Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0306899	01/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Urology Associates, Pc - Franklin	4601 Carothers Parkway, Suite 475, Franklin, TN	

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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on review of the personnel records, the 2018 and 2019 proficiency testing (PT) records and interview with the technical consultant, the laboratory failed to include all testing personnel to participate in the PT events in 2018 and 2019. The findings include: 1) Review of the 2018 and 2019 PT records and testing personnel records revealed no participation in the 2018 and 2019 PT urinalysis microscopic exams for testing personnel numbers two, three and four; and no participation in 2018 and 2019 vaginal wet prep for testing personnel number one; no participation in 2018 and 2019 for two of the providers for post vas sperm check. 2) Interview on January 28, 2020 at 2:55 p.m. with the technical consultant confirmed that in 2018 and 2019 the PT samples were not rotated among all the testing personnel.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual and quality assessment (QA) procedures, and interview with the technical consultant,

	the laboratory failed to establish and ensure protection from biohazardsous materials, in the laboratory. The findings include: 1) Observation of the laboratory on January 28, 2020 at 1:50 p.m. revealed the laboratory space in use for patient urine sample testing. Testing personnel number two had a bottle of disposable water on the counter for drinking. Testing personnel number three had a personnel beverage bottle on the counter for drinking. There were no biohazard signs and "no eating or drinking in the laboratory" signs. 2) Review of the laboratory procedure manual and QA procedures revealed there is no safety procedure established for biohazard in the laboratory. 3) Interview on January 28, 2020 at 2:00 p.m. with the technical consultant confirmed testing personnel had drinks in the laboratory, there were no biohazard signs in the laboratory and there were no established safety procedures for biohazard in the laboratory.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records, the 2019 proficiency testing (PT) records, and interview with the technical consultant, the laboratory failed to verify the accuracy of the urine microscopic sediment and the vaginal wet prep at least twice a year in 2019. The findings include: 1. Review of the PT records revealed urine sediment failed the 2019 event three, resulting no accuracy twice per year in 2019; and, no participation in the vaginal wet prep resulting in no accuracy twice per year in 2019. 2. Interview on January 28, 2020 at 4:15 p.m. with the technical consultant confirmed the urine microscopic sediment and the vaginal wet prep were not verified for accuracy at least twice a year in 2019.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) plan, the quarterly patient test management records and interview with the technical consultant, the laboratory failed to maintain a QA plan for the post-analytic process for the urine microscopic testing, in 2018 and 2019. The findings include: 1) Review of the QA plan revealed that quarterly review of patient results were to be performed and documented. 2) Review of the 2018 and 2019 quarterly patient test management records revealed the post vas sperm checks and vaginal wet prep were not included. 3) Interview on January 28, 2020 at 4:45 p.m. with the technical consultant confirmed the post vas sperm checks and vaginal wet prep were not included in the 2018 and 2019 quarterly patient test management reviews.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory personnel records and interview with the technical consultant, the technical consultant failed to evaluate and document the performance of one testing personnel for vaginal wet prep in 2019. The findings include: 1. Review of the laboratory personnel records revealed testing personnel number one did not have vaginal wet prep competency documented in 2019. 2. Interview on January 28, 2020 at 2:30 p.m. confirmed testing personnel number one performed patient vaginal wet prep in 2019 and no annual competency was performed and documented.