Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2319484	01/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Image One	8707 Complex Dr, 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
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and an interview with the Testing Personnel (TP) on December 18, 2025, the laboratory did not maintain any record of participation in proficiency testing in 2025. The findings included: 1. It was the practice of the laboratory to perform moderate complexity testing for creatinine within the specialty of routine chemistry. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing (PT) program for this test. 2. On December 18, 2025, at around 11:00 am, the TP provided the PT testing results on the instrument, but the laboratory did not keep any record of the PT program participation or any attestation form that signed by either the testing personnel or laboratory director.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel competency assessment records, review six (6) randomly selected patient test records, and interview with the laboratory 's staff, the laboratory failed to assess employee competency before starting testing. The findings include: 1. It was the practice of the laboratory to perform creatinine analyte testing using the I-STAT Portable Clinical Analyzer Model 3002. According to the record the laboratory began testing and reporting results on 06/26/2025. The first competency assessment of 2 of 2 testing personnel was signed by the technical consultant on 12/11 /2025. 2. On December 18, 2025, at approximately 10:00 a.m., the testing personnel affirmed that the laboratory had not conducted competency assessments of both testing personnel for 5 months and 15 days after starting testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manuals and an interview with the Laboratory Testing Personnel (TP) on December 18, 2025, it was determined that the laboratory director failed to approve and sign the procedure before laboratory began using it. The findings included: 1. It was the practice of the laboratory to perform creatinine analyte testing using the I-STAT Portable Clinical Analyzer Model 3002. The laboratory followed the step-by-step testing procedure outlined in the manufacturer's operator manual. 2. On December 18, 2025, at approximately 10:30 a. m., the TP confirmed that the laboratory director did not approve, sign and date the step-by-step testing procedure before laboratory use it.
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 review of policies and procedures for monitoring and assessing analytic systems, review of laboratory records, and an interview with the Laboratory Testing Personnel (TP) on December 18, 2025, it was determined that the laboratory failed to perform the monthly quality assessments as specified in the laboratory procedure manuals. The findings included: 1. It was practice of the laboratory to perform routine chemistry. According to the laboratory procedure manual, the laboratory must conduct a monthly quality assessment (QA) review based on the specified checklist. 2. On December 18, 2025, at approximately 11:00 am, the TP affirmed the laboratory did not review the monthly QA.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on an interview with testing personnel, review of laboratory's policies and procedures manuals, Quality Assessment (QA) records, Competency Assessment records and Proficiency Testing (PT) records, it was determined that the Laboratory Director (LD) failed to provide overall management and direction in accordance with 493.1407 of this subpart. The findings included: 1. The laboratory director failed to ensure that the laboratory participated in the proficiency testing event. See D2089 2. The laboratory director failed to ensure that personnel competency assessments were completed before employees began testing. See D5209 3. The LD failed to approve, sign, and date procedures. See D5407 4. The laboratory director failed to ensure the laboratory followed monthly quality assessments as specified in the laboratory procedure manuals. D5791
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's records of competency training and evaluation, six (6) randomly selected patient test records, and interview with the laboratory 's staff, the Laboratory Director (LD) failed to delegate or approve Technical Consultant (TC) responsibilities and duties in writing. The findings included: 1. The Technical Consultant signed the competency assessment for 2 of 2 testing personnel. The laboratory did not have any written records of authorization from the Laboratory Director for the Technical Consultant to approve the competency assessment. 2. On December 18, 2025, at approximately 10:00 a.m., the testing personnel confirmed that the laboratory did not maintain a copy of the previously approved duties and responsibilities for the TC.