Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0882869	07/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
University Health Service Clinical Laboratory	2222 Bancroft Way, Berkeley, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 laboratory personnel interviews and the laboratory's 2022 and 2023 proficiency testing record review on July 18, 2023 at 09:30 am, the laboratory failed to maintain documentation to indicate that the laboratory director had attested to the routine integration of proficiency testing samples into the patient workload using the laboratory's routine methods. Findings included: a. For 2022 and 2023, it was the practice of the laboratory to test proficiency testing samples obtain from the American Proficiency Institute (API). b. The laboratory maintained copies of attestation statements provided by API. However, the copies of attestation statements for the following proficiency testing events showed that the laboratory director had not signed the attestation statements, documenting that proficiency testing samples were tested in the same manner as patient specimens: Chemistry for the first, second, and third events of 2022, Hematology for the first, second, and third events of 2022, Microbiology for the first, second, and third events of 2022, Chemistry for the first and second events of 2023, Hematology for the first event of 2023, and Microbiology for the first and second event of 2023. c. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and the laboratory's general laboratory systems quality assessment record review on July 18, 2023 at 10:00 am, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems specified in 493.1231 through 493.1236. Findings included: a. According to laboratory personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems specified in 493.1231 through 493.1236. No such written policies and procedures existed. b. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and test requisition record review on July 18, 2023 at 09:50 am, the laboratory failed to ensure that test requisitions solicited the time of patient specimen collection. Findings included: a. It was the practice of the laboratory to receive and maintain patient test requisitions electronically. b. According to laboratory personnel, even though the laboratory's test requisition did not include documentation of the time patient specimens were collected, the time patient specimens were collected was handwritten on the specimens' labels. However, once patient specimens were discarded, the laboratory maintained no documentation of the time of collection handwritten on the specimens' labels. The laboratory could not provide the time patient specimens were collected for specimens that had been discarded. c. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and the laboratory's general laboratory systems quality assessment record review on July 18, 2023 at 10:00 am, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified in 493.1241 through 493.1242. Findings included: a. According to laboratory personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified in 493.1241 through 493.1242. No such written policies and procedures existed. b. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.
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 the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to perform, at least once each day patient specimens were assayed, D-Dimer quality control procedures that included external two quality control materials of different concentrations (see D5447); maintain documentation to indicate that, each day of use, manual white blood cell differential stains were verified for intended reactivity to ensure predictable staining characteristics (see D5473); and establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified the analytic systems (see D5791).
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on testing personnel interview and hematology D-Dimer quality control record

	review on July 18, 2023 at 12:30 pm, the laboratory failed to perform, at least once each day patient specimens were assayed, D-Dimer quality control procedures that included two external quality control materials of different concentration. Findings included: a. In hematology, the laboratory performed and reported patient D-Dimer test results using the Alere D-Dimer Test. b. According to testing personnel, the laboratory performed D-Dimer quality control procedures using two external quality control materials of different concentration on the day when the laboratory begins using a new lot or shipment of D-Dimer test materials. However, any other day patient D-Dimer tests were performed using established D-Dimer test materials, the laboratory monitored patient D-Dimer tests using procedural or electronic quality controls only, and not external quality control materials of different concentrations. NOTE: "External quality control materials" have a similar matrix to that of patient specimens, are treated in the same manner as patient specimens, and go through all analytic phases of testing. c. According to testing personnel, the laboratory performs and reports approximately 60 patient D-Dimer test annually.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on testing personnel interviews and hematology manual differential quality control record review on July 18, 2023 at 11:10 am, the laboratory failed to maintain documentation that would indicate that, each day of use, manual white blood cell differential strains were verified for intended reactivity to ensure predictable staining characteristics. Findings included: a. It was the practice of the laboratory to perform and report patient specimen manual white blood cell differentials when required. Patient blood smears were stained using a Diff-Quik stain set. b. The laboratory maintained no documentation to indicate that, for each day of use, the laboratory had tested staining materials for intended reactivity to ensure predictable staining characteristics. Laboratory personnel confirmed that the laboratory maintained no such documentation. c. According to testing personnel, the laboratory performed approximately 160 patient manual white blood cell differentials 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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and the laboratory's general laboratory systems quality assessment record review on July 18, 2023 at 11:00 am, the laboratory failed to establish 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, including ensuring that the laboratory's criteria for acceptability for routine chemistry quality control materials were accurately entered into the laboratory's monitoring system. Findings included: a. It was the practice of the laboratory to test patient routine chemistry samples using the Horiba Abx Pentra 400. i. To monitor patient routine chemistry testing using the Horiba Abx Pentra 400 each day of use, the laboratory used two levels of assayed quality control materials and the criteria for acceptability of the quality control materials established by the quality control materials' manufacturer. ii. With each new lot of quality control materials, the manufacturer's routine chemistry quality control materials' criteria for acceptability was manually entered by the laboratory into the Horiba Abx Pentra 400's data system so that the instrument's data system could monitor the acceptability of the quality control materials' test results automatically. iv. On the day of this survey (July 18, 2023), a random review of the level 1 quality control material's criteria for acceptability for eight routine chemistry analytes in use showed that the acceptable range of test results entered into the Horiba Abx Pentra 400 for 2 of the analytes differed from the acceptable range established by the manufacturer. The criteria for acceptability entered into the instrument for chloride was 79.8 - 94.6, whereas the criteria for acceptability established by the manufacturer was 79.8 - 94.0. The criteria for acceptability entered into the instrument for creatine was 0.930 - 1.200, whereas the criteria for acceptability established by the manufacturer was 0.911 - 1.195. v. The laboratory failed to establish written policies and procedures to ensure the accurate manual entry of routine chemistry quality control materials' criteria for acceptability. No such written policies and procedures existed. b. Furthermore, according to laboratory personnel, the laboratory failed to establish 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. No such written policies and procedures existed. b. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and the laboratory's postanalytic systems quality assessment record review on July 18, 2023 at 10:00 am, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems specified in 493.1291, including the laboratory's mechanism to ensure all patient test results were reported timely. Findings included: a. According to testing personnel, it was the practice of the laboratory to review pending patient test result logs daily to ensure all patient test results were reported timely. The laboratory maintained no written protocols for this postanalytic systems quality assessment activity and no documentation that this activity occurred daily. b. Furthermore, according to laboratory personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the postanalytic systems specified in 493.1291. No such written policies and procedures existed. c. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.
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 the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing: Laboratory Director was not met. The laboratory director failed to ensure that proficiency testing samples were tested as required under subpart H of this part (see D6089); an approved corrective action plan was followed when any proficiency testing result was found to be unacceptable of unsatisfactory (see D6092); quality control programs were established and maintained (see D6093); quality assessment programs were established and maintained (see D6094); and, written policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency (see D6103).
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and the laboratory's 2022 and 2023 proficiency testing record review on July 18, 2023 at 09:40 am, the laboratory director failed to ensure that proficiency testing samples were tested as required under subpart H of this part. Findings included: a. The laboratory failed to maintain documentation to indicate that the laboratory director had attested to the routine integration of proficiency testing samples into the patient workload using the laboratory's routine methods. See D2009. b. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure 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 laboratory personnel interviews and the laboratory's 2022 and 2023 proficiency testing record review on July 18, 2023 at 09:40 am, the laboratory director

	failed to ensure that an approved corrective action plan was followed when any proficiency testing result was found to be unacceptable or unsatisfactory. Findings included: a. For 2022 and 2023, it was the practice of the laboratory to enroll and test proficiency testing samples obtain from the American Proficiency Institute (API). b. Laboratory personnel confirmed that the laboratory maintained no written protocols that have been approved by the laboratory director which were to be followed in the event the laboratory's proficiency testing results were found to be unacceptable or unsatisfactory. No such written protocols existed. c. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 laboratory personnel interviews and laboratory quality control record review on July 18, 2023, the laboratory director failed to ensure that quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings included: a. Based on the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. See D5400. b. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 laboratory personnel interviews and the laboratory's quality assessment record review on July 18, 2023 at 10:00 am, the laboratory failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failure in quality as they occur. Findings included: a. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems specified in 493.1231 through 493.1236. See D5291. b. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified in 493.1241 through 493.1242. See D5391. c. The laboratory failed to establish 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. See D5791. d. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the postanalytic systems specified in 493.1291. See D5891. e. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 laboratory personnel interviews and laboratory personnel competency record review on July 18, 2023 at 1:00 pm, the laboratory director failed to ensure that written policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency. Findings included: a. It was the practice of the laboratory to perform and maintain documentation of laboratory personnel competency evaluations pursuant to 42 CFR 493.1451(b)(9). b. However, the laboratory maintained no written policies and procedures detailing the laboratory's personnel competency evaluation protocols. NOTE: The procedures for the evaluation of the competency of the staff must include, but are not limited to the items indicated at 42 CFR 493.1451(b)(8). Laboratory personnel confirmed that no such written policies and procedure existed. c. According to current laboratory records, the laboratory annually performs approximately 61,000 patient chemistry tests, 8800 patient hematology tests, and 21,000 microbiology tests.