Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520888	06/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Urology Associates Of Idaho Falls	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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant, the laboratory failed to follow the Nanotek Frend analyzer instruction to include the identity of the prostate-specific antigen (PSA) test methodology on 2 out of 2 patient PSA test reports reviewed in May 2019. Findings: 1. A review the of Nanotek Frend assay instruction sheet for PSA reagent revealed the requirement for the test methodology be indicated on the patient results reported to providers. 2. A review of 2 out of 2 patient PSA reports from May 2018, revealed the patient reports failed to include the identity of the PSA assay to providers. 3. The laboratory performed approximately 600 PSA tests in 2018. 4. An interview with the technical consultant on June 25, 2019 at 12:15 PM, confirmed the patient PSA reports failed to include the identity of the PSA methodology.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:

	Based on a review of quality control records and an interview with the technical consultant, the laboratory failed to use in-date quality control materials for the prostate-specific antigen (PSA) test performed on the Nanotek Frend on April 26, 2019. Findings: 1. A review of the PSA quality control (QC) records revealed the laboratory failed to use in-date quality control materials for April 2019 QC performance. 2. The laboratory performed approximately 66 PSA tests on patients in April 2019. 3. An interview with the technical consultant on June 25, 2019 at 11:35 AM, confirmed the laboratory staff failed to perform QC activities with quality control materials not expired.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the technical consultant, the laboratory failed to document the training for 1 out of 3 testing personnel performing Prostate-specific antigen (PSA) tests on the Nanotek Frend since November 2018. Findings: 1. A record review of personnel documents revealed training documents for 1 out of 3 testing personnel performing PSA tests on the Frend analyzer was not documented prior to testing patients in November 2018. 2. An interview with the technical consultant on June 25, 2019 at 11:10 AM, confirmed the 1 laboratory testing person failed to have documented training prior to testing patient samples.