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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 49D0225848 | (X3) Date Survey Completed 11/23/2020 |
| Name of Provider or Supplier Urological Associates, Ltd | Street Address, City, State 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 |
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| D0000 | An announced on-site CLIA recertification survey was conducted at Urological Associates, LTD on November 23, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 11/02/2020 and virtual record review conducted on 11/04/2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows: |
| D5421 | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory equipment, performance verification records for Qualigen FastPack IP System 2 analyzers, patient test logs, lack of documentation, and interviews, the laboratory director (LD) failed to document review/evaluation of the accuracy, precision, and reportable range for Prostate Specific Antigen (PSA) assays prior to reporting three hundred twenty-five (325) patient results on a newly installed instrument from May 4, 2020 to the date of the inspection record review on November 11, 2020. Findings include: 1. During an entrance interview with the laboratory's office manager and primary testing personnel (TP) on 11/2/20, the inspector was informed of and noted the following four (4) Qualigen FastPack analyzer serial numbers (SN) in use for patient immunoassay PSA and Testosterone testing: Machine 1 (SN 0894; for PSA and Testosterone), Machine 2 (SN 01181; for</p> |

PSA), Machine 3 (SN 0163; for PSA and Testosterone), Machine 4 (SN 0019; for PSA). 2. Review of all analyzer performance verification documentation records, during a virtual record review on 11/4/20, revealed that the laboratory installed two (2) new FastPack instruments in calendar year 2020 (SN 0894 installed on 5/4/20 and SN 1181 installed on 7/13/20). The review of validation documentation for analyzer SN 0894 revealed no LD evaluation or verification of PSA accuracy, precision, or reportable range. The inspector requested to review documentation that the LD verified the Qualigen FastPack validation studies for SN 0894 prior to patient PSA testing. No documentation was available. The primary TP stated: "I recall that we ran the validation samples but I do not have the completed report. The LD has not reviewed, but I can contact Qualigen to find out what happened to our submitted data". 3. Review of patient test logs revealed that the laboratory reported 325 patient PSA results from analyzer (SN 0894) from May 2020 to the date of the survey on 11/4/20. 4. In an exit interview with the office manager and primary TP, on 11/23/20 at approximately 3:30 PM, the above findings were confirmed.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on a review of laboratory equipment, procedures, maintenance logs, lack of documentation, and interviews, the laboratory failed to define and document function checks for centrifuge revolutions per minute (RPM) for five (5) of 5 centrifuges during the twenty-four (24) months reviewed. Findings include: 1. During an entrance interview with the laboratory's office manager and primary testing personnel (TP) on 11/2/20, the inspector was informed of and noted the following Unico Power Spin centrifuge serial numbers (SN) in use for urine microscopy specimen processing: SN L1909029, SN L0807299, SN L0807162, SN L0807187, SN L71608125. 2. Review of the laboratory's procedures revealed a Microscopic Study of the Urinary Sediment Examination protocol that stated "Centrifuge urine at 1,500 to 2,000 RPM for 5 minutes". 3. Review of the laboratory's maintenance documentation revealed no records of RPM verifications for the 5 Unico centrifuges outlined above. The inspector requested to review centrifuge RPM verification records for the timeframe of November 2018 to the date of the on-site tour on 11/23/20. No documentation was available for review. 4. In an exit interview with the primary TP and office manager, on 11/23/20 at approximately 3:30 PM, the above findings were confirmed.