Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	39D0678813	06/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Uniontown Urology Associates	100 Woodlawn Avenue, Suite 5, Uniontown, PA	

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
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 peer review policies and interview with the technical consultant (TC), the laboratory failed to at least twice annually, verify the accuracy of 1 of 1 high complexity testing personal (TP) performing Histopathology, Cytology, and Fluorescence in situ hybridization (FISH) examinations from 2018 to the date of survey. Findings Include: 1. The Cytology and FISH peer review policy states " The purpose is to provide a peer review of two urine cytology and two FISH cytologies every year. 2. The Proficiency Testing (PT) and Continuing Education policy states " The purpose of this policy is to ensure the pathologist is enrolled in the College of American Pathology (CAP) continuing education program in surgical pathology and medical oncology. 3. On the day of survey, 06/20/2019, the TC could not provide documentation of peer review for 1 of 1 high complexity TP who performed cytology and FISH examinations from 2018 and 2019. The TC could not provide documentation of CAP PT for pathology slide examination performed by 1 of 1 high complexity TP from 2018 to 2019. 4. The TC confirmed the findings above on 06/20 /2019 around 10:30 am.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The

	laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with the technical consultant (TC), the laboratory failed to document all quality assessment (QA) activities for Prostate-specific antigen (PSA) and testosterone testing in 2018. Findings Include: 1. On the day of survey, 06/20/2019, the laboratory could not provide documentation of QA activities that review the laboratories pre-analytical, analytical, and post analytic systems for PSA and testosterone tests performed on the Sekisui Diagnostics FastPack IP System in 2018. 2. In 2018, 9,753 PSA and testosterone tests were analyzed in 2018. 3. The TC confirmed the findings above on 06/20/2019 around 9:32 am.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (TC), the laboratory failed to establish and document maintenance protocols for 1 of 1 Power Centrifuge, used to spin Prostate-specific antigen (PSA) and testosterone specimen from 2017 to the date of survey. Findings Include: 1. On the day of survey, 06/20/2019, the TC could not produce a maintenance policy or maintenance documentation performed on the Power Centrifuge, used to spin Prostate-specific antigen (PSA) and testosterone specimen from 10/19/2017 to 06/20/2019. 2. In 2018, 9,753 PSA and testosterone tests were analyzed. 3. The TC confirmed the findings above on 06/20/2019 around 9:30 am.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control

	materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration verification (Cal Ver.) records and interview with the technical consultant (TC), the laboratory failed to perform cal. ver. for Prostate-specific antigen (PSA) and testosterone performed on 1 of 1 Sekisui Diagnostics FastPack IP System once every 6 months in 2017 and 2018. Findings include: 1. The testosterone and PSA Calibration Verification Records policies state, "Complete every 6 months using low, mid and high reportable range samples". 2. On the day of survey, 06/20/2019, the TC could not provided documentation of cal. ver. performed for PSA and testosterone performed on 1 of 1 Sekisui Diagnostics FastPack IP System performed every 6 months in 2017 and 2018. 3. In 2018, 9,753 PSA and testosterone tests were analyzed. 4. The TC confirmed the findings above on 06/20/2019 around 9:35 am.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and interview with the technical consultant (TC), the laboratory failed to establish a maximum workload limit for 1 of 1 cytotechnologist from 2017 to the date of survey. Findings Include: 1. On the day of survey, 06/20/2019, the TC could not produce a policy for analyzing the maximum workload limit for 1 of 1 cytotechnologist performing cytology examination from 10/19/2017 to 06/20/2019. 2. The TC confirmed the finding above on 06/20/2019 around 10:45 am.