Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0253791	10/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Allendale County Hospital	1787 Allendale-Fairfax Highway, Fairfax, SC	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, and interview with testing personnel (TP1), the laboratory failed to monitor storage temperature for reagents and tubes used for patient testing for 34 of 34 months. Findings include: 1. Observation on 10/07/2024 at 3:00 pm identified reagents stored in blood draw room and storage room without a thermometer. 2. On 10/07/2024, reviews of manufacturer's instructions required room temperature requirement as follows: 15-30 Celsius (C) for the following: a. 1 box, Quidel, QuickVue+ Strep A Test, Lot#709411 expiration(exp) 05-14-2025 b. 2 boxes, Quidel, Sofia SARS Antigen FIA, Lot#709161 exp. 02-28-2025 c. 2 boxes, Quidel, Sofia Influenza A+B FIA, Lot#709197 exp. 08-06-2025 d. 1 box, Quidel, QuickVue+ RSV Test, Lot#709663 exp. 06-16-2025 e. 1 box, Para-Pak CLEAN, Lot#507710Q exp. 09-01-2030 15-30C for the following: f. 4 boxes, Sure-Vue, Serum/Urine hCG-STAT, Lot#0000698356 exp. 03-15-2025 g. 1 box, Para-Pak C&S, Lot#516140Q exp. 04-19-2025 4 -25C for the following: h. 7 packs of BD Vacutainer K2 EDTA (Purple) Blood collection Tubes, Lot# 3 4137171 exp. 09-30-25. i. 2 packs of BD Vacutainer SST (Gold) Blood collection Tubes, Lot # 4046162 exp. 01-31-2025 j. 2 packs of BD Vacutainer (Red) Serum Blood collection Tubes, Lot# 4198161 exp. 07-31-2026 k. 3 packs of BD Vacutainer (Yellow) Sodium Polyanetholesulfonate Blood Collection Tubes for Microbiological Studies, Lot # 4102217 exp. 04-30-2025 l. 1 pack of BD Vacutainer (Grey) Sodium Fluoride 10mg Potassium Oxalate 8mg Blood Collection Tubes, Lot# 4166522 exp. 10-31-2025 m. 13 packs of Vacuette Tube (Green) 3.5 LH Lithium Heparin, Lot# B240534U exp. 07-31-2025 n. 15 packs of Vacuette Tube 3.5ml (Red)

	CAT Serum Sep Clot Activator, Lot# B240833F exp.10-31-2025 3. On 10/07/24, review of the laboratory environmental records revealed no documentation of room temperature monitoring of blood draw room or storage room. 4. An interview on 10/07 /2024 at 3:50 pm with the CEO and TP1 confirmed the findings above.
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 review of laboratory policies and procedures, lack of laboratory records, and interview, the laboratory failed to follow written policies and procedures to assess the competency of nine out of ten testing personnel in 2022, four out of ten in 2023, and eight out of ten to the date of the survey in 2024. Findings included: 1. Review of policies and procedures titled "Technical Personnel Competency" states "laboratory testing and reporting is evaluated and documented at least semiannually during the first year of employment and at least once annually thereafter". The documents titled Laboratory/Blood Bank Technical Competency failed to indicate semiannually or annually. 2. Review of Laboratory/Blood Bank Technical Competency records revealed a lack of documentation for four out of ten testing personnel. Reviewed 26 out of 26 months (2022, 2023, and 2024). 3. In an interview on 10/07/2024 at 3:50 pm with CEO and TP 1 confirmed the findings above.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of policies and procedures, lack of documentation and interviews with TP1 and the Chief Executive Officer (CEO), the laboratory failed to verify the accuracy of urine sediment examinations, and cerebrospinal fluid (CSF) cell counts for three of three years. Findings include: 1. On 10/07/24 at 1:00 pm, testing person TP1 stated the laboratory performed urine sediment examinations, and cerebrospinal fluid (CSF) cell counts. 2. A review of policies and procedures titled "Analysis of Cerebrospinal Fluid (SCF)" revealed that the laboratory perform microscopic analysis. 3. On 10/07/24, review of test accuracy verification documentation revealed no evidence of twice a year accuracy for urine sediment examinations, and CSF cell counts during 2022, 2023, and 2024. 4. In an interview at 3:50 pm on 10/07/2024 with the CEO and TP1 confirmed the findings above.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a)

The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses

qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:
Based on a review of the CMS 209 personnel form and interview with TP1 and CEO, the laboratory failed to have a qualified laboratory director for moderate complexity testing for five of five months. Findings included: 1. On 10/07/2024 at 1:00 pm TP1 confirmed the labortaory performed the following moderate compelexity testing: a. Lipid Panel b. Basic Metabolic Panel (BMP) c. Complete Blood Count (CBC) d. Coagulation (Prothrombin Time (PT/INR), Partial Thromboplastin Time (PPT), D-Dimer) e. Troponin I, f. Urine Toxicology Screen, 9 Panel Test 1. Amphetamines 2. Barbituates 3. Benzodiazepines 4. Cannabinoids 5. Cocaine 6. Methadone 7. Opiates 8. Phencyclidine 9. Tricyclic antidepressants g. CBC with diff, h. Renal Panel i. Sed Rate j. Iron/TIBC k. Triiodothyronine (T3 uptake) l. Thyroxine (T4) m Vitamin .B12, n. Reticulocyte Count o. Vitamin D p. Urinalysis, (Macroscopic (Dipstick), Microscopic) q. Creatine phosphokinase-MB (CPK-MB) r. Beta HCG Quantitative s. Thyroid-Stimulating Hormone (TSH) t. Free throxine (Free T4) u. PSA Screen/Total v. Parathyroid Hormone (PTH) w. Folate x. Ferritin y. Comprehensive Metabolic Panel (CMP) z. Hepatic Function Panel AA. Gamma-Glutamyl Transferase (GGT) BB. Lactate Dehydrogenase (LDH) CC. Transferrin DD. Uric Acid EE. Amylase FF. Lipase GG. Phoshorous HH. Maganesium II. C-Reactive Protein JJ. Ammonia KK. Lactic Acid LL. Digoxin MM.Dilantin NN. Theophylline OO. Phenobarbital PP. Valproic Acid QQ. Gentamycin RR. Vancomycin SS. Carbamazepine TT. Acetaminophen UU. Salicylate VV. Ethonol (ETOH) WW.Microalbumin XX. Urine Chemistries YY. B-type Natriuretic Peptide (BNP) 2. On 10/07/24, record review of patient testing revealed patient testing was performed from 04/01/24 through 10/07

/24. Examples of patient testing include: Patient Identifier Test Date of patient test 1. 0403:C00012R Vitamin B12 04/03/2024 Free T4 TSH 0403:CG0003R PT/INR 04/03 /2024 2. 0409:C0006R Sodium (NA) 04/09/2024 Potassium (K) Chloride (CL) Carbon Monoxide (CO) ANION GAP (calculation) Blood urea nitrogen (BUN) Creatinine (Creat) Glomerular filtration rate GFR (calculation) Glucose (Glu) Calcium (CA) Total Bilirubin Aspartate transferase (AST) Alanine Transaminase (ALT) Total Protein (TP) Vitamin D25 OH Albumin (Alb) Triglycerides (Trig) Cholesterol (Chol) High-density lipoprotein (HDL) Low-density lipoprotein (Clac LDL) Very Low-density lipoprotein (VLDL) Total Cholesterol/HDL= Ratio Alkaline phosphatase (Alk Phos) Thyroxine (T4) Triiodothyronine (T3 Uptake) Thyroid-stimulating hormone (TSH) 0409:C0007R Hemoglobin A1C (HGB A1C) 3. 0413: H00004S White Blood Cells (WBC) 04/13/2024 Red Blood Cells (RBC) HGB (Hemoglobin) Hematocrit (HCT) Mean corpuscular volume (MCV) Mean corpuscular hemoglobin (MCH) Mean Corpuscular Hemoglobin Concentration (MCHC) Platelet (Plt) w/Cell Count Differential Neutrophils percent Automated (Neut Pct Auto) Lymphocytes percent Automated (Lymph Pct Auto) Monocytes percent Automated (Mono Pct Auto) Eosinophils percent Automated (Eos Pct Auto) Basophils percent Automated (Baso Pct Auto) Immature Granulocytes percent Automated (Imm Gran Pct Au) 0413:U00004S Urine (Ur) Color Ur Clarity Ur pH Ur SG Ur Protein (Prot) Ur Glucose (Glu UA) Ur Ketones (Keto) Ur Occult Blood (Oclt Bld) Ur Nitrite Ur Bilirubin Ur Urobilinogen (Uro) Ur Leukocyte esterase (Leu Esterase) Ur Red Blood Cells (RBC) Ur White Blood Cells (WBC) Ur Squamous Epithelial Cells (Suam Epi) Ur Bacteria (Bact) 0413:C00004S Sodium (NA) 04/13/2024 Potassium (K) Chloride (CL) Carbon Monoxide (CO) ANION GAP (calculation) Blood urea nitrogen (BUN) Creatinine (Creat) Glomerular filtration rate GFR (calculation) Glucose (Glu) Calcium (CA) Total Bilirubin Aspartate transferase (AST) Alanine Transaminase (ALT) Total Protein (TP) Vitamin D25 OH Albumin (Alb) Triglycerides (Trig) Cholesterol (Chol) High-density lipoprotein (HDL) Low-density lipoprotein (Clac LDL) Very Low-density lipoprotein (VLDL) Total Cholesterol/HDL= Ratio Alkaline phosphatase (Alk Phos) 4. 0423:H00010S WBC 04/23/2024 RBC HGB HCT MCV MCH MCHC PLT w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Au 5. 0503:C00009R Total Bilirubin 05/03/2024 Direct Bilirubin (Bili) AST Alt TP Alb Alk Phos 6. 0507:H00029S WBC 05/07/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Au 0507:IM00003S COVID-19 05/08/2024 7. 0509:H00009R White Blood Cells (WBC) 05/09/2024 Red Blood Cells (RBC) HGB (Hemoglobin) Hematocrit (HCT) Mean corpuscular volume (MCV) Mean corpuscular hemoglobin (MCH) Mean Corpuscular Hemoglobin Concentration (MCHC) Platelet (Plt)r 0509:C00011R Sodium (NA) 05 /09/2024 Potassium (K) Chloride (CL) Carbon Monoxide (CO) ANION GAP (calculation) Blood urea nitrogen (BUN) Creatinine (Creat) Glomerular filtration rate GFR (calculation) Glucose (Glu) Calcium (CA) Iron (FE) Transferrin Ferritin Total Bilirubin Aspartate transferase (AST) Alanine Transaminase (ALT) B-type Natriuretic Peptide (BNP) Total Protein (TP) Vitamin D25 OH Albumin (Alb) Triglycerides (Trig) Cholesterol (Chol) High-density lipoprotein (HDL) Low-density lipoprotein (Clac LDL) Very Low-density lipoprotein (VLDL) Total Cholesterol /HDL= Ratio Alkaline phosphatase (Alk Phos) Vitamin B12 TSH 8. 0514:C00035R NA 05/14/2024 K CL CO2 Gap BUN Create GFR Glu CA Total Bilirubin AST Alt CK TP Alb Alk Phos 0514:H00023R WBC 05/14/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Auto 9. 0604:U00007S Urine (Ur) Color 06/04 /2024 Ur Clarity Ur pH Ur SG Ur Protein (Prot) Ur Glucose (Glu UA) Ur Ketones (Keto) Ur Occult Blood (Oclt Bld) Ur Nitrite Ur Bilirubin Ur Urobilinogen (Uro) Ur

Leukocyte esterase (Leu Esterase) Ur Red Blood Cells (RBC) Ur White Blood Cells (WBC) Ur Squamous Epithelial Cells (Suam Epi) Ur Bacteria (Bact) Ur Pregnancy 10. 0609:C00006R BNP 06/09/2024 0609:C00007R NA 06/09/2024 K CL CO2 Gap BUN Create GFR Glu CA Total Bilirubin AST Alt TP Alb Alk Phos 0609:H00005R WBC 06/09/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Auto 11. 0610:CG0004R PT/INR 06/10/2024 12. 0610:C00001R NA 06/10 /2024 K CL CO2 Gap BUN Create GFR Glu CA Total Bilirubin AST Alt TP Alb Alk Phos 0610:H00001R WBC 06/10/2024 RBC HGB HCT MCV MCH MCHC Plt w /Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Auto 13. 0704:C00005R NA 07/04/2024 K CL CO2 Gap BUN Create GFR Glu CA Phos MG FE TIBC Percent Iron Saturation (Pct FE Sat) Transferrin Ferritin Alt Alb Trig Chol HDL Calc LDL VLDL Chol HDL Ratio 0704:H00005R WBC 07/04/2024 RBC HGB HCT MCV MCH MCHC Plt 0704: U00002R Ur Create Ur Microalb Ur Microalb Cre 14. 0705:C00011R TSH 07/05 /2024 NA 07/05/2024 K CL CO2 Gap BUN Create GFR Glu CA Phos MG FE TIBC Pct FE Sat Transferrin Ferritin Total Bilirubin Folate AST TP Vitamin D25 OH Alt Alb Trig Chol HDL Calc LDL VLDL Chol HDL Ratio Alk Phos B12 T4 T3 Uptake 15. 0705:C00012R HGB A1C 16. 0705:H0007R WBC 07/05/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Auto Retic Count 0705: U00004R Ur Color 07/05/2024 Ur Clarity Ur pH Ur SG Ur Prot Ur Glu UA Ur Keto Ur Oclt Bld 17. 0711:H00001S WBC 07/11/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Auto 18. 0711:C00011R NA 07/0/2024 K CL CO2 Gap BUN Create GFR Glu CA Total Bilirubin Folate AST TP Alt Alb Alk Phos Lip Free T4 T4 T3 Uptake TSH 0711:H00010R WBC 07/11/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Auto 19. 0812:H00007R WBC 08/12/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Auto 20. 0812:C00008R NA 08/12/2024 K CL CO2 Gap BUN Create GFR Glu Uric CA Total Bilirubin AST TP Alt Alb Trig Chol HDL Calc LDL VLDL Chol HDL Ratio Alk Phos PSA Scrn TSH 21. 0806:C00012R NA 08/12/2024 K CL CO2 Gap BUN Create GFR Glu 22. 0806:C00012R NA 08/06/2024 K CL CO2 Gap BUN Create GFR Glu CA Phos Alb Parathyroid Hormone (Para Horm Intac) 23. 0806: H00008R WBC 08/06/2024 RBC HGB HCT MCV MCH MCHC Plt 0806:U0003R Ur Creat Ur Microalb Ur Microalb Cre 24. 0813:H00002R WBC 08/13/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Au 0813:C00002R NA 08/13/2024 K CL CO2 Gap BUN Create GFR Glu CA Total Bilirubin AST TP Alt Alb Alk Phos 0813:H00012S Retic Count 0813:C00015S FE 08/13/2024 TIBC Pct FE Sat Transferrin Folate B12 25. 0802:H00002S WBC 08/02/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Au 0802:C00002S NA 08 /02/2024 K CL CO2 Gap BUN Create GFR Glu CA Total Bilirubin AST TP Alt Alb Alk Phos 26. 0903:C00006R HGB A1C 09/03/2024 0903:c00007R NA 09/03/2024 K CL CO2 Gap BUN Create GFR Glu CA Total Bilirubin AST TP Alt Alb Trig Chol HDL Calc LDL VLDL Chol HDL Ratio Alk Phos TSH 0903:H00006R WBC 09/03 /2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Au 27. 0911:H00003R WBC 09/11/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct

	Auto Imm Gran Pct Au 0911:C00004R NA 09/11/2024 K CL CO2 Gap BUN Create GFR Glu CA Total Bilirubin AST TP Alt Alb Alk Phos 28. 0906:H00014S WBC 09 /06/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Au 0906:C00023S NA 09/06/2024 K CL CO2 Gap BUN Creat GFR Glu CA Total Bilirubin AST TP Alt Alb 29. 0927:H00002S WBC 09/27/2024 RBC HGB HCT MCV MCH MCHC Plt w/Cell count different Neut Pct Auto Lymph Pct Auto Mono Pct Auto Eos Pct Auto Baso Pct Auto Imm Gran Pct Au 0927:C00002S NA 09/27 /2024 K CL CO2 Gap BUN Create GFR Glu CA Total Bilirubin AST TP Alt Alb Alk Phos 3. Interview on 10/07/2024 at 1:00 pm with the CEO and TP1 confirmed the laboratory failed to have a qualified laboratory director for moderate complexity testing for five of five months.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the CMS 209 personnel form and interview with TP1 and CEO, the laboratory failed to have a qualified technical consultant for moderate complexity testing for five of five months. Findings include: 1. On 10/07/2024 a review of the CMS 209 personnel form revealed the laboratory failed to have a qualified technical consultant for moderate complexity testing for five of five months. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived

	testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of the CMS 209 personnel form and interview with TP1 and CEO, the laboratory failed to have a qualified technical consultant for moderate complexity testing for five of five months. Findings include: 1. On 10/07/2024 at 1:00 pm, testing person TP1 confirmed the laboratory performed the following moderate complexity testing: a. Lipid Panel b. Basic Metabolic Panel (BMP) c. Complete Blood Count (CBC) d. Coagulation (Prothrombin Time (PT INR), Partial Thromboplastin Time (PPT), D-Dimer) e. Troponin I, f. Urine Toxicology Screen, 9 Panel Test 1. Amphetamines 2. Barbiturates 3. Benzodiazepines 4. Cannabinoids 5. Cocaine 6. Methadone 7. Opiates 8. Phencyclidine 9. Tricyclic antidepressants g. CBC with diff h. Renal Panel i. Sed Rate j. Iron/TIBC k. Triiodothyronine (T3 uptake) l. Thyroxine (T4) m Vitamin. B12 n. Reticulocyte Count o. Vitamin D p. Urinalysis, (Macroscopic (Dipstick), Microscopic) q. Creatine phosphokinase-MB (CPK-MB) r. Beta HCG Quantitative s. Thyroid-Stimulating Hormone (TSH) t. Free thyroxine (Free T4) u. PSA Screen/Total v. Parathyroid Hormone (PTH) w. Folate x. Ferritin y. Comprehensive Metabolic Panel (CMP) z. Hepatic Function Panel AA. Gamma-Glutamyl Transferase (GGT) BB. Lactate Dehydrogenase (LDH) CC. Transferrin DD. Uric Acid EE. Amylase FF. Lipase GG. Phosphorous HH. Magnesium II. C-Reactive Protein JJ. Ammonia KK. Lactic Acid LL. Digoxin MM. Dilantin NN. Theophylline OO. Phenobarbital PP. Valproic Acid QQ. Gentamycin RR. Vancomycin SS. Carbamazepine TT. Acetaminophen UU. Salicylate VV. Ethanol (ETOH) WW. Microalbumin XX. Urine Chemistries YY. B-type Natriuretic Peptide (BNP) 2. On 10 /07/2024 a review of the CMS 209 personnel form revealed the laboratory failed to have a qualified technical consultant for moderate complexity testing for five of five months (from 04/01/24 through 10/07/24). 3. Interview on 10/07/2024 at 1:00 pm with the CEO and TP1 confirmed the laboratory failed to have a qualified technical consultant for moderate complexity testing for five of five months.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on a review of the CMS 209 personnel form and interview with TP1 and CEO, the laboratory failed to have a qualified clinical consultant for moderate complexity testing for five of five months. Findings include: 1. On 10/07/2024 a review of the CMS 209 personnel form revealed the laboratory failed to have a qualified clinical consultant for moderate complexity testing for five of five months. Refer to D6057

D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on a review of the CMS 209 personnel form and interview with TP1 and CEO, the laboratory failed to have a qualified clinical consultant for moderate complexity testing for five of five months. Findings include: 1. On 10/07/2024 at 1:00 pm, testing person TP1 confirmed the laboratory performed the following moderate complexity testing: a. Lipid Panel b. Basic Metabolic Panel (BMP) c. Complete Blood Count (CBC) d. Coagulation (Prothrombin Time (PT INR), Partial Thromboplastin Time (PPT), D-Dimer) e. Troponin I, f. Urine Toxicology Screen, 9 Panel Test 1. Amphetamines 2. Barbiturates 3. Benzodiazepines 4. Cannabinoids 5. Cocaine 6. Methadone 7. Opiates 8. Phencyclidine 9. Tricyclic antidepressants g. CBC with diff h. Renal Panel i. Sed Rate j. Iron/TIBC k. Triiodothyronine (T3 uptake) l. Thyroxine (T4) m Vitamin. B12 n. Reticulocyte Count o. Vitamin D p. Urinalysis, (Macroscopic (Dipstick), Microscopic) q. Creatine phosphokinase-MB (CPK-MB) r. Beta HCG Quantitative s. Thyroid-Stimulating Hormone (TSH) t. Free thyroxine (Free T4) u. PSA Screen/Total v. Parathyroid Hormone (PTH) w. Folate x. Ferritin y. Comprehensive Metabolic Panel (CMP) z. Hepatic Function Panel AA. Gamma-Glutamyl Transferase (GGT) BB. Lactate Dehydrogenase (LDH) CC. Transferrin DD. Uric Acid EE. Amylase FF. Lipase GG. Phosphorous HH. Magnesium II. C-Reactive Protein JJ. Ammonia KK. Lactic Acid LL. Digoxin MM. Dilantin NN. Theophylline OO. Phenobarbital PP. Valproic Acid QQ. Gentamycin RR. Vancomycin SS. Carbamazepine TT. Acetaminophen UU. Salicylate VV. Ethanol (ETOH) WW. Microalbumin XX. Urine Chemistries YY. B-type Natriuretic Peptide (BNP) 2. On 10 /07/2024 a review of the CMS 209 personnel form revealed the laboratory failed to have a qualified clinical consultant for moderate complexity testing for five of five months (from 04/01/24 through 10/07/24). 3. In an interview on 10/07/2024 at 1:00 pm with the CEO and TP1 confirmed the laboratory failed to have a qualified clinical consultant for moderate complexity testing for five of five months.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b) (1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to

	practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on a review of the CMS 209 personnel form and interview with testing person TP1 and Chief Executive Officer (CEO), the laboratory failed to have a qualified laboratory director for high complexity testing for five of five months. Findings include: 1. On 10/07/2024 at (time), the testing person (TP1) confirmed the laboratory performed the following high complexity testing: A. Blood Bank Blood Type (ABO Type) Rh Type Direct Coombs Indirect Coombs (Ab Screen) Compatibility Studies (Crossmatch AHG) B. CSF PROCEDURES Cell Count Gram Stain 2. On 10/07/2024 a review of the CMS 209 personnel form revealed the laboratory failed to have a qualified laboratory director for high complexity testing for five of five months (from 04/01/24 through 10/07/24). 3. On 10/07/24, a record review of patient testing revealed patient testing was performed from 04/01/24 through 10/07/24. Examples of patient testing include: B. Patient Identifier Test Date of patient test 1. 0423: BB00001S O Positive Blood Transfused 04/23/2024 Antibody Screen Crossmatch (AHG) Red Blood Cells W186224026352 Red Blood Cells W186224026625 2. 0507: BB00001S B Positive Blood Transfusion Antibody Screen Crossmatch Red Blood Cells W181724028894 Red Blood Cells W180924034076 3. 0604:BB00002S A Positive Antibody Screen Crossmatch (AHG) Red Blood Cells W186224040785 4. 0711:BB00001S O Positive 07/11/2024 Antibody Screen Crossmatch (AHG) Red Blood Cells W186224065148 Red Blood Cells W181224058889 5. 0906:BB00001S O Positive 09/06/2024 Antibody Screen Crossmatch (AHG) Red Blood Cells W186224068205 Red Blood Cells W180324088399 6. 24:M0000001S CSF Cell Count 09/13/2024 Cel Differential (Gram Stain) 4. Interview on 10/07/2024 at 1:00 pm with the CEO and TP1 confirmed the laboratory failed to have a qualified laboratory director for high complexity testing for five of five months.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in

	accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the CMS 209 personnel form and interview with TP1 and CEO, the laboratory failed to have a qualified technical supervisor for high complexity testing for five of five months. Findings include: 1. On 10/07/2024 at 1:00 pm a review of the CMS 209 personnel form revealed the laboratory failed to have a qualified technical supervisor for high complexity testing for five of five months. Refer to D6111.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or

doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be

a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be

a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical

laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have

successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training

	or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology. This STANDARD is not met as evidenced by: Based on a review of the CMS 209 personnel form and interview with TP1 and CEO, the laboratory failed to have a qualified technical supervisor for high complexity testing for five of five months. Findings include: 1. On 10/07/2024 at 1:00 pm, testing person TP1 confirmed the laboratory performed the following high complexity testing: A. Blood Bank Blood Type (ABO Type) Rh Type Direct Coombs Indirect Coombs (Ab Screen) Compatibility Studies (Crossmatch AHG) B. CSF PROCEDURES Cell Count Gram Stain 2. On 10/07/2024 a review of the CMS 209 personnel form revealed the laboratory failed to have a qualified technical supervisor for high complexity testing for five of five months (from 04/01/24 through 10/07/24). 3. Interview on 10/07/2024 at 1:00 pm with the CEO and TP1 confirmed the laboratory failed to have a qualified technical supervisor for high complexity testing for five of five months
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8)

	Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on laboratory personnel report CMS 209, testing personnel records review, and testing personnel interview, the laboratory director/technical supervisor failed to ensure that competency assessments were performed annually as required (see D6135).
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the CMS 209 personnel form and interview with TP1 and CEO, the laboratory failed to have a qualified clinical consultant for high complexity testing for five of five months. Findings include: 1. On 10/07/2024 a review of the CMS 209 personnel form revealed the laboratory failed to have a qualified clinical consultant for high complexity testing for five of five months. Refer to D6135
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on a review of the CMS 209 personnel form and interview with TP1 and CEO, the laboratory failed to have a qualified clinical consultant for high complexity testing for five of five months. Findings include: 1. On 10/07/2024 at 1:00 pm, testing person TP1 confirmed the laboratory performed the following high complexity testing: A. Blood Bank Blood Type (ABO Type) Rh Type Direct Coombs Indirect Coombs (Ab Screen) Compatibility Studies (Crossmatch AHG) B. CSF PROCEDURES Cell Count Gram Stain 2. On 10/07/2024 a review of the CMS 209 personnel form revealed the laboratory failed to have a qualified laboratory director for high complexity testing for five of five months (from 04/01/24 through 10/07/24). 3. Interview on 10/07/2024 at 1:00 pm with the CEO and TP1 confirmed the laboratory failed to have a qualified clinical consultant for high complexity testing for five of five months.