

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0918140	(X3) Date Survey Completed 10/17/2022
Name of Provider or Supplier Southwest Urology Inc	Street Address, City, State 3647 Medina Road, Medina, OH	
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
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Operations Manager (COM), the Technical Consultant (TC) failed to evaluate and document the competency of four out of 11 Testing Personnel (TP) in 2021 assuring their competency was maintained in order to perform moderately complex routine chemistry and hematology testing procedures and report the test results promptly, accurately, and proficiently. All testing conducted by TP#1, TP#2, TP#3 and TP#4 for two out of two test systems from 01/01/2021 to 10/07/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Laboratory Competency Policy ", provided on the date of the inspection, found the following instructions for TP competency assessments: "3. A Six Month & Annual Laboratory Competency Assessment will be conducted yearly on each employee performing patient testing." 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 10/17/2022, revealed 11 TP listed and credentialed to perform moderately complex chemistry and hematology testing procedures. 3. Review of the laboratory's 2021 competency assessment records did not find a competency assessment for TP#1, TP#2, TP#3 and TP#4 who conducted post-vasectomy presence or absence of sperm and urinalysis with microscopic testing. The Inspector requested the 2021 competency assessment for TP#1, TP#2, TP#3 and TP#4 from the COM. The COM confirmed, via an electronic email on 10/18/2022 at 2:48 PM, that the 2021 competency assessment for TP#1, TP#2, TP#3 and TP#4 was not completed as required and was unable to provide the requested documentation.</p>