

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0918140	(X3) Date Survey Completed 10/26/2020
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
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: Based on record review and interviews with the Office Manager and former Laboratory Director (LD), the laboratory failed to ensure that the position of Laboratory Director was filled according to the qualification requirements of 493.1405 of this subpart in order to provide overall management and direction in accordance with 493.1407 of this subpart. All patients tested at this laboratory from 1/29/2020 to 10/26/2020 had the potential to be affected. Findings include: 1. Review of the CMS-116 and CMS-209 forms, on 10/21/2020, found that the Clinical Consultant (CC) and Technical Consultant (TC), designated by the former LD, had approved the CMS-116 and CMS-209 forms via signature and date of 10/19/2020. 2. Review of the CMS-209 form, on 10/21/2020, failed to find an individual listed as the Laboratory Director to provide overall management and direction in accordance with 493.1407 of this subpart. 3. An email interview with the Office Manager ,on 10/21/2020 at 4:40 PM, revealed that the former LD had retired as of 1/29/2020, but was '... still available for consult,' and that the formerly designated CC and TC had approved the CMS-116 and CMS-209 forms via signature and date in the former LD's absence. 4. A telephone interview with the former LD, on 10/22/2020 at 1:01 PM, confirmed that he had retired on 1/29/2020, was not performing the responsibilities of the lab director after 1/29/2020, and had no knowledge of the testing of patient specimens after 1/29/2020; thus, the laboratory failed to ensure that the position of the LD was filled, after 1/29/2020, according to the qualification requirements of 493.1405 of this subpart in order to provide overall management and direction in accordance with 493.1407 of this subpart. 5. An on-site review of laboratory policies, procedures and</p>

documentation, on 10/26/2020 at 9:30 AM, confirmed that former LD had not preformed the responsibilities of the LD after 1/29/2020.