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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>44D0688158              | <b>(X3) Date Survey Completed</b><br><br>03/08/2018 |
| <b>Name of Provider or Supplier</b><br><br>Tennessee Valley Urology Center Pc  | <b>Street Address, City, State</b><br><br>400 Berywood Trail Nw, Suite B, Cleveland, TN |   |
| 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>D5209</b>              | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES<br/>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:</p> <p>_____ Based on a review of the procedure manual, employee training/competency records for 2016 and 2017 and interview with the Clinical Coordinator, the laboratory failed to document training and competency upon hire and at the 6 months interval for new personnel. The findings include: 1. Review of the procedure manual revealed training and competencies were required for new hire lab personnel "prior to analyzing patient specimens and at least semi-annually during the first year". 2. Review of the employee training/competency records for 2016 and 2017 revealed no training documented for Clinical Coordinator hired 9/5/17 and no semi-annual competency documented for testing person # 3 hired 3/07/16. 3. Upon interview March 8, 2018 at approximately 12:00 p.m. with the Clinical Coordinator, it was confirmed the laboratory failed to document training and competency upon hire and semi-annually.</p> <p>_____</p> |
| <b>D6070</b>              | <p>TESTING PERSONNEL RESPONSIBILITIES<br/>CFR(s): 493.1425(b)(1)</p> <p>Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.</p>   |

This STANDARD is not met as evidenced by:

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Based on observation of laboratory centrifuge for spinning urines at approximately 9:15 a.m. March 8, 2018, review of urine sediment procedure and interview with the Clinical Coordinator, determined the testing personnel failed to ensure laboratory procedure for processing urine sediment was followed upon installation of new centrifuge 3/05/18. The findings include: 1. Observation of laboratory centrifuge at approximately 9:15 a.m. March 8, 2018, for spinning urines, revealed spin speed at 3334 RPM's (revolutions per minute) and spin time at 10 minutes. 2. Review of urine sediment procedure revealed urine sediment to be spun at 2000 RPM's for 5 minutes. 3. Interview at approximately 11:30 a.m. March 8, 2018 with the Clinical Coordinator confirmed the laboratory testing personnel failed to ensure laboratory procedure for processing urine sediment was followed when the new urine centrifuge was installed 3/5/18.

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