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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>26D0446151       | <b>(X3) Date Survey Completed</b><br><br>02/15/2023 |
| <b>Name of Provider or Supplier</b><br><br>Urology Care Inc  | <b>Street Address, City, State</b><br><br>3207 W Truman Blvd, Jefferson City, MO |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D2003</b>              | <p><b>ENROLLMENT</b><br/>CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by:<br/>Based on of proficiency records for 2021, 2022 and to date February 6, 2023, review of patient reports and interview with the testing personnel (TP) #3, the laboratory failed to establish a means to verify the accuracy of the non-regulated analyte for urine microscopic testing twice a year. Findings: 1. Review of proficiency records for 2021, 2022 and to date February 6, 2023, showed the laboratory failed to prove accuracy on the non-regulated analyte urine microscopic exam since April 8, 2021. 2. Review of patient results confirmed the laboratory reports out results for urine microscopic exams. 3. Interview with the TP #3 on February 6, 2023 at 2:00 PM confirmed the laboratory failed to establish a means to verify the accuracy of the non-regulated analyte for urine microscopic testing twice a year.</p> |
| <b>D6045</b>              | <p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b><br/>CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of competencies and interview with testing personnel # 3, the</p>  |

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|                     | <p>technical consultant (whom is also the laboratory director) failed to identify training needs for one of one testing personnel in 2022. Findings: 1. Review of laboratory competencies showed no documentation of initial training for testing personnel # 4. 2. Interview with testing personnel #3 on February 6, 2023 at 2:00 PM confirmed the technical consultant failed to identify initial training needs for one testing personnel in 2022.</p>  |
| <p><b>D6053</b></p> | <p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b><br/>CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the performance evaluations and interview with testing personnel #3, the technical consultant (whom is also the laboratory director) failed to evaluate and document performance evaluations at least semiannually during the first year for one of one testing personnel. Findings: 1. Review of performance evaluations showed no semiannual performance evaluation was documented for testing personnel #4. 2. Interview with testing personnel #3 on February 6, 2023 at 2:00 PM confirmed the technical consultant did not evaluate and document the semiannual performance evaluation for testing personnel #4.</p> |
| <p><b>D6054</b></p> | <p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b><br/>CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of performance evaluations and interview with testing personnel #3, the technical consultant (whom is also the laboratory director) failed to evaluate and document annual performance evaluations for three of three testing personnel in 2021 and 2022. Findings: 1. Review of performance evaluations showed no annual performance evaluation for testing personnel #1, #2 and #3 in 2021 and 2022. 2. Interview with testing personnel #3 on February 6, 2023 at 2:00 PM confirmed the technical consultant failed to evaluate and document annual performance evaluation for testing personnel #1, #2 and #3 in 2021 and 2022.</p>                                 |