Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2194734	07/14/2023
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the 2021, 2022, and 2023 proficiency testing (PT) results, review of patient records, and interview with the technical consultant (TC) and testing personnel (TP) #1, the laboratory failed to enroll in an approved proficiency testing program for the analytes of sodium, potassium, chloride, glucose, blood urea nitrogen, and creatinine in the specialty of routine chemistry and hemoglobin and hematocrit in the speciality of hematology. Findings: 1. Review of the 2021, 2022, and 2023 PT results showed no values for the first event 2022 for sodium, potassium, chloride, glucose, blood urea nitrogen,and creatinine in the specialty of routine chemistry and hemoglobin and hematocrit in the speciality of hematology. 2. Review of proficiency records from 2021, 2022, 2023, revealed a lack of enrollment for sodium, potassium, chloride, glucose, blood urea nitrogen,and creatinine in the specialty of routine chemistry and hemoglobin and hematocrit in the speciality of hematology. 3. Interview with the TP #1 on July 14, 2023 at 11:00 AM confirmed, "American Proficiency Testing Program would not allow enrollment and we were unable to gain access. API considered us not enrolled due to lack of payment." 4. Interview with the TC on July 14, 2023 at 11:00 AM confirmed the laboratory failed to enroll in an approved PT program for the regulated analytes of sodium, potassium, chloride,

	glucose, blood urea nitrogen, and creatinine in the specialty of routine chemistry and hemoglobin and hematocrit in the speciality of hematology. 5. The laboratory reports approximately 3500 tests annually in the specialties of routine chemistry and hematology.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of 2021, 2022, and 2023 hematology proficiency testing (PT) results reported to the CLIA database by the PT provider and interview with the technical consultant, the laboratory failed to successfully participate in PT. See D-tag 2130; unsatisfactory performance in two consecutive prothrombin time challenges. See D-tag 2131; failure to attain an overall testing event score of satisfactory performance in the speciality of hematology for two consecutive PT events.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of hematology proficiency testing (PT) results for 2021, 2022, and 2023 and interview with the technical consultant, the laboratory failed to achieve satisfactory performance for prothrombin time in two consecutive PT events. Findings: 1. Review of hematology PT results for the second event of 2022 revealed the laboratory obtained an unacceptable score of 0 percent for prothrombin time. 2. Review of hematology PT results for the third event of 2022 revealed the laboratory obtained an unacceptable score of 60 percent for prothrombin time. 3. Interview with the technical consultant on July 14, 2023 at 11:00 AM confirmed the laboratory failed to achieve satisfactory performance for prothrombin time in two consecutive testing events. 4. The laboratory reports approximately 890 prothrombin patient tests annually.

D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of hematology proficiency testing (PT) results for 2021, 2022, and 2023 and interview with the technical consultant, the laboratory failed to attain an overall testing event score of satisfactory performance for two consecutive PT events. Findings: 1. Review of hematology PT results for the second event of 2022 showed the laboratory obtained an overall testing score of 66 percent. 2. Review of hematology PT results for the third event of 2022 revealed the laboratory obtained an overall testing score of 20 percent. 3. Interview with the technical consultant on July 14, 2023 at 11:00 AM confirmed the laboratory failed to attain an overall testing event score of satisfactory performance for two consecutive testing events for hematology. 4. The laboratory reports approximately 890 prothrombin patient tests annually in the speciality of hematology.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the Individualized Quality Control Plan (IQCP) for the Abbott iSTAT, review of 2021, 2022, and 2023 chemistry panel 8 (Chem 8) and prothrombin time (PT) quality control (QC) documentation, patient reports, and interview with the technical consultant (TC), the laboratory failed to follow the procedure for QC frequency. Findings: 1. Review of the Abbott iSTAT IQCP for chem 8 and PT showed "external control testing at least every 30 days." 2. Review of the Abbott iSTAT QC logs for PT testing revealed the laboratory failed to perform 2021 QC for May, July, September, November, and 2022 QC for January, February, May, July, and November. 3. Review of the Abbott iSTAT QC logs for Chem 8 showed no QC performed in 2021 for the months of May, June, July, August, September, and November. No QC was performed for 2022 for the months of January, July, August, and November. 4. Interview with the TC on July 14, 2023 at 11:00 AM confirmed the laboratory failed to follow the procedure for performing QC every 30 days for Chem 8 and PT tests. 5. The laboratory results approximately 3500 chemistry and hematology patient tests annually.