

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2319484	(X3) Date Survey Completed 01/25/2026
Name of Provider or Supplier Image One	Street Address, City, State 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
D0000	A proficiency testing desk review survey as performed on 01/25/2026, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful [proficiency testing] participation; and D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
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 the review of the form CMS-2567 received on 1/12/2026, the laboratory failed to successfully participate in a proficiency testing program approved by HHS for each specialty, subspecialty and analyte or test in which the laboratory is certified

	under CLIA, The laboratory failed to achieve satisfactory performance for creatinine in two consecutive testing events constituting unsuccessful PT performance. See D2087.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in 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 the laboratory's proficiency testing (PT) records, an interview with the Testing Personnel (TP) and the responses on the statement of deficiency, it was determined that the laboratory did not participate in proficiency testing program and failed to achieve satisfactory performance for the subspecialty of routine chemistry in two consecutive testing events which is unsuccessful performance. The findings included: 1. It was the practice of the laboratory to perform moderate complexity testing for creatinine testing within the subspecialty 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 approximately 11:00 am, the testing personnel informed the surveyor that she was unable to obtain the record of the proficiency testing (PT) program participation and attestation form, signed by either the testing personnel or laboratory director, for the second and third events of 2025. 3- On January 12, 2026, the surveyor received form CMS-2567. The form stated that the lab did not participate in the PT program for the second and third events of 2025. Failure to achieve satisfactory performance for creatinine in two of three consecutive PT results resulted in an initial unsuccessful performance for the analyte.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the review of the form CMS-2567 received on 1/12/2026, the laboratory director failed to ensure successful participation in an HHS proficiency testing program. See D2096.