Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2314231	05/15/2026
Name of Provider or Supplier	**Street Address, City, State**	
Invision Diagnostics	11026 Ventura Blvd Ste 14, Studio City, 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 Surveyor review of laboratory's policy & procedure, test requisition, instrument print out, final report and interview with the laboratory technical supervisor on May 15, 2026, at 1:25 p.m., the laboratory failed to follow its swab specimen acceptability and rejection procedure for 2 patients out of 10 patients, reviewed. The findings include: 1: (a) According to the laboratory's protocol, the swab sample remains stable for up to three days when stored in a refrigerator after collection. However, the laboratory did not follow its procedure to reject the sample # 260213007 that was collected on 2/13/2026 and stored for more than 3 days before performing the test on 2/23/2026. The laboratory reported the result as negative. The laboratory tested the sample about 10 days after the collection which exceeded the storage limit. The laboratory should have rejected the sample since it had exceeded the storage time limit and should not have been tested and reported the results. The reported negative test results which could have been due to the compromised sample integrity. As a result, the reliability of laboratory test results cannot be guaranteed, which may potentially harm patients. Additionally, sample #260429015, collected on April 29, 2026, was discovered in the refrigerator on May 15, 2026, awaiting testing. The laboratory did not keep any record of past sample rejection. (b) The laboratory did not have service manual for sample referral to the Rapid lab. It sent out sputum samples to the Rapid lab for pneumonia panel testing. There were 2 samples in the

	refrigerator awaiting send out; sample #260512002 was collected on 5/13/ 2026, and #260513015 was collected on 5/12/2026. There was no way to confirm whether these samples had been compromised. 2. The laboratory technical supervisor on May 15, 2026, at 1:25 p.m., affirmed that the sample, 260213007, was stored longer than the procedure instructed before testing. 3. The laboratory's testing declaration form signed by the laboratory director on 02/01/2026, stated that the laboratory performed approximately 48,000 molecular tests, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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 Surveyor review of laboratory's policy & procedure, test requisition, instrument print out, final test report and interview with the laboratory technical supervisor on May 15, 2026, at 1:25 p.m., the laboratory director failed to assure laboratory's compliance with the applicable regulations and in reporting accurate results, and potentially harmed patients. The findings include: See D5311, D6087 and D6106.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, test requisition, instrument print out, final report and interview with the laboratory technical supervisor on May 15, 2026, at 1:25 p.m., the laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The findings include: The laboratory personnel used a compromised sample to test and reported the test results, and potentially harmed patients. See D5311.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

	This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, test requisition, stored samples and interview with the laboratory technical supervisor on May 15, 2026, at 12: 50 p.m., the laboratory director failed to ensure that the laboratory had procedure for sample referral. The findings include: See D5311.