Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0700682	05/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sharp Healthcare Laboratory	5651 Copley Drive, San Diego, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation, laboratory personnel interviews, and laboratory specimen labeling policies and procedures record review on May 12, 2026 at 11:30 am, the laboratory failed to follow written policies and procedures for specimen labeling. Finding included: a. According to the laboratory's protocol titled "Specimen Collection, Labeling, and Transport Requirements," patient specimens must be labeled with patient information, including the "initials or username of the person collecting the sample." b. On May 12, 2026 at 11:30 am, there were no observed patient specimens with labels that included the "initial or username of the person collecting the sample." c. These findings were confirmed by laboratory personnel on May 12, 2026 at 11:30 am. d. According to laboratory records, the laboratory performed and reported approximately 1,977,721 patient clinical laboratory tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on technical supervisor and testing personnel interviews and bacteriology quality control organisms record review on May 13, 2026 at 11:00 am, the laboratory failed to have a procedure manual that included a written procedure for the culturing of bacteriology quality control organisms used to ensure that media, reagents, stains, identification systems, and testing assays were functioning properly to perform and report patient bacteriology culture results. Findings included: a. According to testing personnel, In bacteriology, each month, the laboratory cultured bacteriology quality control organisms from frozen stocks of reference bacteria strains. From the cultures of the frozen stocks of reference bacteria stains, daily cultures were made which were used to ensure media, reagents, stains, identification systems, and testing assays were functioning properly to perform and report patient bacteriology culture results. b. The laboratory maintained no written protocols detailing this bacteriology quality control organism procedure. c. The technical supervisor confirmed these finding on May 13, 2026 at 11:00 am. d. According to laboratory records, the laboratory performed and reported approximately 200,000 patient bacteriology tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, technical supervisor interview, and ambient temperature record review on May 14, 2026 at 11:00 am, the laboratory failed to establish criteria consistent with manufacturers' instructions for the proper storage of reagents and collection devices. Findings included: a. During a tour of the laboratory on May 14, 2026 at 11:00 am, the following reagents and collection devices were observed being

	stored at ambient temperature: i. QuantiFERON - TB Gold Plus (QFT-Plus) blood collection tubes - lot number 581011619, expiration date November 30, 2026. ii. Beckman Coulter Diagnostics AUH1011 ISE buffer solutions - lot number M601701, expiration date May 31, 2027. b. According to manufacturers' instructions, these reagents and collection devices are to be stored at 2 to 25 degrees Celsius. c. Review of the laboratory's temperature monitoring records indicated that the ambient temperature range where these reagents and collection devices were stored was set at 20 - 30 degrees Celsius. That is, appropriate laboratory personnel were notified only when the ambient temperature was below 20 degrees Celsius or above 30 degrees Celsius. d. The technical supervisor confirmed on May 14, 2026 at 11:00 am that the monitoring of ambient temperatures where the QFT-Plus blood collection tubes and AUH1011 ISE buffer solutions were stored was not consistent with manufacturers' instructions. e. According to laboratory personnel, the laboratory performed and reported approximately 10,400 patient routine chemistry tests weekly using the Beckman Coulter Diagnostics AUH1011, and performed and reported approximately 1,800 patient mycobacteriology tests monthly using the QuantiFERON - TB Gold Plus.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and Roche Ventana HE 600 maintenance record review on May 12, 2026 at 01:30 pm, the laboratory failed to perform all Roche Ventana HE 600 maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings included: a. In anatomic pathology, it was the practice of the laboratory to perform hematoxylin and eosin staining of patient microscope slides using four (4) Roche Ventana HE 600 instruments. b. According to the Roche Ventana HE 600 system's "Operator Notebook," daily maintenance of each Roche Ventana HE 600 included "check[ing] the coverslip waste dispensary." The laboratory maintained no documentation that this manufacturer daily maintenance had been performed on any of the laboratory's four Roche Ventana HE 600's. c. These findings were confirmed by laboratory personnel on May 12, 2026 at 01:30 pm. d. According to laboratory records, the laboratory performed and reported approximately 400,000 patient anatomic pathology tests annually.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and laboratory microscope maintenance policies and procedures record review on May 12, 2026 at 02:00 pm, the laboratory

	failed to perform all anatomic pathology microscope maintenance as defined by the laboratory and with at least the frequency specified by the laboratory. Findings included: a. In anatomic pathology, it was the practice of the laboratory to perform reviews of patient anatomic pathology slides using microscopes. According to laboratory personnel, the anatomic pathology section of the laboratory maintain approximately 12 microscopes. b. According to the laboratory's written protocol titled "Microscopes," daily maintenance of each microscope included: "wipe oil from objective, condenser, and stage with lens paper," "turn off microscope light source," and "replace microscope cover." The laboratory maintained no documentation that this laboratory required daily maintenance had been performed on any of the anatomic pathology laboratory's microscopes. c. These findings were confirmed by laboratory personnel on May 12, 2026 at 02:00 pm. d. According to laboratory records, the laboratory performed and reported approximately 400,000 patient anatomic pathology tests annually.
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 laboratory personnel interviews, and Roche Ventana HE 600 quality control and quality assessment policies and procedures record review on May 12, 2026 at 01: 30 pm, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 42 CFR 493.1251 through 493.1283. Findings included: a. In anatomic pathology, it was the practice of the laboratory to perform hematoxylin and eosin staining of patient microscope slides using four (4) Roche Ventana HE 600 instruments. b. Each day of use, the laboratory maintained written quality control records titled "Histology HE600 Daily Quality Control" for each of the four Roche Ventana HE 600's. c. According to the laboratory's written protocol titled "Quality Management Quality Control Plan," "each section shall maintain a regular schedule for reviewing (at least monthly). . .quality control records." d. Based on a review of the laboratory's "Histology HE600 Daily Quality Control" records from January 2026 to April 2026, the laboratory maintained no documentation of monthly review as required by the laboratory's protocol titled "Quality Management Quality Control Plan" for the: i. Roche Ventana HE 600 instrument #2 in March 2026 and April 2026; ii. Roche Ventana HE 600 instrument #3 in March 2026 and April 2026; and, iii. Roche Ventana HE 600 instrument #4 in March 2026 and April 2026. e. These findings were confirmed by laboratory personnel on May 12, 2026 at 01:30 pm. f. According to laboratory records, the laboratory performed and reported approximately 400,000 patient anatomic pathology tests annually.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

	This STANDARD is not met as evidenced by: Based on technical supervisor interview and ANA (anti-nuclear antibody) proficiency testing record review on May 14, 2026 at 10:00 am, the laboratory director, high complexity testing, failed to ensure that an approved corrective action plan was followed when ANA proficiency testing results were found to be unacceptable. Findings included: a. In diagnostic immunology, the laboratory performed and reported patient ANA tests and was enrolled in appropriate ANA proficiency testing. b. According to the laboratory's protocol titled "Proficiency Testing," ""unacceptable" [proficiency testing] results must be review[ed] and investigation documented using the SHC Proficiency Testing exception Response (PTER) Form." c. Laboratory proficiency testing records indicate that in the second event of 2024, the laboratory received an unacceptable ANA proficiency testing score. The laboratory maintained no documentation to indicate that the unacceptable ANA proficiency testing result had been "review[ed] and investigation documented." d. According to laboratory records, the laboratory performed and reported approximately 250,000 patient diagnostic immunology patient tests annually.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) 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 technical supervisor interview, and laboratory personnel competency and duties and responsibilities records review on May 12, 2026 at 10:30 am, the laboratory director, high complexity testing, failed to ensure that prior to testing patients' specimens, all personnel had demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings included: a. For 1 of 1 randomly selected written testing personnel duties and responsibilities reviewed, the laboratory director specified in writing that the testing personnel was delegated to performed all clinical laboratory testing within the laboratory's defined category of "pathogenic bacteriology." b. However, the laboratory maintained no documentation to indicate that the laboratory had determined this testing personnel to be trained and competent to perform all clinical laboratory testing within the laboratory's defined section of "routine cultures," which was a section within the category of "pathogenic bacteriology." c. The technical supervisor confirmed these finding on May 12, 2026 at 10:30 am. d. According to laboratory records, the laboratory performed and reported approximately 200,000 patient bacteriology tests annually.