

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2325006	(X3) Date Survey Completed 08/26/2026
Name of Provider or Supplier Regents Of The Uc UCLA Urology Andrology	Street Address, City, State 2901 Wilshire Blvd Ste 400, Santa Monica, 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
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 Surveyor review of laboratory's DNA fragmentation test records, test validation documents, and interview with the laboratory testing persons on August 8, 2026, at 4:30 p.m., it was determined that the laboratory did not meet the requirement under 493.1253 to fulfil the analytic systems condition. The laboratory's failure to meet the conditions may potentially harm and affect patient care. The findings include: 1. The laboratory failed to establish and verify (validation) its DNA fragmentation test performance specifications, see D5423. 2. The laboratory failed to determine the control procedure for DNA fragmentation test, see D5425.
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 Surveyor review of laboratory's DNA fragmentation test validation documentation, and interview with the laboratory testing persons on August 8, 2026, at 4:30 p.m., the laboratory failed to verify the test accuracy and pertinent performance specifications which could lead to an inaccurate result. The findings include: 1. The laboratory performed DNA fragmentation test on semen sample. The test result was reported as DNA fragmentation index in percentage. The test is not approved by FDA; therefore, the laboratory requires to establish the test performance specifications. However, the laboratory did not validate or establish the test performance specifications. 2. The laboratory testing person on August 8, 2026, at 4:30 p.m., affirmed that the laboratory did not validate the test. 3. The laboratory's testing declaration form signed by the laboratory director on 07/29/2026, stated that the laboratory performed approximately 3,020 tests, annually.

D5425

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(3)

(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's quality control and patient test records, and interview with the laboratory testing persons on August 26, 2026, at 3:55 p.m., the laboratory failed to determine a control procedure for the DNA fragmentation test. The findings include: 1. The laboratory tested patient #4602056 on 8/21/2026. There was no quality control data on that day for the DNA fragmentation test. The testing person #1 informed that there was no established quality control procedure for the test. 2. The laboratory testing person on August 26, 2026, at 3:55 p.m., affirmed that the laboratory is not running any quality control material for the DNA fragmentation test. 3. The laboratory's testing declaration form signed by the laboratory director on 07/29/2026, stated that the laboratory performed approximately 3,020 tests, annually.

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's test validation, quality control and patient test records and interview with the laboratory testing persons on August 8, 2026, at 4:30 p.m., and the severity and the number of deficiencies found and cited herein, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory, hence the Condition: Laboratories performing high

	complexity testing; laboratory director was not met. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: 1. The laboratory director failed to ensure that the test verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the DNA fragmentation method, see D6086. 2. The laboratory director failed to ensure that the quality control programs are established for the DNA fragmentation test, see D6093. 3. The laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience to perform high complexity DNA fragmentation test, see D6102.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's DNA fragmentation test records, test validation documents, and interview with the laboratory testing persons on August 8, 2026, at 4:30 p.m., the laboratory director failed to ensure that the test verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. The findings include: The laboratory failed to establish and verify (validation) its DNA fragmentation test. So, the accuracy of the patients' test results rendered by the laboratory cannot be assured and might have harmed patients, see D5423.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control and patient test records, and interview with the laboratory testing persons on August 26, 2026, at 3:55 p.m., the laboratory director failed to ensure that the quality control programs are established for the DNA fragmentation test. The findings include: See D5425.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's test records, instrument print out, personnel

	records and interview with the laboratory testing persons on August 26, 2026, at 4:35 p.m., the laboratory director failed to ensure that the testing personnel have the appropriate education for the high complexity DNA fragmentation test. The findings include: See D6171
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's test records, instrument print out, personnel records and interview with the laboratory testing persons on August 26, 2026, at 4:35 p.m., it was determined that the laboratory performing high complexity testing; testing personnel condition was not met. The findings include: The laboratory did not have qualified testing personnel to perform the high complexity DNA fragmentation test. See D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in

respiratory therapy or cardiovascular technology from an accredited institution; or (b) (6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's test records, instrument print out, personnel records and interview with the laboratory testing persons on August 26, 2026, at 4:35 p.m., the laboratory testing personnel who are running the high complexity DNA fragmentation test, 3 out of 4 did not meet the high complexity testing personnel qualifications. The findings include: 1. The laboratory used QwikCheck DFI Kit to perform the DNA fragmentation test. The test is not FDA approved and considered as high complexity laboratory developed test. The test procedure includes 14 different manual steps before putting into the SQA-Vision instrument for the final signal detection. All those manual steps are part of the high complexity test procedure. Therefore, these procedures should be performed by testing personnel that are qualified to run high complexity tests. It was found that 3 of the testing personnel were not qualified to run high complexity tests. 2. The laboratory testing person on August 26, 2026, at 3:55 p.m., affirmed that the 3 testing persons did not have the qualifications to run the DNA fragmentation test. 3. The laboratory's testing declaration form signed by the laboratory director on 07/29/2026, stated that the laboratory performed approximately 3,020 tests, annually.