

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0336272	<b>(X3) Date Survey Completed</b>  07/19/2018
<b>Name of Provider or Supplier</b>  Southwest Urology, Llc	<b>Street Address, City, State</b>  6900 Pearl Road, Suite 200, Middleburg Heights, OH	
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>
<b>D2087</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and an interview with the Project Manager (PM), the laboratory failed to attain a PT analyte score of at least 80 percent (%) for urinalysis. Findings Include: 1. Review of three out of five of the laboratory's 2016 and 2017 API PT events, provided on the date of survey, found 2016 3rd event, 2017 1st event and 2017 3rd event for urinalysis scores of 50%. 2. The PM confirmed the API PT event scores of 50% for urinalysis. The interview occurred on 07/19/2018 at 1:40 PM.</p>
<b>D2096</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and an interview with the Project Manager (PM), the laboratory failed to achieve satisfactory PT performance for the Urinalysis test in two out of three consecutive testing events. Findings Include: 1. Review of three out of three of the laboratory's 2016 API urinalysis PT events, provided on the date of the</p>

survey, found a 2016 3rd event urinalysis score of 50% for specific gravity. 2. Review of three out of three of the laboratory's 2017 API urinalysis PT events, provided on the date of the survey, found a 2017 1st event urinalysis score of 50% for bilirubin. 3. The PM confirmed the laboratory received a 50% score for urinalysis in two out of three consecutive API PT events. The interview occurred on 0719/2018 at 1:40 PM.