Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2103276	06/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Illuminate Diagnostics Inc	18331 Gridley Road, Ste C, Cerritos, 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
D5301	TEST REQUEST CFR(s): 493.1241(a) (a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of patient requisition information and interviews with laboratory personnel during the onsite survey conducted on June 2, 2026, it was determined that the laboratory failed to ensure that all tests were ordered by authorized individuals prior to accepting test requisitions. 180 of the 1712 tests were ordered by individuals who were not authorized to order clinical laboratory tests in the state of California. The findings included: 1. The reference laboratory performed high-complexity virology testing for the detection of sexually transmitted infections (STIs). 2. On the day of the survey, the surveyor reviewed patient requisitions from 05/20/2026 to 06/01 /2026. The surveyor observed that on 06/01/2026, approximately 180 tests had been ordered by an individual who did not have the qualifications required to order clinical laboratory tests in the state of California. On June 2, 2026, at approximately 1:00 pm, testing personnel confirmed that these tests had been ordered by an unauthorized person. 3. According to laboratory records, the laboratory performed and reported approximately 1712 STIs tests from May 20, 2026, through June 1, 2026.
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 ensure that laboratory personnel followed the written procedures manual. See D5401 The laboratory failed to establish a written procedure manual that included the entering results into patient records and reporting patient results. See D5403 The laboratory failed to establish test performance specifications before reporting patient results. See D5423
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the written procedure manuals, test records, including thirteen (13) patient sample reports from 05/20/2026 to 06/01/2026, and interviews with laboratory testing personnel on June 2, 2026, it was determined that laboratory personnel did not follow the written procedures manual for repeat criteria. The findings included: 1. The laboratory performed high-complexity virology testing for the detection of Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Mycoplasma genitalium (MG) and Trichomonas vaginalis (TV). According to the laboratory procedure manual, if the internal control (IC) fails, the extraction should be repeated. If IC fails again, the result must be reported as invalid. 2. On June 2, 2026, at approximately 12:00 p.m., laboratory testing personnel stated that the laboratory repeated all positive tests in duplicate and accepted the results if both results matched. During the survey, the surveyor reviewed 13 repeated samples and found inconsistencies with the established policies and procedures. ACC# 2434589U: The initial run failed for IC; the test was repeated in duplicate. The results of one repeat were positive for CT, and one was negative for CT; the test was reported as positive for CT. ACC# 2434461U: On the initial run, CT and MG were positive; the test was repeated once. The result of the single repeat was positive for MG and negative for CT; the test was reported as positive for MG and negative for CT. ACC# 24344754U: On the initial run, CT was positive; the test was repeated in duplicate. The results of one repeat were positive for CT, the other was negative for CT; the test was reported as inconclusive. 3. According to laboratory records, the laboratory performed and reported approximately 1712 STIs tests from May 20, 2026, through June 1, 2026.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of

	results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of policy and procedure manuals, test records, including thirteen (13) patient sample reports from 05/20/2026 to 06/01/2026, and interviews with laboratory testing personnel on June 2, 2026, it was determined that the procedure manual did not include the laboratory's system for entering results into patient records and reporting patient results. The findings included: 1. The laboratory performed high-complexity virology testing for the detection of sexually transmitted infections (STIs). The laboratory analyzed STI panels utilizing Alldx reagents on QuantStudio 5 Real-Time PCR Systems. The laboratory office staff entered results manually into the customized LIS system. 2. On the day of the survey, the laboratory did not have a procedure in place for reporting test results using the laboratory's customized LIS. On June 2, 2026, at approximately 1:30 p.m., laboratory testing personnel verified that these documents were not retained. 3. According to laboratory records, the laboratory performed and reported approximately 1712 STIs tests from May 20, 2026, through June 1, 2026.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory's test validation records, and interview with the laboratory testing personnel on June 2, 2026, it was determined that the laboratory failed to establish test performance specifications before reporting patient sexually transmitted infections (STIs) test results. The findings included: 1. The laboratory performed high-complexity virology testing for the detection of sexually transmitted infections (STIs). The laboratory implemented molecular assays for STIs panels utilizing Alldx reagents on QuantStudio?5 Real-Time PCR Systems that were not

	FDA-cleared assays. 2. On the day of the survey, the laboratory did not provide documentation showing that test performance specifications for the STIs laboratory-developed test (LDT) were established prior to reporting patient test results, as required by 493.1253. On June 2, 2026, at approximately 12:00 pm, laboratory testing personnel confirmed that these documents were not maintained. 3. According to laboratory records, the laboratory performed and reported approximately 1712 STIs tests from May 20, 2026, through June 1, 2026.
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 Surveyor review of laboratory director's qualifications, training and experiences, and interview with the laboratory testing personnel during an onsite survey of the laboratory on June 2, 2026, it was determined that the Condition: Laboratories performing high complexity testing laboratory director was not met. The findings included: The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests. See D6078.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii) Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the

	director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology. This STANDARD is not met as evidenced by: Based on review of laboratory director's qualifications, training and experiences, and interview with the laboratory testing personnel during the onsite survey of the laboratory on June 2, 2026, it was determined that the laboratory director failed to be qualified to direct a laboratory performing high complexity in 2025 and 2026. The findings included: 1. The laboratory performed high-complexity virology testing for the detection of sexually transmitted infections (STIs). 2. On the day of the survey, the surveyor requested documentation from the laboratory testing personnel to verify the laboratory director's qualifications for overseeing a High Complexity Virology Laboratory. The testing personnel were unable to provide the requested documentation. On June 4, 2026, the laboratory owner emailed the laboratory director's CV, which indicated that the director did not possess at least two years of experience directing or supervising high complexity testing, nor did they have at least 20 CE credit hours in laboratory practice covering the responsibilities defined in 493.1445. 3. According to laboratory records, the laboratory performed and reported approximately 1712 STIs tests from May 20, 2026, through June 1, 2026.
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 the review of the laboratory policies and procedures, test validation records, patient requisition and interviews with laboratory personnel during the onsite survey conducted on June 2, 2026, it was determined that the Laboratory Director (LD) failed to provide comprehensive management and direction as required under 493.1445 of this subpart. The findings included: 1. The laboratory director failed to ensure that laboratory personnel followed the written procedures manual. See 5401 2. The laboratory director failed to ensure that the laboratory had procedures for entering results into patient records and reporting patient results. See 5403 3. The laboratory director failed to ensure that the laboratory established test performance specifications before reporting patient results. See D5423 4. The laboratory director failed to ensure

	that all tests were ordered by authorized individuals prior to accepting test requisitions. See D5301