Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0890174	01/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Healthcare Partners Affiliates	797 S Fair Oaks Ave, Pasadena, CA	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the surveyor's observation and interview with testing personnel (TP); it was determined that the laboratory lacked an eyewash in the testing area. The laboratory failed to observe safety procedures to ensure protection from biohazardous materials. The findings included: 1. On the day of the survey January 30, 2024, at approximately 1:00 p.m. the surveyor observed that the laboratory lacked an eyewash in the area where blood samples are processed. 2. The TP affirmed the lack of an eyewash in the testing area. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 1/30/2024, the laboratory processes and reports approximately 70,030 samples tested.
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 the lack of laboratory written policies and procedures and interview with the testing personnel (TP), it was determined that the laboratory failed to have available

	and follow written procedures for chemistry, hematology, and SARS-CoV-2 tests performed in the laboratory. The findings included: 1. On the day of the survey on January 30, 2024, at approximately 12:40p.m., the laboratory failed to provide written policies and procedures for chemistry, hematology, and SARS-CoV-2 test procedures performed in the laboratory. 2. For seven (7) out of seven (7) randomly selected patient test results reviewed covering period from 08/20/2021 to 11/15/2023, all the patients had chemistry, hematology, and SARS-CoV-2 test ordered, analyzed, and reported for which the laboratory had no written policies and procedures available. 3. The TP confirmed on 01/30/2024 at approximately 12:45 p.m. that the laboratory did not have written policies and procedures available for chemistry, hematology, and SARS-CoV-2 tests performed in the laboratory.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records and interview with the laboratory director (LD) and laboratory staff (LS), it was determined that the laboratory failed to establish and follow written policies and procedures to set and to verify the criteria for acceptability of all control materials for chemistry. The findings included: 1. The laboratory performed routine chemistry tests on the i-STAT using only performing quality controls for new batch and new lot numbers. 2. Review of QC records and policies and procedures indicated lack of an Individualized Quality Control Plan (IQCP) performed. 3. Interview with the LD and LS on 1/30/2024, confirmed that the laboratory lacked a written and approved IQCP for the determination of quality control frequency performance. 4. Review of the laboratory's testing volume, the LD signed a total of 38,607 chemistry samples tested and reported without performing QC with the frequency indicated by the manufacturer.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: The Laboratory Director is herein cited for deficient practice in overall administration of the laboratory to ensure that an eyewash is available in the testing area, the frequency of testing of Quality Control materials for routine chemistry is established and that an approved procedure manual signed and dated is always available for chemistry, hematology, and SARS-CoV-2 sample testing. See D3011, D5401 and D5469.