratory director or designee and the testing personnel must sign on the result form." 2. A review of the laboratory's CAP proficiency testing records from 2025 revealed the attestation form for the following events were missing the laboratory director and/or testing personnel's signatures: - FH2-B 2025 Hematology Auto Differentials, FH2 - missing laboratory director and

	testing personnel's signatures - MGL1-A 2025 Molecular Genetics Series- missing laboratory director and testing personnel's signatures - HMS-A 2025 Homocysteine- missing laboratory director's signature 3. In an interview on 7/9/25 at 12:00 p.m. in the laboratory, after review of the records, testing person #4 (as indicated on the CMS 209 form) confirmed the above findings.
D3003	FACILITIES CFR(s): 493.1101(a)(2) (a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, contamination monitoring Wipe Test records and staff interview, the laboratory failed to follow its own protocols to perform Wipe Test at least monthly for four of eighteen months reviewed from January 2024 through June 2025. Findings included: 1. Review of laboratory's policy "Wipe Test (swab test)" (effective 04/18/2023) revealed: "Molecular Lab Technicians must ensure that routine Wipe Tests are conducted in their laboratories. Normally these wipe tests are conducted on a monthly basis at a minimum." 2. Review of the monthly Wipe Test records from 2024 and 2025 revealed there was no documentation of Wipe Tests for the following four of eighteen months reviewed: March 2024 October 2024 January 2025 May 2025 3. In an interview on 07/10/2025 at 1310 hours in the conference room Testing Person number 1 (as indicated on submitted Form CMS 209), after review of the policies and data, confirmed the findings.
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, review of laboratory's safety guidelines, and staff interview, the laboratory failed to designate test plates containing radioactive material with appropriate radiation warning symbols for thirty-one of thirty-one Micronutrient test plates observed siting on the countertop ready for harvest. Findings included: 1. Surveyor's observations on 07/10/2025 at 1155 hours at the laboratory's harvesting bench revealed a stack of thirty-one plates marked with a green line or the letter "T". Surveyor asked TP7 (Testing Person number seven - as indicated on submitted Form CMS 209) as to the meaning of the green line/T designation and was informed that those designations indicated that the plates had added Tritiated Thymidine (a radioactive form of thymidine). There was no other indication on these plates that they contained radioactive material. 2. Review of laboratory's "Radiation Safety Precautions" guidelines (License No. L04617, Radiation Safety Manual, Updated 2022) revealed: "Every bottle, flask, tube, etc., which contains a radioactive material must be identified by a proper radiation warning symbol." 3. In an interview on 07/10 /2025 at 1155 hours at the laboratory's harvesting bench, the facility's TP7 confirmed the 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: Based on a review of the laboratory's CMS 209 form, the laboratory's records, and staff interview, the laboratory failed to have documentation of a procedure to assess the competency for 2 of 2 technical supervisors and 10 of 10 testing personnel performing high complexity testing in 2024 and 2025. Findings include: 1. A review of the laboratory's CMS 209 form revealed the laboratory employed 2 technical supervisors and 10 testing personnel performing high complexity testing in 2024 and 2025. 2. A review of the laboratory's records revealed no procedure to assess the competency of the technical supervisors and testing personnel. 3. In an interview on 7 /10/25 at 1:30 p.m. in the conference room, after review of the records, the laboratory director confirmed the above findings. **NOTE** This is a repeat deficiency from the survey performed in November 2023.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists (CAP) proficiency testing records from 2025 and staff interview, the laboratory failed to have documentation of evaluating the proficiency testing results for two of six events in 2025. Findings include: 1. A review of the laboratory's CAP proficiency testing records from 2025 revealed the laboratory failed to have documentation of evaluating the proficiency testing results for the following events: - FH2-B 2025 Hematology Auto Differentials, FH2 - MGL1-A 2025 Molecular Genetics Series 2. In an interview on 7/9/25 at 12:00 p.m. in the laboratory, after review of the records, testing person #4 (as indicated on the CMS 209 form) confirmed the above findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the Participant Summary report, the laboratory's College of American Pathologists (CAP) proficiency testing records from 2025, and staff interview, the laboratory failed to have documentation of verifying the accuracy of analytes that were 'not graded' by the proficiency testing program for three of six proficiency testing events in 2025. Findings include: 1. A review of the Participant

	Summary report revealed the following: "The CAP uses exception reason codes that signify the proficiency testing (PT) for an analyte has not been graded. Exception Reason Code Description: 20 - Response was not formally graded due to insufficient peer group data. Action Required: Applies to a response that is not formally evaluated when a peer group is not established due to fewer than 10 laboratories reporting. Document that the laboratory performed a self-evaluation using the data presented in the participant summary and compare its results to a similar method, all method, all participant statistics, or data tables for groups of 3-9 laboratories, if provided. Perform and document the corrective action of any unacceptable results." 2. A review of the laboratory's CAP results from 2025 revealed the following three proficiency testing events included analytes that were scored with exception code 20 and the laboratory failed to have documentation of a self-evaluation: a) FH2-A 2025 Hematology Auto-Differentials, FH2 - White Blood Cell Count specimens FH2-01, FH2-02, FH2-03, FH2-04, FH2-05 - Lymphocytes specimens FH2-01, FH2-02, FH2-03, FH2-04, FH2-05 - Lymph Absolute specimens FH2-01, FH2-02, FH2-03, FH2-04, FH2-05 b) FH2-B 2025 Hematology Auto-Differentials, FH2 - White Blood Cell Count specimens FH2-06, FH2-07, FH2-08, FH2-09, FH2-10 - Lymphocytes specimens FH2-06, FH2-07, FH2-08, FH2-09, FH2-10 - Lymph Absolute specimens FH2-06, FH2-07, FH2-08, FH2-09, FH2-10 c) C-A 2025 General Chemistry/Therapeutic Drugs - LDL, measured specimens CHM-01, CHM-02, CHM-03, CHM-04, CHM-05 3. In an interview on 7/9 /25 at 12:00 p.m. in the laboratory, after review of the records, testing person #4 (as indicated on the CMS 209 form) 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 surveyor's observations, review of laboratory's records, policies/procedures and staff interview, the laboratory failed to meet analytic systems requirements for two of six laboratory's test platforms. Findings included: 1. The laboratory failed to have written protocols for performing instrument to instrument comparison for two of two in use Top Count instruments. (Refer to D5401) 2. The laboratory's Micronutrient Test-Precisions Test QC for Vitamin B12 failed the meet the laboratory's acceptability criteria. (Refer to D5481A) 3. The laboratory failed to follow its own protocols for acceptability of Micronutrient testing Harvest QC. (Refer to D5481B) 4. The laboratory failed to label secondary reagent containers used for the laboratory's micronutrient testing, with the contents' identity, preparation dates, and expiration dates. (Refer to D5415) 5. The laboratory failed to document number of piercings of control vials (required for verifying control stability) for Beckman Coulter hematology controls in use. (Refer to D5417A) 6. The laboratory failed to ensure reagents were not used beyond their expiration dates. (Refer to D5417B) 7. The laboratory failed to define the performance specifications for patient specimens collected in ACD tubes, modified specimen type, and acceptability criteria for establishment study results. (Refer to D5423) 8. The laboratory failed to document acceptable QC for monthly Isolation Comparison QC. (Refer to D5441A) 9. The

	laboratory failed to fully define the step-by-step QC process, acceptability criteria and requirements for documentation of new lot QC for inhouse prepared PHA-P (Phytohemagglutinin) reagent used in Micronutrient testing. (Refer to D5441B) 10. The laboratory failed to define in writing the process and acceptability criteria of new lot QC for inhouse prepared HEPES VWR (buffer) used in Micronutrient testing. (Refer to D5441C) 11. The laboratory failed to fully define and document individual steps for QC performance, QC statistical analysis and QC calculations of cell activity values used for acceptability criteria for inhouse prepared media used in Micronutrient testing. (Refer to D5469) 12. The laboratory's quality assurance failed to identify and correct issues with analytic aspects of testing. (Refer to D5791)
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 surveyor's observations, review of laboratory's policies procedures, random quality control (QC) records and staff interview the laboratory failed to have written protocols for performing instrument to instrument comparison for two of two in use Top Count instruments (used in Micronutrient testing) in 2024 and 2025, Top Count E and F. Findings included: 1. Surveyor's observations on 07/08/2025 at 0945 hours in the laboratory revealed the laboratory used two Top Count instruments, designated E and F, for determining patient's cell proliferation for its laboratory developed Micronutrient testing. 2. In an interview on 07/10/2025 at 1545 hours in the conference room TP1 (Testing Person number one - as indicated on submitted Form CMS 209) stated that Top Count comparison is performed using the "Micronutrient Test - Harvest QC" that compares the cell harvesting instruments, specifically, the "recount" portion compares the Top Counts' accuracy. 3. Review of laboratory's "Micronutrient Test - Harvest QC" policy (document: SPEC-MNT-HQC-POL-001 re. 1, last reviewed 11/23/23) revealed no reference of this protocol to performing instrument to instrument comparison for the Top Count instruments. 4. Review of laboratory's random "Daily Harvest QC" worksheets from July 2024 and June 2025 revealed that Top Count instruments were designated by numbers "4" and "5" on the worksheet instead of the designation "E" and "F" indicated on the instrument. There was no explanation of the correlation of numerical to letter designation for the instruments either in the policy or the worksheet. 5. In an interview on 07/10/2025 at 1545 hours in the conference room TP1 (Testing Person number one - as indicated on submitted Form CMS 209), after review of the policies and data, confirmed the findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 review of laboratory's personnel records, policies/procedures and staff interview the current Laboratory Director (LD) failed to sign and date two of twelve reviewed policies/procedures upon taking on his duties as LD in March 2025. Findings included: 1. Review of laboratory's personnel records revealed the current LD joined the facility in March 2025. 2. Review of laboratory's "Micronutrient Test - Harvest QC" policy (document: SPEC-MNT-HQC-POL-001 re.1) revealed it was last reviewed on 11/23/23 by previous LD. There was no signature and date of current LD documenting his approval of the policy. 3. Review of laboratory's policy "Wipe Test (swab test)" (effective 04/18/2023) revealed it did not have signature and date of current LD documenting his approval of the policy. 4. In an interview on 07/10/2025 at 1545 hours in the conference room TP7 (Testing Person number seven - as indicated on submitted Form CMS 209), after review of the policies and data, confirmed the findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, surveyor observation, and staff interview, the laboratory failed to have documentation of monitoring the temperature in the storage room where laboratory supplies for patient testing were stored for 181 of 181 days from January 1, 2025 to June 30, 2025. Findings include: 1. Surveyor observation of the laboratory on 7/8/25 at 10:45 a.m. revealed a storage room that stored the following laboratory supplies used for patient testing, with no documentation of temperature monitoring from January 1, 2025 to June 30, 2025: - 6, 666 BD Vacutainer ACD Solution A tubes - 618 Greiner Bio-One Vacuette 3 ml 9NC Coagulation sodium citrate 3.2% tubes - 300 Greiner Bio-One Vacuette 2 ml K2EDTA tubes - 500 BD Vacutainer SST tubes 2. A review of the manufacturer's instructions for the above listed supplies revealed the following temperature requirements: - BD Vacutainer ACD Solution A tubes- store between 4 - 25C - Greiner Bio-One Vacuette 3 ml 9NC Coagulation sodium citrate 3.2% tubes- store between 4 - 25C - Greiner Bio-One Vacuette 2 ml K2EDTA tubes- store between 4 - 25C - BD Vacutainer SST tubes- store between 4 - 25C 3. In an interview on 7/8/25 at 11:00 a.m. in the storage room, after review of the records, the CEO confirmed the above findings. Key: C = Degrees Celsius
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent

	information required for proper use. This STANDARD is not met as evidenced by: **NOTE**: This is a repeat deficiency from the survey completed on 11/02/2023. Based on surveyor's observations and staff interview, the laboratory failed to label two of two 500 mL bottles of MSG (Monosodium Glutamate), twenty-four of twenty-four 50mL opened conical tubes of aliquoted MSG, twenty-four of twenty-four 50mL opened conical tubes of Lymphoprep, and seventeen of seventeen one-gallon bottles of autoclaved water, used for the laboratory's micronutrient testing, with the contents' identity, preparation dates, and expiration dates. Findings included: 1. Surveyor's observations on 07/08/2025 at 0945 hours in the "Isolation" room revealed two medium sized closed bottles of pink solution, twenty-four open 50mL conical tubes with pink solution and twenty-four open 50mL conical tubes with clear solution sitting under the hood. None were labeled with contents' identity, preparation dates, and expiration date. When asked, TP8 (Testing Person number eight - as indicated on submitted Form CMS 209) identified the pink solution as MSG and the clear solution as Lymphoprep, solutions used for specimen processing. 2. Surveyor' observations on 07/08/2025 at 0955 hours in the Plate Preparation (Janus) room revealed seventeen one-gallon containers of clear solution. None were labeled with contents' identity, preparation dates, and expiration date. When asked, TP7 (Testing Person number seven) identified the clear solution as autoclaved water. 3. In an interview on 07/08 /2025 at 1000 hours in the laboratory TP7 (as indicated on submitted Form CMS 209) confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 surveyor's observation, a review of patient test records, and staff interview, the laboratory failed to ensure one of one patient tube had not exceeded its expiration date prior to using it for patient testing on July 8, 2025. Findings include: 1. Surveyor observation of the specimen receiving are in the laboratory on 7/8/25 at 11:40 a.m. revealed one blue top patient specimen tube had been received for Telomere testing. 2. Further observation of the patient specimen tube revealed the following: Patient ID: 2507080065 Vacuette ref # 454334 Lot: B2310337 Exp: 9/30/2024 3. A review of patient test records confirmed the expired patient specimen tube was used for Telomere testing and the test was resulted on 7/25/25. 4. In an interview on 7/11/25 at 1:05 a.m. in the conference room, after review of the records, the laboratory director confirmed the above findings. 44698 **NOTE**: This is a repeat deficiency from the survey completed on 11/02/2023. A. Based on surveyor's observations, review of manufacturer instructions and staff interview, the laboratory failed to document number of piercings of control vials (required for verifying control stability) for three of three Beckman Coulter hematology controls in use. Findings included: 1. Surveyor's observations on 07/09/2025 at 1125 hours in the laboratory revealed three vials of hematology controls in use, labeled only with an open date of 07/08/2025. These were: Control Level 1: Abnormal Low Lot: 352517311 Exp: 2025-08-05 Open date: 07/08/2025 Control Level 2: Normal Lot: 352517312 Exp: 2025-08-05 Open

	date: 07/08/2025 Control Level 1: Abnormal Hiogh Lot: 352517313 Exp: 2025-08-05 Open date: 07/08/2025 There was no documentation of how many times the vials were pierced to date. 2. Review of the Beckman Coulter hematology controls' instructions for use, "Table of Expected Results" (document C21336-AC) revealed: "Assumes that the Instructions for Use section of the Consumable IFU/ Setting Sheet is performed a maximum of 16 times within 16 days, provided they are handled properly." 3. In an interview on 07/09/2025 at 1125 hours in the laboratory, Testing Person number eight (as indicated on submitted Form CMS 209) confirmed the findings. B. Based on surveyor's observations and staff interview the laboratory failed to ensure reagents were not used beyond their expiration dates for four of four reagents /working solutions observed. Findings included: 1. Surveyor's observations on 07/08 /2025 at 1005 hours in the Media Preparation room revealed one in-use expired bottle of BioRad PBS (Phosphate Buffered Saline) solution (Batch:64445749, Expiration: 2024-10-07), used for media preparation, sitting on the countertop. 2. Surveyor's observations on 07/08/2025 at 1015 hours in the laboratory revealed the following expired nutrient working solutions stored in the freezer: Nutrient: CoQ10 Prepared: 05 /19/2025 Expired: 07/01/2025 Nutrient: Vitamin C Prepared: 05/19/2025 Expired: 07 /01/2025 Nutrient: Vitamin K2 Prepared: 05/19/2025 Expired: 07/01/2025 3. In an interview on 07/08/2025 at 1110 hours in the laboratory, Testing Person number seven (as indicated on submitted Form CMS 209) confirmed the findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: **NOTE**: This is a repeat deficiency from the survey completed on 11/02/2023. Based on review of laboratory's instructions to clients, manufacturer instructions for use, laboratory's policies/procedures, test establishment studies and staff interview, the laboratory failed to define the performance specifications for patient specimens collected in ACD tubes, modified specimen type, and acceptability criteria for establishment study results for one of one new instrument implemented in 2024 , the Beckman Coulter DxH 500 (serial number: BH050086), used in determination of lymphocyte content in laboratory developed Micronutrient (MNT) testing. Findings included: 1. Review of laboratory's instructions to clients for collection of samples for MNT testing revealed: Collection Tube: ACD (Acid Citrate Dextrose) Solution A (Yellow Top 8.5ml) Whole Blood. 2. Review of the manufacturer's "Instructions for Use" (Version: v2, document PN C42118AA, March 2019) for the Beckman Coulter DxH 500 instrument revealed: "All performance claims in this manual are based on data from specimens collected into the anticoagulants indicated below. The recommended anticoagulants are K2 or K3 EDTA." 3. Review of laboratory's procedure "Micronutrient Test - Isolation" (SOP-PROD-MNT-002 rev.2, last

	reviewed 03/18/2025) revealed the patient's whole blood sample in the ACD tube underwent modification to separate, wash and resuspend patient's lymphocytes prior to being tested on the Beckman Coulter DxH 500 instrument. Refer to master document attached. 4. Review of laboratory's test establishment studies for the Beckman Coulter DxH 500 instrument revealed the studies did not address the modifications to the manufacturer requirements for specimen type or transport tube. 5. Further review of the Beckman Coulter DxH 500 instrument's establishment studies revealed a set of results from 10/04/2024 with a %CV (Percent Coefficient of Variation) of 66.67% for WBC (white blood cell) counts and 100% for LY (lymphocyte count). The laboratory did not have a written plan for the establishment studies for the DxH 500 where an acceptable %CV was defined. It was unclear if this set of data was used for calculating precision and evaluating performance specifications. 6. In an interview on 07/09/2025 at 1000 hours in the laboratory, Testing Person number seven (as indicated on submitted Form CMS 209) confirmed the 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. This STANDARD is not met as evidenced by: **NOTE**: This is a repeat deficiency from the survey completed on 11/02/2023. A. Based on review of laboratory's policies/procedures, quality control (QC) records, patient test volumes and staff interview, the laboratory failed to document acceptable QC for two of six monthly Isolation Comparison QC from January to June 2025. Findings included: 1. Review of laboratory's policy "Micronutrient Test - Isolation Comparison" (document SPEC-MNT-ISOCOMP-POL-001 rev.1, last reviewed 03/18 /2025) revealed: "5.1 The Isolation Comparison QC will be performed monthly." 2. Review of laboratory's QC records from January to June 2025 revealed the laboratory did not have documentation of acceptable Isolation Comparison QC for two of the 6 months reviewed, January and February 2025. 3. Review of laboratory's patient test volumes revealed the laboratory performed on average 1,666 Isolation procedures per month. 4. In an interview on 07/10/2025 at 1545 hours in the conference room, Testing Person number one (as indicated on submitted Form CMS 209) confirmed the findings. B. Based on review of laboratory's quality control (QC) records, policies /procedures and staff interview, the laboratory failed to fully define the step-by-step QC process, acceptability criteria and requirements for documentation of new lot QC for one of four inhouse prepared reagents used in laboratory developed Micronutrient testing, the PHA-P (Phytohemagglutinin) reagent. Findings included: 1. Review of laboratory's QC records for the new lots of PHA-P revealed it was documented using "PHA-P Lot# Dosage Growth Response Curve Comparison" and/or "New PHA Source Comparison" worksheets. 2. Review of laboratory policy "PHA-P Lot# Dosage Growth Response Curve Comparison" (no document number, no review date)

revealed: "To determine the optimum dosage level for each new lot number of PHA-P received and to ensure that a comparable level of lymphocyte stimulation is achieved with each batch of media prepared regardless of the PHA-P lot number used." And, "The concentration of the new PHA-P Lot is determined by comparing the growth response of the current 100% media and the corresponding concentration of the new PHA-P lot. The acceptable ratio is between 90% and 110%." 3. Review of laboratory's "New PHA Source Comparison" worksheets revealed: "This worksheet is used to compare the new PHA concentrations vs the current PHA. Grater than 88% Average ratio is acceptable." 4. In an interview on 07/11/2025 at 0930 hours in the conference room, TP1 (Testing Person number one - as indicated on submitted Form CMS 209) when asked to explain the processes for new lot of PHA-P QC stated that: First, the new PHA-P lot is prepared at various concentrations and tested with 6 different patients against the current PHA-P lot. The growth response ratio (new to old lot) must fall between 90-110% to be acceptable. Second, the PHA-P concentrations of the new lot that have the growth response ratio falling between 90-110% were then compared again to the old lot by two separate TPs with three patients each using the "New PHA Source Comparison" worksheet. For this comparison, greater than 88% CV Average ratio is acceptable. 5. Further review of laboratory's policies procedures revealed there were no written instructions for performing the "New PHA Source Comparison" portion for different concentrations of PHA-P, nor acceptability criteria for which of the concentrations should be used if multiple concentrations have similar results. 6. The laboratory was asked to provide protocols for performing of "New PHA Source Comparison" on different concentrations of PHA-P and no such document was available for review. 7. A review of random QC records from January to April 2025 for the new lots of inhouse prepared PHA-P revealed there were inconsistencies in documentation. Sometimes only the Dosage Growth Response Curve worksheet was used, other times only the PHA Source Comparison worksheet was used. There was no documentation of the current PHA-P lot the new lot was compared to, and not all PHA Curve studies' or PHA Source Comparison worksheets had documented conclusion as to which concentration is being placed in use. The data was presented as follows: Dosage Growth Response Curve: acceptable ratio 90% -110%. Batch: B250103 Date: 01/17/2025 PHA curve for lot# 0000306265 evaluation (there was no documentation of current lot #) Comment and conclusion: "1. Results showed_____ mcg/ml is the best concentration." - was left blank. Batch: B240104 Date: 01/17/2025 PHA curve for lot# 0000306265 evaluation (there was no documentation of current lot #) Comment and conclusion: "1. Results showed _____ mcg/ml is the best concentration." - was left blank. Two concentrations of new PHA-P were within the 90-110% acceptable CV: 0.5 mcg/ml: CV 96% 0.75 mcg/ml: CV 107% There was no documentation of PHA Source Comparison to determine which concentration was chosen for use. PHA Source Comparison: Average acceptable ratio greater than 88% CV Batch: 250314 Worksheet date: 04/03/2025 There was no documentation of PHA curve Comparison for this batch. No new vs. old PHA-P lot numbers were documented on the worksheet. There was no designation of which concentrations of new lor PHA-P were tested. Results were: Plate 9989: % Ratio New /Old = 70 Plate 9990: % Ratio New/Old = 122 Plate 9993: % Ratio New/Old = 97 Plate 9994: % Ratio New/Old = 75 Plate 9964: % Ratio New/Old = 100 Plate 9965: % Ratio New/Old = 128 Comment: "Due to patient issue, 4/6 passed." There was no documentation of which set of data was used for acceptability criteria or which concentration of new lot PHA-P was accepted for use. 8. In an interview on 07/11 /2025 at 1030 hours in the conference room, TP1 confirmed the findings. C. Based on review of laboratory's quality control (QC) records, policies/procedures and staff interview, the laboratory failed to define in writing the process and acceptability criteria of new lot QC for one of four inhouse prepared reagents used in Micronutrient

	testing, HEPES VWR (buffer). Findings included: 1. Review of laboratory's QC records for the new lots of HEPES VWR revealed it was documented using the "HEPES VWR Lot Comparison" worksheets. 2. Review of laboratory's policies /procedures and worksheets revealed there were no written protocols in place for performing HEPES VWR QC. The "HEPES VWR Lot Comparison" worksheet did not specify procedural steps or acceptability criteria. 3. In an interview on 07/11/2025 at 1110 hours in the conference room, Testing Person number one (as indicated on submitted Form CMS 209), stated that QC for new lot of HEPES VWT solutions was performed the same way as the one for PHA-P solution, but the policy for HEPES VWR QC could not be located. This confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, quality control (QC) records and staff interview, the laboratory failed to fully define and document individual steps for QC performance, QC statistical analysis (accounting for extreme variability of results in cell activity percentage) and QC calculations of cell activity values used for acceptability criteria for inhouse prepared media used in one of three laboratory developed tests performed in 2024 and 2025, Micronutrient Test. Findings included: 1. Review of laboratory's policy "Micronutrient Test -Media Test Policy" (document SPEC-MNT-MT-POL-001 rev.1, last reviewed 03/18/2025) revealed: "The purpose of the Media Test is to demonstrate the reproducibility of the culture media between batch to batch and determine the media technicians' competency." And, "5.1 ...The Micronutrient test depends on relative lymphocyte proliferation in different (nutritional) conditions. Therefore, a proprietary media is made with a mix of nutrient materials and mitogens to encourage lymphocytes to proliferate outside human lymph nodes." And, "The Media Test will be performed every new batch of Media prepared." And, "5.6 The Media Test will be based on 12 different samples, each sample being used for a Plate 1 and 2 using the current approved media and another Plate 1 and 2 using the new batch of media being evaluated." And, "5.9 There is an individual score for each analyte in the media test using the cell growth from the new media lot made and the current media lot being used. 5.10 There are a total of 12 sets of plates being compared. For each analyte the %(percent) cell growth is calculated by taking the % new media growth and dividing it by the % current media growth and multiplying by 100. 5.11 The 12 sets of plates average % cell growth are calculated for each analyte 5.12 A score of 87.5% - 112.5% must be obtained to be considered acceptable." 2. Review of laboratory's QC "Media Test Validation Sheet Edited Data" worksheets revealed: "To determine acceptable media, calculate the percent cell growth activity using the following formula (% new media/ % current media)x 100 for each nutrient. Minimal to no growth plates (100% count ,1001) may be excluded.

	Using any 3 or more %-cell growth results from acceptable plates, calculate the average for each component nutrient. The average must exhibit +/- 12.5% cell growth activity of the previous lot # media (87.5% - 112.5%). Up to three plates with poor duplication among triplicate wells may be excluded at the discretion of the laboratory manager." 3. Review of laboratory's QC records for new lots of Media revealed the following variability in obtained cell activity % for Vitamin B2 nutrient media: Lot#: 3 /20/2025 Compared to lot: 03/12/2025 Component: Vitamin B2 Sample 14: 60.8% Sample 15: 106.5% Sample 16: 87.7% Sample 17: 121.9% Sample 19: 53.1% Sample 23: 114.0% Sample 25: 84.8% Sample 27: 81.9% Sample 31: 68.0% Sample 32: 110.4% Sample 33: 76.7% Sample 34: 116.0% The documented calculated cell activity Average for this media was 96.6%. There was no documentation of which values were used for calculating the Average acceptability of cell activity %, or which samples were excluded. There was no evaluation of why there was such large variability in individual samples cell activity % (ranging from 53.1% to 121.9%), considering both plates (new and old media lots) were prepared with the same patient sample, same lymphocyte population and proliferation capability. 4. Review of laboratory's QC records for new lots of Media revealed the following variability in obtained cell activity % for Vitamin B12 nutrient media: Lot#: 10/24/2022 Compared to lot: "?" (not documented) Component: Vitamin B12 Sample 99: no result was calculated - left blank (New lot value of 43/current lot value of 18 = 2.388 x100 = 238.8%) Sample 101: 40.5% Sample 105: 84.2% Sample 106: 103.3% Sample 115: 67.9% Sample 116: 61.7% Sample 118: 132.2% Sample 119: 108.2% Sample 123: no result was calculated - left blank (New lot cell activity of 140/current lot cell activity of 63 = 2.222 x100 = 222.2%) Sample 124: 96.6% Sample 130: 164.6% Sample 131: 150.3% The documented calculated cell activity Average for this media was 101.0%. There was no documentation of which values were used for calculating the Average acceptability of cell activity %, or which samples were excluded. There was no evaluation of why there was such large variability in individual samples cell activity % (ranging from 40.5% to 238.8%), considering both plates (new and old media lots) were prepared with the same patient sample, thus same lymphocyte population and proliferation capability. 5. In an interview on 07/10/2025 at 1545 hours in the conference room, Testing Person number one (as indicated on submitted Form CMS 209) confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of laboratory's policies/procedures, quality control (QC) records and staff interview, the laboratory's Micronutrient Test-Precisions Test QC for Vitamin B12 failed the meet the laboratory's acceptability criteria for one of fourteen weeks reviewed from March to June 2025. Findings included: 1. Review of laboratory's "Micronutrient Test - Precision Test Policy" (document SPEC-MNT-PREC-POL-001 rev.1, last reviewed 03/15/2025) revealed: "5.7 A CV score of 20% percent(sic) or lower must be obtained to be considered acceptable." 2. Review of Micronutrient Test weekly precision test QC worksheets from March to June 2025 revealed this QC was performed in duplicate by two different testing personnel (TP), and the following one of fourteen weeks reviewed Vitamin B12 CV exceeded 20% for

	both TPs: Date: 05/29/2025 Batch: 250529 TP1: CV = 89.35 TP2: CV = 72.00 3. In an interview on 07/10/2025 at 1545 hours in the conference room, Testing Person number one (as indicated on submitted Form CMS 209) confirmed the findings. B. Based on review of laboratory's policies procedures, random quality control (QC) records and staff interview the laboratory failed to follow its own protocols for acceptability of Harvest QC for four of four instances CV (Coefficient of Variation) was above the required value, 20%. Findings included: 1. Review of laboratory's "Micronutrient Test - Harvest QC" policy (document: SPEC-MNT-HQC-POL-001 re. 1, last reviewed 11/23/23) revealed: "The HQC will be based using 100% media plates from 2 isolation technicians each using a single specimen." And, "5.6 A CV score of 20% or less must be obtained for the harvester to be used on patient samples. 5.7 A harvester with a score higher than 20% will need to have second HQC performed." The policy did not specify individual steps of the HQC procedure, required calculations, or which CV values (original reading, recount or average) were part of the acceptability criteria. 2. Review of random Daily Harvest QC records from July 2024 revealed the following CV values were outside the 20% CV requirements: Date:07/03/2024 Harvester #4(number 4): TC Recount CV = 20.51 (Tech 2) Harvester #5: CV = 22.38 (Tech 2) Harvester #4: TC Recount CV = 21.77 (Tech 2) There was no documentation of a second HQC performed (per the policy). Date: 07/04 /2024 Harvester #4: CV=20.34 (Tech 1) There was no documentation of a second HQC performed (per the policy). 3. In an interview on 07/10/2025 at 1545 hours in the conference room TP1 (Testing Person number one - as indicated on submitted Form CMS 209), after review of the policies and 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. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's policies/procedures, new instrument verification studies, quality control records/quality assurance records and staff interview, the laboratory's quality assurance failed to identify and correct issues with four of four analytic aspects of testing: 1. Unlabeled reagents' secondary containers. (Refer to D5415) 2. Amending expiration dates and expired reagents /working solutions in use. (Refer to D5417A and B) 3. New instrument verification studies. (Refer to D5423) 4. Quality control performance, evaluation and documentation. (Refer to D5441A, B, C, 5469 and D5481A and B)
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 a review of the laboratory's records, the laboratory's personnel records, and staff interview, the laboratory director failed to provide overall management of the

	laboratory for five of five high complexity tests performed in 2024 and 2025. Findings include: 1. The laboratory director failed to ensure verification procedures were adequate for one of one new instrument implemented in 2024, the DxH 500 hematology analyzer. (Refer to D6083) 2. The laboratory director failed to ensure the proficiency testing results for two of six events in 2025 were evaluated. (Refer to D6091) 3. The laboratory director failed to ensure test systems quality assurance is maintained for two of three aspects of test performance, preanalytic and analytic. (Refer to D6093) 4. The laboratory director failed to ensure testing personnel had documentation of training and education to qualify them to perform high complexity testing on patient specimens. (Refer to D6102) 5. The laboratory director failed to ensure procedures were established to assess the competency of laboratory personnel for high complexity testing performed in 2024 and 2025. (Refer to D6103)
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on review of laboratory's new instrument verification studies and staff interview, the laboratory director failed to ensure verification procedures were adequate for one of one new instrument implemented in 2024, the DxH 500 hematology analyzer. (Refer to D5423)
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists (CAP) proficiency testing results from 2025 and staff interview, the laboratory director failed to ensure the proficiency testing results for two of six events in 2025 were evaluated. Findings include: 1. The laboratory failed to have documentation of evaluating the proficiency testing results for two of six events in 2025. (Refer to D5211)
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 surveyor's observations, review of laboratory's policies/procedures, new instrument verification studies, quality control records/quality assurance records and staff interview, the laboratory director failed to ensure test systems quality assurance

	is maintained for two of three aspects of test performance, preanalytic and analytic. (Refer to D5791)
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) 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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory director failed to ensure the following: a) two of ten testing personnel had documentation of education to qualify them to perform high complexity testing on patient specimens from November 2024 to July 2025. b) two of ten testing personnel had documentation of training for high complexity testing on patient specimens from November 2024 to July 2025. Findings include: 1. A review of the laboratory's submitted CMS-209 form listed 10 testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have the following: a) Documentation of education for the following 2 testing personnel that met the qualifications of a high complexity testing person: - Testing person #5 - hired for patient testing in November 2024 - Testing person #10 - hired for patient testing in March 2025 b) Documentation of training for high complexity testing on patient specimens from November 2024 to July 2025: - Testing person #2 - hired for patient testing in March 2025- missing training for Janus testing - Testing person #5 - hired for patient testing in November 2024- missing training for Telomere testing 3. In an interview on 7/10/25 at 9:40 a.m. in the office, after review of the records, the human resources employee confirmed the above findings. **NOTE** This is a repeat deficiency from the survey performed in November 2023.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, the laboratory director failed to ensure procedures were established to assess the competency of laboratory personnel for high complexity testing performed in 2024 and 2025. (Refer to D5209)
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's validation studies for the Beckman Coulter DxH 500 hematology analyzer, the laboratory's personnel files, and staff interview, the technical supervisor failed to ensure three of three testing personnel received training and evaluated their competency on a new hematology analyzer in October 2024. Findings include: 1. A review of the laboratory's validation studies revealed the laboratory received a new instrument, a Beckman Coulter DxH 500 hematology analyzer in October 2024. 2. A review of the laboratory's personnel files revealed that testing performance for the DxH 500 had not been evaluated and documented prior to reporting patient test results for the following 3 testing personnel (as indicated on the CMS 209 form): - Testing person #1 - Testing person #3 - Testing person #8 3. In an interview on 7/9/25 at 3:00 p.m. in the laboratory, after review of the records, testing person #7 confirmed the above findings. B. Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, the laboratory failed to have documentation of the technical supervisor performing competency assessments for four of ten testing personnel for high complexity testing in 2024. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 10 testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed that the laboratory failed to have documentation of the technical supervisor performing competency assessment for the following 4 testing personnel in 2024: a) Testing person #1 - Personnel Assessment LPP & Chemistry Department for 2024 b) Testing person #3 - Personnel Assessment- Micronutrient (MNT): Isolation Department for 2024 c) Testing person #4 - Personnel Assessment LPP & Chemistry Department for 2024 d) Testing person #9 - Personnel Assessment- Micronutrient (MNT): Media Department for 2024 3. In an interview on 7/10/25 at 2:40 p.m. in the laboratory, after review of the records, testing person #3 (as indicated on the CMS 209 form) confirmed the above findings. **NOTE** This is a repeat deficiency from the survey performed in November 2023.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of education to qualify two of ten testing personnel to perform high complexity testing from November 2024 to July 2025. (Refer to D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to ensure two of ten testing personnel met the requirements to perform high complexity testing from November 2024 to July 2025. Findings include: 1. A review of the laboratory's submitted CMS-209 form listed 10 testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for the following 2 testing personnel that met the qualifications of a high complexity testing person: - Testing person #5 - hired for patient testing in November 2024 - Testing person #10 - hired for patient testing in March 2025 3. In an interview on 7/10/25 at 9:40 a.m. in the office, after review of the records, the human resources employee confirmed the above findings.