

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1063918	(X3) Date Survey Completed 04/23/2025
Name of Provider or Supplier Orange County Urology Associates Pathology Lab	Street Address, City, State 23961 Calle De Magdalena, Suite 500, Laguna Hills, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures manuals and interview with the Laboratory Director (LD) on April 23, 2025, it was determined that the laboratory director failed to approve, sign, and date all policies and procedures. The findings include: 1. It was the practice of the laboratory to perform microbiology testing, histopathology grossing and urine cytology processing. 2. On April 23, 2025, at approximately 2:30 pm, the LD affirmed that the laboratory maintained no documentation indicating that written policies and procedures had been approved, signed, and dated by the current laboratory director. 3. The laboratory's testing declaration form, signed by the laboratory director on April 8, 2025, stated that the laboratory performed approximately 2900 tests annually.</p>
D5779	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records and interview with the laboratory staff on April 23, 2025, at 12:20 pm, the laboratory failed to take corrective</p>

action for unacceptable proficiency results for 1 of 2 unacceptable PT results. The findings include: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for Urinary Tract Infection (UTI) testing using Bio-Rad CFX in 2023, 2024 and 2025. According to the API evaluation, the laboratory attained an unacceptable score in the third event of 2023 and 1st event of 2024 for Mycoplasma genitalium. 2. On April 23, 2025, at approximately 12:20 pm, the laboratory staff affirmed that the laboratory did not take any corrective action for the unacceptable score in the 1st event of 2024 for Mycoplasma genitalium. 3. The laboratory's testing declaration form, signed by the laboratory director on April 8, 2025, stated that the laboratory performed approximately 400 UTI 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 interviews with the Laboratory Director (LD), review of the laboratory policies and procedures manuals, Proficiency Testing records, and performance records on April 23, 2025, the laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The findings include: 1. The laboratory Director failed to approve, sign, and date all policies and procedures. See D5407. 2. The laboratory Director failed to ensure corrective action was taken for unacceptable proficiency results. See D5779. 3. The laboratory director did not ensure that prior to testing patients' specimens, all personnel possess a current license issued by the State of California. See D6170

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's records of personnel training, competency evaluation, laboratory policies and procedures, Proficiency Testing, twenty (20) randomly selected patient testing records, and interview with the laboratory 's staff, the laboratory failed to provide records showing that the laboratory director (LD) has

authorized, delegated, and approved lab personnel of responsibilities and duties in writing. The findings included: 1. Laboratory manager signed the competency assessment for 2 of 2 Histology Technicians. The laboratory did not maintain any records of written delegation and authorization of responsibilities and duties by the LD for the Laboratory manager. 2. On April 23, 2025, at approximately 12:45 pm the LM confirmed that the laboratory did not maintain a copy of the previously approved duties and responsibilities for the LM. 3. The laboratory's testing declaration form, signed by the laboratory director on April 8, 2025, stated that the laboratory processed approximately 2500 slides annually.

D6170

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(a)

Each individual performing high complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

This STANDARD is not met as evidenced by:
Based on laboratory personnel interviews, molecular testing record review and review of Ten (10) randomly selected patient test results on April 23, 2025, it was determined that the individual performed high complexity Urinary Tract Infection (UTI) testing failed to possess a current license issued by the State of California. The findings include: 1. It was the practice of the laboratory to perform high complexity Urinary Tract Infection (UTI) testing using Bio-Rad CFX instrument. The laboratory has 11 physicians who order the tests, and it is classified as an independent laboratory. A person who performs high complexity testing in the State of California must possess a current license issued by the State of California. 2. Between March 28, 2023, and March 03,2025, California unlicensed testing personnel reviewed and released UTI testing results. On April 23, 2025, at approximately 11:30 am, the laboratory unlicensed staff affirmed that he reviewed and released UTI testing results without any further review by a California licensed testing person.