Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2194734	07/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Freedom Health Interventional Centers	6036 N 19th Ave Ste 204, Phoenix, AZ	

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	A recertification survey was performed on July 22, 2025. The facility was found to be NOT in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1210 - Routine Chemistry 493.1409 - Technical Consultant - Moderate Complexity 493.1421 - Laboratory Testing Personnel
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for testing performed in the subspecialty of Routine Chemistry and interview with the testing personnel (TP-1) on 7/22/25 at 11:03 AM, the laboratory director failed to sign the PT attestation statements for 3 out of 5 PT events during 2024 and 2025. Findings include: 1. The laboratory performs Chem8+ testing on the i-Stat analyzer in the subspecialty of Routine Chemistry with a reported annual test volume of 2,160. 2. The PT attestation statements presented for review for the 2nd event of 2024, 1st event of 2025 and 2nd event of 2025 lacked the signature of the laboratory director. 3. TP-1 interviewed on 7 /22/25 at 11:03 AM confirmed that the PT attestation statements indicated above were not signed by the laboratory director.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record

	proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2025 and interview with the testing personnel (TP-1) on 7/22/25 at 11:03 AM, the laboratory failed to maintain a copy of the i-Stat instrument printouts documenting the examination of the PT samples for the 1st event of 2025, and failed to maintain a copy of the American Proficiency Institute (API) program report form used by the laboratory to record PT results for the 1st event of 2025. Findings include: 1. The laboratory performs Chem8+ testing on the i-Stat analyzer in the subspecialty of Routine Chemistry with a reported annual test volume of 2,160. 2. The laboratory failed to provide evidence of the i-Stat instrument printouts showing the PT samples were tested by the laboratory for the 1st testing event of 2025. 3. The laboratory failed to provide evidence of the API program report form used by the laboratory to record PT results for the 1st testing event of 2025. 4. TP-1 interviewed on 7/22/25 at 11:03 AM confirmed the i-Stat instrument printouts and API report form for the 1st PT event of 2025 were not available for review during the survey.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review for Chem8+ testing performed on the i-Stat analyzer and testing personnel interview, the laboratory failed to meet the requirements for the subspecialty of Routine Chemistry specified in 493.1230 through 493.1256 and 493. 1281 through 493.1299, as evidenced by: - The laboratory failed to ensure positive identification of one out of three patient's specimens (Refer to D5203) - The laboratory failed to review PT results obtained from the 1st and 2nd testing events of 2025 (Refer to D5211) - The laboratory failed to document the acceptability of shipping temperatures for each shipment of test cartridges and control materials (Refer to D5411) - The laboratory failed to perform an electronic simulator check on each day of testing (Refer to D5431) - The laboratory failed to perform 2 levels of liquid control material with the frequency established by the laboratory (Refer to D5445) - The laboratory failed to perform Quality Assessment activities specific to the analytic test systems (Refer to D5791)
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

	This STANDARD is not met as evidenced by: Based on review of i-Stat test procedures, i-Stat test records and interview with the testing personnel (TP-1) on 7/22/25 at 11:37 AM, the laboratory failed to enter the patient ID into the i-Stat analyzer for 1 out of 3 patient test records reviewed during the survey. Findings include: 1. The laboratory performs Chem8+ testing on the i-Stat analyzer in the subspecialty of Routine Chemistry with a reported annual test volume of 2,160 2. The laboratory's established test procedure for the i-Stat analyzer states, "Follow handheld prompts. Enter Operator ID number as assigned to each user. Enter Patient ID number...Complete all information on the Laboratory Report Form, including all requested patient identifiers. Attach ISTAT printout results to box on report form." 3. The laboratory report form for 1 out of 3 patients (MR# 10185 from 1 /03/24 at 07:51) reviewed during the survey failed to include the Patient ID on the i-Stat instrument printout attached to the report form. 4. TP-1 interviewed on 7/22/25 at 11:37 AM confirmed the laboratory failed to provide evidence that the Patient ID was entered into the i-Stat analyzer prior to testing the patient's sample indicated above.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records from 2025 and interview with the testing personnel (TP-1) on 7/22/25 at 11:05 AM, the laboratory failed to provide evidence of a documented review of the PT results obtained for the 1st and 2nd testing events of 2025 for testing performed in the subspecialty of Routine Chemistry. Findings include: 1. The laboratory is enrolled in PT with American Proficiency Institute (API) for Chem8+ testing performed on the i-Stat analyzer and participates in 3 PT events annually. 2. No written comment or signature was documented by laboratory personnel on the PT records from the 1st and 2nd testing events of 2025, to indicate a review and evaluation of the PT results obtained from API. 3. TP-1 interviewed on 7/22/25 at 11:05 confirmed that the PT results indicated above were not reviewed by laboratory personnel. 4. The laboratory reports an annual test volume of 2,160 in the subspecialty of Routine Chemistry.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the i-Stat operator manual, the laboratory's i-Stat shipping log and interview with the testing personnel (TP-1) on 7/22/25 at 11:46 AM, the laboratory failed to verify the shipping temperature of each shipment of i-Stat test cartridges and control material received by the laboratory from 8/6/24 through 7/22/25. Findings include: 1. The Abbott i-Stat operator manual states, "Verify that the transit

	temperatures were satisfactory by reading the temperature strip included in each shipping container." 2. The laboratory failed to document the i-Stat shipping log from 8/6/24 through 7/22/25, which tracks the date received, the control material or cartridge type received, lot number, quantity and whether or not the transit temperature strip included in each shipment was within the acceptable temperature range. 3. TP-1 interviewed on 7/22/25 at 11:46 AM confirmed the laboratory failed to document the i-Stat shipping log, including acceptable shipping temperatures, for each shipment of test cartridges and control material received by the laboratory from 8/6/24 through 7/22/25. 4. The laboratory performed 300 Chem8+ tests in 2024 and 175 Chem8+ tests from January 1, 2025 through July 22, 2025.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on review of i-Stat instrument records, reveiw of Quality Control (QC) policies and interview with the testing personnel (TP-1) on 7/22/25 at 11:49 AM, the laboratory failed to perform and document the electronic simulator check on the i-Stat analyzer prior to use on each day of patient testing from 8/1/24 through 7/22/25. Findings include: 1. The laboratory performs Chem8+ testing on the i-Stat analyzer in the subspecialty of Routine Chemistry with a reported annual test volume of 2,160. 2. The laboratory's QC policy for the i-Stat analyzer indicates that the electronic simulator check must be performed and documented each day of patient testing prior to testing patient specimens. 3. The laboratory failed to perform and document the electronic simulator check on the analyzer prior to testing patients on each day of patient testing from 8/1/24 through 7/22/25. 4. TP-1 interviewed on 7/22/25 at 11:49 AM confirmed the laboratory failed to provide documentation of the electronic simulator check for each testing date during the timeframe of 8/1/24 through 7/22/25. 5. The laboratory performed 300 Chem8+ tests in 2024 and 175 Chem8+ tests from January 1, 2025 through July 22, 2025.
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 review of Quality Control (QC) policies and records, lack of monthly QC documentation for the i-Stat analyzer and interview with the testing personnel (TP-1) on 7/22/25 at 11:44 AM, the laboratory failed to perform and document monthly control procedures as established by the laboratory for testing performed on the i-Stat analyzer. Findings include: 1. The laboratory performs Chem8+ testing on the i-Stat analyzer in the subspecialty of Routine Chemistry with a reported annual test volume of 2,160. 2. The laboratory's QC policy reviewed during the survey for the Chem8+ test indicated that two levels of external QC material (TriControl Level 1 and 3) will be performed with each new lot number or shipment of test cartridges; at minimum, once per month; following software upgrades; and anytime the performance of the instrument is questionable. 3. The laboratory failed to perform and document 2 levels of external QC material at least monthly and for each new lot number or shipment of Chem8+ test cartridges during November 2023, June 2024, July 2024, August 2024, September 2024, November 2024, December 2024, January 2025, February 2025, March 2025, May 2025, June 2025, and July 2025 (through the date of the survey). 4. TP-1 interviewed on 7/22/25 at 11:44 AM confirmed the laboratory failed to perform two levels of external QC material at least monthly and for each new lot number and shipment of Chem8+ test cartridges during the timeframes indicated above. 5. The laboratory performed 300 Chem8+ tests in 2024 and performed 175 Chem8+ tests from January 2025 through July 22, 2025.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on lack of monthly quality assessment (QA) documentation and interview with the testing personnel (TP-1) on 7/22/25 at 11:55 AM, the laboratory failed to perform and document analytic QA activities on a monthly basis for 18 out of 18 months from January 2024 through June 2025. Findings include: 1. It is the policy of the laboratory to complete a monthly QA Review Form to include the monitoring of Quality Control and other analytic activities for the i-Stat analyzer. 2. The laboratory failed to provide evidence of documented QA Review Forms for 18 out of 18 months from January 2024 through June 2025. 3. TP-1 interviewed on 7/22/25 at 11:55 AM confirmed the laboratory failed to perform and document analytic QA activities for the i-Stat analyzer each month during the timeframe listed above.
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 review of the laboratory policy and procedure manual, review of quality control (QC) records, lack of Quality Assessment (QA) documentation and interview

	with the testing personnel (TP-1) on 7/22/25, the laboratory director failed to ensure that the QC and QA programs for the i-Stat analyzer are maintained to assure the quality of laboratory services provided in the subspecialty of Routine Chemistry. Findings include: 1. The laboratory failed to document the shipping temperature of i-Stat test cartridges and control materials, as indicated in the laboratory's quality control policy. See D5411 2. The laboratory failed to perform and document the electronic simulator check prior to testing patient samples on each day of testing, as indicated in the laboratory's quality control policy. See D5431 3. The laboratory failed to perform 2 levels of liquid control materials with the frequency established in the laboratory's quality control plan. See D5445 4. The laboratory failed to perform and document analytic QA activities for testing performed on the i-Stat analyzer, as indicated in the laboratory's QA policies. See D5791 5. TP-1 interviewed on 7/22/25 at 12:00 PM confirmed that the laboratory director failed to ensure that the established QC and QA policies for testing performed on the i-Stat analyzer were maintained and followed by laboratory personnel. 6. The laboratory performed 300 Chem8+ tests in 2024 and 175 Chem8+ tests from January 1, 2025 through July 22, 2025.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on lack of initial training documentation for two out of two testing personnel (TP-1 and TP-2), lack of academic credentials to qualify six out of six TP and interview with TP-1 on 7/22/25 at 10:20 AM, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and have the appropriate training for routine chemistry testing performed on the i-Stat analyer. Findings include: 1. No evidence of academic credentials were presented for review for TP-1, TP-2, TP-3, TP-4, TP-5 and TP-6. See D6065 for findings. 2. No initial training documentation was presented for review for two out of two testing personnel (TP-1 and TP-2) who began patient testing in July 2024. 3. TP-1 interviewed on 7/22/25 at 10:20 AM confirmed the laboratory failed to provide documentation of academic credentials and initial training records for the testing personnel indicated above. 4. The laboratory reports 2,160 Chem8+ tests performed annually in the subspecialty of chemistry on the i-Stat analyer.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY 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 review of the CMS-209, Laboratory Personnel Form and interview with Testing Personnel (TP-1) on July 22, 2025 at 10:15 AM, the laboratory failed to have a Technical Consultant (TC) who meets the qualification requirements for a moderate

	complexity laboratory performing patient testing in the subspecialty of Routine Chemistry. (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 (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 1 year of laboratory training or experience, or both, in nonwaived 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)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on review of the CMS-209, Laboratory Personnel Form, lack of a qualified technical consultant (TC) at the time of the survey conducted on 7/22/25 and interview with the testing personnel (TP-1), the laboratory failed to have an assigned TC since August 2023 who meets the qualification requirements for moderate complexity testing in the subspecialty of Routine Chemistry. Findings include: 1. The CMS-209, Laboratory Personnel Form presented for review on 7/22/25 failed to

	indicate a Technical Consultant. 2. TP-1 interviewed on 7/22/25 at 10:15 AM confirmed the laboratory did not have a qualified TC at the time of the survey and stated that the laboratory has not had a qualified TC since August 2023.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation from 2024 and interview with the testing personel (TP-1) on 7/22/25 at 10:20 AM, the technical consultant failed to evaluate and document the performance of two of two testing personnel (TP-1 and TP-2), at least semiannually during the first year the individuals tested patient specimens on the i-Stat analyzer. Findings include: 1. The laboratory failed to provide evidence of semiannual competency evaluation documentation for TP-1 and TP-2 who began patient testing on the i-Stat analyzer in July 2024. 2. TP-1 interviewed on 7/22/25 at 10:20 AM confirmed the technical consultant failed to perform and document a semiannual competency evaluation during 2024 for TP-1 and TP-2. 3. The laboratory reports approximately 2,160 chemistry (Chem8+) tests annually in the subspecialty of Routine Chemistry.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on lack of annual competency evaluation documentation from 2024 and 2025 and interview with the testing personnel (TP-1) on 7/22/25 at 10:20 AM, the technical consultant (TC) failed to evaluate and document the performance for one out of one testing personnel at least annually during 2024 and three out of of three testing personnel in 2025 who perform testing on the i-Stat analyzer in the subspecialty of Routine Chemistry. Findings include: 1. The TC failed to evaluate and document the performance of one testing personnel (TP-6) during 2024 who performs Chem8+ testing on the i-Stat analyzer. 2. The TC failed to evaluate and document the performance of three out of three testing personnel (TP-1, TP-2 and TP-6) during 2025 who perform Chem8+ testing on the i-Stat analyzer. 3. TP-1 interviewed on 7/22/25 at 10:20 AM confirmed the technical consultant failed to evaluate and document the performance of TP-6 at least annually during 2024 and TP-1, TP-2 and TP-6 during 2025.
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 review of personnel records and interview with the facility personnel on 7/22 /25 at 10:20 AM, the laboratory failed to have academic credentials required to qualify six out of six testing personnel for moderate complexity testing in the subspecialty of Routine Chemistry. (Refer to 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 lack of personnel records and interview with testing personnel (TP-1) on 7 /22/25 at 10:20 AM, the laboratory failed to have documentation of academic credentials to qualify six out of six testing personnel (TP) for moderate complexity testing in the subspecialty of Routine Chemistry. Findings include: 1. Review of the personnel records for six out of six testing personnel for the subspeciality of Routine Chemistry revealed the laboratory failed to have academic credentials to qualify TP -1 through TP -6. 2. Interview with TP-1 on 7/22/25 at 10:20 AM confirmed the laboratory failed to have the required documentation to qualify TP-1 through TP-6 for moderate complexity testing. 3. The laboratory reports 2,160 chemistry (Chem8+) tests annually in the subspecialty of Routine Chemistry.