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| <p>Statement of Deficiencies</p> | <p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>05D1063918</p> | <p>(X3) Date Survey Completed</p> <p>01/13/2022</p> |
| <p>Name of Provider or Supplier</p> <p>Orange County Urology Associates Pathology Lab</p> | <p>Street Address, City, State</p> <p>23961 Calle De Magdalena, Suite 500, Laguna Hills, CA</p> | |
| <p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p> | | |

| <p>(X4) ID Prefix Tag</p> | <p>Summary Statement of Deficiencies</p> |
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| <p>D5209</p> | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review lack of the laboratory competency evaluation records, and interview with the laboratory personnel, it was determined that the laboratory failed to document the competency evaluation for the testing personnel. The findings included: a. The laboratory is a histopathology grossing and processing laboratory. b. The laboratory failed to make the competency evaluation records available at the time of survey (01/13/2022 @ 11:5 am) when requested.</p> |
| <p>D5411</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory's Fisher brand thermometer, the temperature records, and interview with the testing personnel, it was determined that the laboratory failed to perform following the manufacturer's instructions and in a manner that provides test results/storage temperature monitoring within the laboratory's stated</p> |

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| | <p>performance specifications. The findings included: a. The laboratory is a histopathology grossing and urine cytology processing laboratory. b. A refrigerator is used to store urine specimens when received and before processed. c. A Fisher brand digital thermometer was used to monitor its storage temperature set between 0 to 7 degree Celsius. d. At the time of survey (01/13/2022 @ 11AM), the thermometer indicated its Min at -2 and Max at 25 degree Celsius which, in the past, were outside of the laboratory's setting of acceptable temperature range between 0 to 7 degree Celsius. e. The laboratory failed to notice and take corrective actions for these out-of-control temperature conditions.</p> |
| <p>D5413</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory facility, the temperature records, and interview with the testing personnel, it was determined that the laboratory failed to monitored and documented temperature daily use for its water bath equipment. The findings included: a. The laboratory is a histopathology grossing and tissue slides processing laboratory. b. A water bath is used to allow tissue to relax and smooth out prior to being mounted on a glass slide. c. The laboratory failed to document and record the water bath temperature in the daily uses.</p> |
| <p>D5415</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and tour of the laboratory facility, and interview with the laboratory personnel, it was determined that the laboratory failed to indicate, including but is not limited to the following information: reagent/supply's preparation and expiration dates. The findings included: a. The laboratory is a histopathology and urine cytology process laboratory. b. The laboratory used reagents including alcohol, xylene, hematoxylin, and eosin, etc. c. The laboratory failed to indicate the open date and/or expiration date when the reagents were opened for use.</p> |
| <p>D5781</p> | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> |

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory's Fisher brand thermometer, the temperature records, and interview with the testing personnel, it was determined that the laboratory failed to document all corrective actions taken, when any equipment that performed outside of established operating parameters or performance specifications. The findings included: a. The laboratory is a histopathology grossing and urine cytology processing laboratory. b. A refrigerator is used to store urine specimens when received and before processed. c. A Fisher brand digital thermometer was used to monitor its storage conditions and acceptable temperature range was set between 0 to 7 degree Celsius. d. At the time of survey (01/13/2022 @ 11AM), the thermometer indicated its Min at -2 and Max at 25 degree Celsius which happened, in the past, were outside of the laboratory's setting of acceptable temperature between 0 to 7 degree Celsius, see D-5411 e. The laboratory personnel affirmed that the laboratory failed to notice and/or familiarize the digital thermometer features and functions.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the 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 observation of the laboratory's Fisher brand thermometer, the temperature records, lack of the competency evaluation records, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory is a histopathology grossing, tissue slides processing, and urine cytology processing laboratory. b. Lack of competency evaluation records available at the time of survey (01/13/2022 @ 10:50 AM), see D-5209 c. The laboratory failed to familiarize a Fisher brand digital thermometer's features and functions, and failed to notice the temperature was out of the acceptable temperature range, see D-5411 and D-5413 d. The laboratory failed to indicate opened date and/or expiration date on a label once the reagents or supplies opened to be used, see D-5415 e. The laboratory failed to notice and take corrective actions for these out-of-control temperature conditions see D-5781.

D6096

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(7)

The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory's Fisher brand thermometer, the temperature records, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance characteristics were identified a. The laboratory is a histopathology grossing, tissue slides processing, and urine cytology processing laboratory. b. The laboratory failed to familiarize a Fisher brand digital thermometer's features and functions, and failed to notice the temperature was out of the acceptable temperature range, see D-5411. c. The laboratory failed to notice the temperature was outside of acceptable temperature range, and take corrective actions for these out-of-control temperature conditions see D-5781.