

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0685228	(X3) Date Survey Completed 04/30/2019
Name of Provider or Supplier Urology Associates Of The Central Coast	Street Address, City, State 35 Casa St Ste 370, San Luis Obispo, CA	
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
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories performing moderate complexity testing, testing personnel was not met. See D6064.</p>
D6064	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a)</p> <p>Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor's review of ten (10) randomly selected patient test requisition and patient testing records from 11/09/2017 to 04/23/2019, testing personnel records and interview with the laboratory personnel and on 04/30/2019, the laboratory failed to ensure that the testing personnel performing patient testing on Total PSA using the FastPack system analyzer possessed an appropriate current license issued by the State of California (State Requirement.). The findings include: a. The laboratory failed to employee each individual performing moderate complexity testing to hold a current license issued by the State in which the laboratory is located, if such licensing is required for performing moderate complexity testing. The laboratory performed patient Total PSA testing on the FastPack analyzer. b. On 04/30/2018 30, 12:00 AM (survey date) the laboratory personnel confirmed that a testing personnel CPT listed</p>

on the CMS-209 form performed patient Total PSA testing on the FastPack analyzer which entailed resulting and reporting of patient tests. c. The laboratory testing declaration form, signed by the laboratory Director on 04/20/2018 that the laboratory performs approximately 708 Total PSA tests annually.