

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520888	(X3) Date Survey Completed 06/09/2021
Name of Provider or Supplier Urology Associates Of Idaho Falls	Street Address, City, State 2375 Coronado St, Idaho Falls, ID	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Proficiency Institute (API), the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, competency assessments and an interview with Testing personnel 1 (TP1) on 6/9/2021, the laboratory failed to test PT samples with the regular patient workload by personnel who regularly perform the laboratory testing. The findings include: 1. A review of the CMS 209 and competency assessments identified nine (9) testing personnel testing prostate-specific antigen (PSA) on the Nanoentek Frend analyzer. 2. A review of PT records from API for Chemistry core for 2020 events one, two and three and 2021 event one identified that one of nine testing personnel performed all PT events for 2020 and 2021. The laboratory failed to have eight (8) of (9) personnel who regularly perform PSA testing perform PSA PT testing. 3. An interview with TP1 on 6/9/2021 at 9:20 am confirmed that one (1) of (9) testing personnel performed all the PSA PT testing for 2020 and 2021. 4. The laboratory reports performing 1300 PSA tests annually.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and an interview with the office manager on 6/9/2021, the Laboratory Director failed to approve, sign and date the prostate-specific antigen (PSA) individualized quality control plan (IQCP). The findings include: 1. A record review of laboratory policies and procedures identified that the current laboratory director failed to approve, sign and date the PSA IQCP for the FrenD analyzer. 2. An interview with the office manager on 6/9/2021 at 9:41 am confirmed that the PSA IQCP was not signed by the current laboratory director at the time of survey. 3. The laboratory reports performing 1300 PSA tests annually.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on a random review of temperature logs for 2019, 2020 and 2021 and an interview with testing personnel 2 (TP2) on 6/9/2021, the laboratory failed to document temperatures and humidity to ensure accurate and reliable testing on the Nanoentek FrenD. The findings include: 1. A random review of temperature logs for 2019, 2020 and 2021 identified that the laboratory failed to document temperatures and humidity for all days the laboratory was in operation. Room temperature, humidity, refrigerator and freezer temperatures were not documented 9 of 23 days in July 2020, 8 of 21 days in August 2020, 5 of 22 days in September 2020 and 7 of 22 days in October 2020. The technical consultant reviewed and initialed all temperature logs for the above months but failed to document any corrective actions. 2. An interview with TP2 on 6/9/2021 at 10:20 am confirmed that the laboratory failed to document the above temperatures and humidity as required for testing Nanoentek FrenD PSA.