Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0225848	08/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Urological Associates, Ltd	155 Riverbend Drive, Charlottesville, VA	

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
D0000	An announced CLIA recertification survey was conducted at Urological Associates, LTD on August 9, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on a tour, review of policy and procedure manuals, quality assurance (QA) monthly reports, corrective action records, and an interview, the laboratory failed to document corrective actions taken to resolve the ongoing identified QA problem of erroneous manually transcribed Prostate-Specific Antigen (PSA) and Testosterone patient results during the twenty-four (24) months reviewed. Findings include: 1. During a tour of the laboratory at approximately 1:00 PM, the inspector noted four (4) Qualigen FastPack analyzers in use for patient PSA and Testosterone testing and inquired of the practice manager to describe how patient test results are recorded into the office's Electronic Medical Assistant (EMA) medical record. The practice manager stated: "the lab staff and/or doctors type the results manually into EMA from the print out from the Qualigen instruments". 2. Review of the laboratory's policy and procedure manuals revealed a written and approved QA policy that included a required monthly QA checklist, chart audit of manually transcribed results, and review of corrective action documentation. 3. Review of the laboratory's available QA random chart audit documentation from July 2016 through the date of the survey, 8/9

	/18, revealed the following fifty five (55) patient cases were identified as erroneous manually transcribed Prostate-Specific Antigen (PSA) and Testosterone patient results: July 2016: 69246, 74214, 42907 (twice error on 7/26/16 and 7/29/16), 76530 August 2016: 69859, 61937 September 2016: 68594 October 2016: 76768 November 2016: 57460 December 2016: 44572, 01824 February 2017: 57753, 62004, 63196 March 2017: 02049, 66156 April 2017: Corrective action log for "wrong Testosterone value in chart -no patient case number was included on the documentation dated 4/5 /17, 43095, 59837 May 2017: 60512, 05135, 77638, 78025 June 2017: 41332, 38230, 44182, 75167 August 2017: 50687, 78679, 78809 September 2017: 78919 October 2017: 68016, 78972, 57720, 40444 November 2017: 52442, 47925, 54510, 69019, 35631 December 2017: 14925, 62053, 11458 January 2018: 78465, 69687, 59837 April 2018: 70698, 79640, 57720 May 2018: 80318 June 2018: 70500, 38112, 43449, 53234. The inspector requested documentation of a policy, corrective action or communication addressing the identified transcription errors or a plan to resolve the problem . No documentation was available for review. 4. In an interview with the practice manager and primary testing personnel at approximately 4:00 PM, it was confirmed that the laboratory failed to document QA corrective actions taken to resolve the ongoing erroneous PSA and Testosterone patient results identified as outlined above.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of policy and procedure manuals, quality assurance (QA) monthly reports, corrective action records, and an interview, the laboratory director failed to ensure that QA policies were maintained for Prostate-Specific Antigen (PSA) and Testosterone result reporting during the twenty-four (24) months of July 2016 through the date of the survey on August 9, 2018. Findings include: 1. Review of the laboratory's policy and procedure manuals revealed a written and approved QA policy that included laboratory director review of monthly quality assurance reports and corrective action documentation. 2. Review of the laboratory's available QA documentation from July 2016 through the date of the survey, 8/9/18, revealed fifty-five (55) errors in manually transcribed Qualigen FastPack PSA and Testosterone patient results identified during QA audits. (See D5893.) The inspector requested documentation of laboratory director signature's of review of a corrective action for the audit reports. No documentation was available for review. 3. In an interview with the practice manager and primary testing personnel at approximately 4:00 PM, it was confirmed that the laboratory director failed to review corrective action documentation to ensure that the QA policies for Qualigen FastPack PSA and Testosterone patient results were maintained for the timeframe outlined above.