Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0267397	12/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Flagler Hospital Laboratory	400 Health Park Boulevard, Saint Augustine, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA Validation survey was conducted at UF Health St Johns Flagler Hospital, Inc on 11/18/2025-12/05/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 493.1250 Condition: Analytic Systems D6000 493.1403 Condition: Laboratory Director Moderate Complexity D6063 493.1421 Condition: Laboratory Testing Personnel Moderate Complexity D6076 493.1441 Condition: Laboratory Director High Complexity D6168 493.1487 Condition: Laboratory Testing Personnel High Complexity
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 record review and interview,the lab failed to follow written policies and procedures to assess employee and consultant competencies for two Moderate Complexity Testing Personnel and two of two Technical Consultant competency records reviewed. Findings Included: 1. The D-LAB-GEN-Competency Assessment policy approved by the Laboratory Director stated competencies were to be performed by supervisors delegated by the Medical Director (Laboratory Director) to access the competencies of clinical staff (testing personnel). 2. The Job Description last updated 10/12/2023 for the Medical Director, Laboratory Services (Laboratory Director) stated responsibility to ensure laboratory staff competency assessments. 3. TP # JJJ's competency dated 3/17/2025 and TP # KKKKK's competency dated 4/17/2024 was certified by "Super-Users " not a delegated supervisor. 4. TC #A and TC #B's competencies dated 11/11/2025 or Point of Care (POC) testing indicated no issues needing remedial training with performance of duties however POC testing failed to

	meet Condition for Analytic testing (See D5400) and was delegated responsibility for ensuring POC testing was accurate.
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 observation, record review and interview, the laboratory failed to run controls monthly for 20 out 20 I-stats based on their Individualized Quality Control Plan (IQCP) from January 2024 to November 2025, failed to complete the environment section of their IQCP plan, and failed to create an IQCP for the EG7+ (tests blood gases, electrolytes, and hematocrit) cartridge (see D5445).
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to run controls monthly for 20 out 20 I-stats based on their Individualized Quality Control Plan (IQCP) from January 2024 to November 2025, failed to complete the environment section of their IQCP plan, and failed to create an IQCP for EG7+ (tests blood gases, electrolytes, and hematocrit) cartridge. Finding Included: 1. On 11/18 /2025 at 9:00AM, the Emergency room (ER) 1 had an I-stat (SN:388117) Emergency room#2 had an I-stat (SN:311883) Emergency room #3 had an I-stat (SN:386264) Emergency room #10 had an I-stat (SN:402801) Cardiovascular Unit #5 (CVU)had an I-stat (SN:306867) Respiratory Therapy (RT) 6 had an I-stat (SN:333291) Respiratory Therapy #7 had an I-stat (SN:388753) 5th Floor#8 had an I-stat (SN:372168) 7th Floor#9 had ani-stat (SN:331446) Respiratory Therapy and Birthing Unit (RT BU) 17 had an I-stat (SN:332364) Surgical Intensive Care Unit (SICU)18 had an I-stat (SN: 332364) 4th Floor#19 had an I-stat (SN:372405) Medical Intensive Care Unit (MICU) 20 had an I-stat (SN:364624) Open Heart Recovery (OHR)21 had an I-stat (SN: 382000) Neonatal Intensive Care Unit (NICU)13 had an I-stat (SN:368733) Lab#11 had an I-stat (336579) Cardiovascular Operating Room (CVOR)4 had an I-stat (SN: 423237) CVOR#12 had an I-stat (SN:339519) Radiology (RAD)15 had an I-stat (SN:

338559) Flagler Imaging Center (FIC)14 had an I-stat (SN:392685) 2. On 11/19/2025 at 11:13 AM, CVOR room revealed an I-stat labeled "Annes #12" with no humidity and room temperature monitoring. 3. Review of I-STAT G3+ Cartridge listed the following analytes: potential of hydrogen(pH) partial pressure of carbon dioxide (PCO2) Partial Pressure of Oxygen (PO2) Total Carbon Dioxide (TCO2*) Bicarbonate (HCO3*) Base Excess (BE)* Sulfur Dioxide (sO2) 4. Review of I-STAT CHEM8+ Cartridge insert listed the following analytes: Sodium (Na) Potassium (K) Chloride (Cl) TCO2 Anion Gap* Ionized Calcium (iCa) Glucose (Glu) Urea Nitrogen (BUN)/Urea Creatinine (Crea) Hematocrit (Hct) Hemoglobin* (Hgb) 5. Review of I-STAT EG7+ cartridge insert listed the following analytes: Sodium (Na) Potassium (K) Ionized Calcium (iCa) Hematocrit (Hct) Hemoglobin* (Hgb) pH PCO2 PO2 TCO2* HCO3* Base Excess (BE)* sO2* 6. Review of I-STAT CG8+ Cartridge insert listed the following analytes: Sodium (Na) Potassium (K) Ionized Calcium (iCa) Glucose (Glu) Hematocrit (Hct) Hemoglobin* (Hgb) pH PCO2 PO2 TCO2* HCO3* Base Excess (BE)* sO2* 7. Review of I-STAT CG4+ Cartridge insert listed the following analytes: Lactate pH PCO2 PO2 TCO2* HCO3* Base Excess (BE)* sO2* 8. Review of I-STAT Cartridge listed the following analyte: creatinine (Crea) 9. Review of 2025 I-STAT (Quality Control) QC/Proficiency /CAL Verification Rotation revealed the following about: A. 378634 I-stat had no CHEM8+, CG4+ and CG8+ external controls run from February to November 2025. B. 376008 I-stat had no CHEM8+, CG4+ and CG8+external controls run from February to November 2025. C. 369288 I-stat had no CHEM8+, CG4+and CG8+ external controls run from January, March to July, September to November 2025. 369288 I-stat had no Crea external controls run for January and March to November 2025. D. 380538 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January, March to July, September to November 2025. E. 381537 I-start had no CHEM8+, CG4+ and CG8+external controls run from January, February, April to August July, September to October 2025. F. 388512 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January, February, April to August July, September to October 2025. G. 380947 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January to March, May to October 2025. H. 401191 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January to March, May to October 2025. I. 332589 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January to April, June to October 2025. J. 330679 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January to April, June to October 2025. K. 335161 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January to May, July to November 2025. L. 336542 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January to May, July to November 2025. M. 339274 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January, March to November 2025. N. 33294 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January to February, April to June, September to November 2025. O. 339420 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January to March, May to August, October to November 2025. P. 336579 I-stat had no CHEM8+, CG4+ and CG8+external controls run from January to April, June to September, November 2025. Q. 423237 I-stat had no documentation of external Quality control R. 338559 I-stat had no documentation of external Quality control S. 339519 I-stat had no documentation of external Quality control T. 392685 I-stat had no documentation of external Quality control 10. Review of 2024 I-STAT (Quality Control) QC /Proficiency /CAL Verification Rotation revealed the following about: A. 388117 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from February to June, August to December 2024. B. 311883 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from February to June, August to December 2024. C. 386264 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from

	January, March to July, September to December 2024. D. 402801 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January, March to July, September to December 2024. E. 306867 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to February, April to August, October to December 2024. F. 333291 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to August, October to December 2024. G. 388753 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to March, May to September, November to December 2024. H. 372168 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to March, May to September, November to December 2024. I. 331446 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to October, December 2024. J. 332666 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to April July to October, December 2024. K. 332364 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to May, July to November 2024. L. 372405 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to May, July to November 2024. M. 364624 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January, March to June, August to December 2024. N. 382000 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to February, April to July, September to December 2024. O. 368733 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to March, May to September October to December 2024 P. 336579 I-stat had no CHEM8+, CG4+, Crea and CG8+ external controls run from January to April h to June to September, November to December 2024. Q. 423237 I-stat had no documentation of external Quality control R. 339519 I-stat had no documentation of external Quality control S. 338559 I-stat had no documentation of external Quality control T. 392685 I-stat had no documentation of external Quality control 11. Review of I-stat risk assessment revealed no IQCP was performed for EG7+ cartridge and environment section was not completed for an I-stat in the Annes area. 12. Review of Quality control plan I-stat signed by laboratory director on 01/04/2019 read 'Two levels of external quality controls from manufacturer each new lot and shipment of reagents monthly, and if there is suspicion that the product performance is compromised Monthly review by Point of Care (POC) Department." 13. Review 2024 POC testing revealed on i-stats: 2764 Patients tested for creatinine 2355 Patients tested for Chem8 16423 Patients tested for CG8 1743 Patients tested for blood gas 5539 Patients tested for blood gas + lactate 14. Review 2025 POC testing revealed on i-stats: 497 Patients tested for creatinine 2323 Patients tested for Chem8 857 Patients tested for CG8 1394 Patients tested for blood gas 9411 Patients tested for blood gas + lactate 15. On 11/19/2025 at 10:54 AM, the Director of Quality stated room temperature and humidity were not monitored in the CVOR room and there were no records of monitoring. 16. On 11/20/25 at 11:00 AM, Technical Consultant C stated the laboratory was rotating quality control on I-stat and not performing QC monthly for each I-stat in use. 17. On 11/20/2025 at 3:35 PM, the Laboratory Director confirmed he was unaware the laboratory did not run controls monthly for 20 out 20 I-stats based on their Individualized Quality Control Plan (IQCP) from January 2024 to November 2025, incomplete environment section of their IQCP plan, and did not create an IQCP for EG7+ cartridge. 18. Quality Assurance (QA) reports for 2024-2025 were reviewed with the General Supervisor on 11/20/2025 at 11:26 AM. There was no evidence the laboratory QA had identified the aforementioned problems found during the survey.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the Laboratory Director failed ensure laboratory ran controls monthly for 20 out 20 I-stats based on their Individualized Quality Control Plan (IQCP) from January 2024 to November 2025, failed to completed the environment section of their IQCP plan, failed to create an IQCP for EG7+ cartridges, failed to identify failure in quality as they occurred, and failed to verify the education of 21 out of 152 Testing Personnel performing Moderate Complexity Testing (See D6020), and failed to ensure that policies and procedures were established for monitoring Testing Personnel to assure that they are competent and maintain their competency and to identify needs for remedial training for two Moderate Complexity Testing Personnel and two of two Technical Consultant competency records reviewed (See D6030).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 observation, record review and interview, the Laboratory Director failed ensure the laboratory ran controls monthly for 20 out 20 I-stats based on their Individualized Quality Control Plan (IQCP) from January 2024 to November 2025, failed to completed the environment section of their IQCP plan, failed to create an IQCP for EG7+ cartridges, failed to identify failures in quality as they occurred for two of two years (2024-2025) (Refer to D5445) and the Laboratory failed to verify the education of 21 (Testing Persons #JJ, MM, SS, TT, WW, XX, YY, ZZ, AAA, BBB, PPP, WWW, BBBB, CCCC, QQQQQQ, BBBBBBB, HHHHHHH, IIIIIII, LLLLLLL, UUUUUUU, XXXXXXX,) out of 152 Testing Personnel performing Moderate Testing (Refer to D6065).
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) 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 record review and interview,the Laboratory Director failed to ensure that policies and procedures were established for monitoring Testing Personnel to assure that they are competent and maintain their competency and to identify needs for

	remedial training for two Moderate Complexity Testing Personnel and two of two Technical Consultant competency records reviewed. Findings Included: 1. The D-LAB-GEN-Competency Assessment policy approved by the Laboratory Director stated competencies were to be performed by supervisors delegated by the Medical Director (Laboratory Director) to access the competencies of clinical staff (testing personnel). 2. The Job Description last updated 10/12/2023 for the Medical Director, Laboratory Services (Laboratory Director) stated responsibility to ensure laboratory staff competency assessments. 3. TP # JJJ's competency dated 3/17/2025 and TP # KKKKK's competency dated 4/17/2024 was certified by "Super-Users " not a delegated supervisor. 4. TC #A and TC #B's competencies dated 11/11/2025 or Point of Care (POC) testing indicated no issues needing remedial training with performance of duties however POC testing failed to meet Condition for Analytic testing (See D5400) and was delegated responsibility for ensuring POC testing was accurate. 5. The Laboratory Director on 11/20/2025 at 3:32 PM verified competencies were to be performed by delegated staff only and were usually monitored by the General Supervisor. The Laboratory Director confirmed he had not been aware of the issues identified in D5400 and the deficient practice was not identified during the competencies of TC #A and TC # B.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory failed to verify the education of 21out of 152 Testing Personnel performing Moderate Complexity Testing (See D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to verify the education of 21 out of 152 Testing Personnel performing Moderate Complexity Testing. Findings

	Included: 1. Review of the Form CMS-209 signed and dated by the Laboratory Director on 11/19/2025 revealed 152 Testing Personnel who performed Moderate Complexity Testing. 2. Review of Testing Personnel employment records revealed Testing Persons #JJ, MM, SS, TT, WW, XX, YY, ZZ, AAA, BBB, PPP, WWW, BBBB, CCCC, QQQQQQ, BBBBBBB, HHHHHHH, IIIIIII, LLLLLLL, UUUUUUU, XXXXXXX,) did not have proof of education. 3. Interview on 11/20 /2025 at 10:45 AM., the Human Resource representative confirmed that they did not have documentation of Testing Person ##JJ, MM, SS, TT, WW, XX, YY, ZZ, AAA, BBB, PPP, WWW, BBBB, CCCC, QQQQQQ, BBBBBBB, HHHHHHH, IIIIIII, LLLLLLL, UUUUUUU, XXXXXXX) education.
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 observation, record review and interview, the Laboratory Director failed to provide overall management and direction of the laboratory for two of two years (2024-2025) (See D6079), failed to develop a policy or provide evidence of the required every 6 month onsite visits from 01/2025-11/2025 (See D6080), failed to ensure the quality assessment program was established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occurred (See D6093), and failed to verify the education of 1 (Testing Personnel #C) out of 34 Testing Personnel who perform high complexity testing (See D6101).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with the applicable regulations for two of two years (2024-2025). Findings included: 1. The Laboratory Director failed to develop a policy or provide evidence of the required every 6 month onsite visits from 01/2025-11/2025. (See D6080) 2. The Laboratory Director failed to ensure that the quality assessment program was established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occurred for two of two years

	(2024-2025). (See D6093) 3. The Laboratory Director failed to verify the education of 1 (Testing Personnel #C) out of 34 Testing Personnel who perform high complexity testing. (See D6171) and of 21 (Testing Persons #JJ, MM, SS, TT, WW, XX, YY, ZZ, AAA, BBB, PPP, WWW, BBBB, CCCC, QQQQQQ, BBBBBBB, HHHHHHH, IIIIIII, LLLLLLL, UUUUUUU, XXXXXXX,) out of 152 Testing Personnel performing Moderate Testing.(See D6171)
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to develop a policy or provide evidence of the required every 6 month onsite visits from 01/2025-11/2025. Findings Included: 1. Review of records revealed no approved policy regarding the Laboratory Director being onsite every 6 months in all laboratory testing areas and no evidence of visits for 01/2025 to 11/2025 were presented for review. 2. The Laboratory Director stated via email interview on 11/20/2025 at 3:40 PM., he had visited each of the laboratory testing areas from 01/2025-11/2025 but had not documented visits and there was not an approved policy for the Laboratory Director being onsite every 6 months in all laboratory testing areas.
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 record review and interview, the Laboratory Director failed to ensure that the quality assessment program was established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occurred for two of two years (2024-2025). Findings included: 1. The D-LAB--GEN- Quality Assurance Policy approved by the Laboratory Director original issue date 7/1/1993, indicated under IV- The overall responsibility for the development and implementation of the Quality Assurance program belongs with the "Medical Director" (Laboratory Director). 2. The Job Description for Medical Director of Laboratory Services (Laboratory Director) last updated 10/12/2023 stated the Laboratory Director was to oversee laboratory quality. 3. QA reports for 2024-2025 were reviewed with the General Supervisor on 11/20/2025 at 11:26 AM. There was no evidence the laboratory QA had identified the following problems found during the survey- a. The Laboratory Director failed to develop a policy or provide evidence of the required every 6 month onsite visits from 01/2025-11/2025. (See D6080) b. The Laboratory failed to verify the education of 1 (Testing Personnel #C) out of 34

	Testing Personnel who perform high complexity testing. (See D6171) 4. The Laboratory Director on 11/20/25 at 3:40 PM confirmed the above listed problems found during the survey had not been identified through the laboratory QA process.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) (e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to verify the education of 1 (Testing Personnel #C) out of 34 Testing Personnel who perform high complexity testing (See D6171).
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 record review and interview, the Laboratory failed to verify the education of 1 (Testing Personnel #C) out of 34 Testing Personnel who perform high complexity testing (See 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 record review and interview, the Laboratory failed to verify the education of 1 (Testing Personnel #C) out of 34 Testing Personnel who perform high complexity testing. Findings Included: 1. Review of the FORM CMS-209 signed and dated by the Laboratory Director on 11/19/2025 revealed 34 high complexity Testing Personnel. 2. Review of Testing Personnel education revealed no proof of education for Testing Personnel #C. 3. Interview on 11/20/2025 at 10:45 AM with Human Resources confirmed that they did not have proof of education for Testing Personnel #C.