

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0688158	(X3) Date Survey Completed 07/20/2021
Name of Provider or Supplier Tennessee Valley Urology Center Pc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: ===== The laboratory director failed to ensure personnel were competent to perform test procedures (Refer to D6004) and failed to review proficiency testing records (Refer to D6018). =====</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporitions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: ===== Based on review of the laboratory's competency evaluations and upon interview with the Office Manager, it was</p>

determined that the Laboratory Director did not document annual competency for three of four testing personnel. The findings include: 1. Review of laboratory's annual competency evaluations were not documented by the Laboratory Director in 2020 or 2021 for three of four testing personnel. 2. Interview with the Office Manager at approximately 12:30 p.m. July 20, 2021 confirmed no annual competency evaluations were documented by the Laboratory Director in 2020 or 2021 for three of four testing personnel. =====

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

===== Based on review of Proficiency Testing (PT) records for 2020 and January through June 2021 and interview with the Office Manager, it was determined the Laboratory Director failed to ensure that PT reports were reviewed and evaluated for 2020 and January through June 2021. The findings include: 1. There was no documentation of Laboratory Director review for PT results for 2020 and January through June 2021. 2. An interview with the Office Manager at approximately 12:30 p.m. July 20, 2021 confirmed there was no documentation of Laboratory Director review of PT results for 2020 and January through June 2021 . =====