Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2107454	03/25/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laser Surgery Center Tempe	2000 E Southern Ave, Ste 106, Tempe, AZ	

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	An initial survey was performed on March 25, 2026. The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and Testing of Samples
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of Proficiency Testing (PT) records for 2025 and the 1st Event of 2026, and an interview with the testing personnel (TP-1), the laboratory failed to enroll in an HHS approved PT program for regulated testing performed in the specialties of Hematology and Chemistry, which are included in subpart I. Findings include: 1. The laboratory began utilizing the Chem8+ test cartridge on the I-Stat for patient testing in November 2024 under the specialties of Chemistry and Hematology with a reported annual test volume of 338. 2. The laboratory reports out results on the following regulated analytes: Hemoglobin, Hematocrit, Chloride, Glucose, Potassium, Sodium, PCO2 blood gas, pH blood gas, PO2 blood gas, blood urea nitrogen (BUN), and Creatinine. 3. No documentation was presented for review during the survey conducted on 3/25/26 to indicate the laboratory was enrolled during 2025 and the 1st Event of 2026 in a CMS-approved PT program for regulated analytes indicated above. 4. The TP-1 interviewed on 3/25/26 at 10:30 AM confirmed the laboratory was not

	enrolled in a CMS-approved PT program in 2025 and the 1st Event of 2026 in the specialities of Hematology and Chemistry.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 review of proficiency testing (PT) records from 2024 and 2025 and interview with the testing personnel (TP-1), the laboratory director and testing personnel failed to sign the PT attestation statements. Findings include: 1. The laboratory is enrolled in PT with American Proficiency Institute (API) for Activated Clotting Time (ACT) testing performed on the I-Stat analyzer and participates in 3 PT events annually. 2. The PT attestation statements presented for review for the first, second and third events of 2025 lacked the signatures of the laboratory director and testing personnel. 3. The PT attestation statements presented for review for the third event of 2024 lacked the signature of the laboratory director. 4. The TP-1 interviewed on 3/25/26 at 10:45 AM confirmed that the PT attestation statements indicated above were not signed by the laboratory director and testing personnel. 5. The laboratory reports an annual test volume of 50 under the specialty of Hematology.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records from 2024 and 2025 and interview with the testing personnel (TP-1) on 3/25/26 at 10:45 AM, the laboratory failed to provide evidence of a documented review of the PT results obtained for the 3rd testing event of 2024 and 1st, 2nd, and 3rd testing events of 2025 for testing performed in the specialty of Hematology. Findings include: 1. The laboratory is enrolled in PT with American Proficiency Institute (API) for Activated Clotting Time (ACT) testing performed on the i-Stat analyzer and participates in 3 PT events annually. 2. No written comment or signature was documented by laboratory personnel on the PT records from the 3rd testing event of 2024 and 1st, 2nd and 3rd testing events of 2025, to indicate a review and evaluation of the PT results obtained from API. 3. TP-1 interviewed on 3/25/26 at 10:45 confirmed that the PT results indicated above were not reviewed by laboratory personnel. 4. The laboratory reports an annual test volume of 50 under the specialty of Hematology.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the testing personnel (TP-1), the laboratory failed to verify the accuracy of analytes not included in subpart I at least twice annually during 2025. Findings include: 1. The laboratory began utilizing the Chem8+ test cartridge on the I-Stat for patient testing in November 2024 under the specialties of Chemistry and Hematology with a reported annual test volume of 338. 2. No documentation was presented for review during the survey conducted on 3/25/26 to indicate the laboratory verified the accuracy of the following unregulated analytes: TCO2, HCO3, BE, SO2, Anion Gap, and Ionized Calcium testing at least twice annually during 2025. 3. The TP-1 interviewed on 3/25 /26 at 10:30 AM confirmed the laboratory failed to verify the accuracy of the analytes indicated above at least twice annually during 2025.
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 a lack of established quality assessment (QA) policies and procedures and interview with the testing personnel (TP-1), the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. This laboratory began patient testing in August 2024 utilizing the I-Stat analyzer under the specialties of Chemistry and Hematology with a reported annual test volume of 338. 2. No QA documentation was provided for review during the survey conducted on 03/25/2026 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236, including but not limited to, Proficiency Testing policies and procedures. 3. The TP-1 interviewed on 3/25/26 at 11:00 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's test reports and interview with the testing personnel (TP-1), the laboratory's test report failed to indicate the name and address of the laboratory location where the testing was performed, the specimen source, and the interpretation of results. Findings include: 1. The laboratory began patient testing using the I-Stat in September 2024. The laboratory is currently performing patient testing under the specialties of Chemistry and Hematology with an annual test volume of 338. 2. It is the practice of the laboratory to tape the instrument printout to a piece of paper that includes the patient's information. This is then scanned into the patient's chart. 3. All test reports reviewed during the survey date of 3/25/26 such as: 130199 performed on 3/20/25, failed to include the name and address of the laboratory location where the testing was performed, the specimen source and the interpretation of results. 4. The TP-1 interviewed on 3/25/26 at 11:15 AM confirmed that the laboratory's test reports failed to include the name and address of the laboratory location where testing was performed, the specimen source, and the interpretation of results.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program from November 2024 through the survey date of 3/25/26 for testing of the regulated analytes, Hemoglobin, Hematocrit, Chloride, Glucose, Potassium, Sodium, PCO2 blood gas, pH blood gas, PO2 blood gas, blood urea nitrogen (BUN), and Creatinine, under the specialties of Hematology and Chemistry. See D2000 for findings.