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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 22D0907996 | (X3) Date Survey Completed 11/27/2018 |
| Name of Provider or Supplier Urology Associates Of Cape Cod, Pc | Street Address, City, State 125 Route 6a, Yarmouth Port, MA | |
| 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 | A CLIA recertification survey was conducted for the Urology Associates of Cape Cod, P.C. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. |
| D2003 | <p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on interview and observation, the laboratory failed to establish and maintain the accuracy of its testing procedures in accordance with 493.1236(c)(1) as evidenced by the following: a. The laboratory added Histopathology and Cytology testing on 6/20 /17. b. The practice's surgical director confirmed through interview on 11/27/18 at 12: 00 PM that the laboratory failed to establish procedures to verify accuracy of Histopathology and Cytology testing for 2017 and 2018. c. The laboratory performs 5,348 Histopathology and Cytology tests per year.</p> |
| D5028 | <p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on record review, observation, and interview with the surgical director and</p> |

clinical manager, the laboratory did not meet all the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299. Findings include:
 -Refer to D5217: The laboratory did not evaluate the accuracy of each test twice annually. -Refer to D5401: The laboratory director failed to have a written procedure manual in place for all tests, assays, and examinations performed by the laboratory. -Refer to D5403: The laboratory failed to have a procedure manual which covered all aspects of test procedures. -Refer to D5435: The laboratory director failed to establish a maintenance protocol for the laboratory microscope used to report Histopathology diagnoses. -Refer to D5601: The laboratory failed to document a control slide of known reactivity of fluorescent and immunohistochemical stains with each patient slide or group of patient slides when special staining was performed

D5032

CYTOLOGY
 CFR(s): 493.1221

If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
 Based on record review, observation, and interview with the surgical director and clinical manager, the laboratory did not meet all the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. Findings include:
 -Refer to D5217: The laboratory did not evaluate the accuracy of each test twice annually. -Refer to D5401: The laboratory director failed to have a written procedure manual in place for all tests, assays, and examinations performed by the laboratory. -Refer to D5403: The laboratory failed to have a procedure manual which covered all aspects of test procedures. -Refer to D5435: The laboratory director failed to establish a maintenance protocol for the laboratory microscope used to report Cytology diagnoses. -Refer to D5629: The laboratory failed to document non-gynecological annual statistical laboratory evaluations. -Refer to D5639: The laboratory failed to have a written policy and procedure regarding Cytology workload limits. -Refer to D5645: The laboratory failed to maintain records of Cytology workload limits.

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 interview and observation, the laboratory failed to verify procedures it performs that are not included in subpart I of this part at least twice annually as evidenced by the following: a. The laboratory added Histopathology and Cytology testing on 6/20/17. b. The practice's surgical director confirmed through interview on 11/27/18 at 12:00 PM that the laboratory failed to verify Histopathology and Cytology testing at least twice annually in 2017 and 2018. c. The laboratory performs 5,348 Histopathology and Cytology tests per year.

D5401

PROCEDURE MANUAL
 CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on observation and interview, the laboratory failed to have a written procedure manual in place for all tests, assays, and examinations performed by the laboratory as evidenced by the following: On the day of the survey, surveyors asked the surgical director to produce policies and procedures for Histopathology and Cytology testing. The surgical director confirmed in an interview on 11/27/18 at 12:15 PM that there were no written procedures available for Histopathology and Cytology testing.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on observation and interview, the laboratory failed to have a procedure manual which covered all aspects of test procedures as evidenced by the following: On the day of the survey, surveyors asked the surgical director to produce policies and procedures for Histopathology and Cytology testing. The surgical director confirmed in an interview on 11/27/18 at 12:15 PM that there were no written procedures covering all aspects of Histopathology and Cytology testing.

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 observation and interview, the laboratory failed to establish a maintenance protocol for the laboratory microscope as evidenced by the following: On the day of the survey, surveyors asked the surgical director to produce a maintenance policy for microscope maintenance. The surgical director confirmed in an interview on 11/27/18 at 12:15 PM that there was no written policy regarding microscope maintenance to ensure accurate and reliable test results and reporting.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to document a control slide of known reactivity of fluorescent and immunohistochemical stains with each patient slide or group of patient slides when special staining was performed as evidenced by the following: a. Six (6) patient biopsy requisitions and final reports were reviewed on 11/27/18 at 12:35 PM. Two (2) prostate biopsy requisitions indicated orders for immunohistochemical (IHC) stains. b. There was no documentation of the reactions of the control slide with each IHC stain. c. The surgical director confirmed in an interview on 11/27/18 at 12:35 PM that the results of the IHC control slide were being reviewed by the Pathologists but the results were not being documented.

D5629

CYTOLOGY
CFR(s): 493.1274(c)(5)

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

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| | <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to document annual statistical laboratory evaluations as evidenced by the following: a. The laboratory added non-gynecological Cytology testing on 6/20/17. b. On the day of the survey, surveyors asked the surgical director to produce Cytology statistical evaluations. The surgical director confirmed in an interview on 11/27/18 at 12:30 PM that there were no written procedures or documentation of statistical evaluations of non-gynecological Cytology specimens.</p> |
| <p>D5639</p> | <p>CYTOLOGY CFR(s): 493.1274(d)(2)(i)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to have a written policy and procedure regarding Cytology workload limits evidenced by the following: On the day of the survey, surveyors asked the surgical director to produce Cytology workload limit policies. The surgical director confirmed in an interview on 11/27/18 at 12:30 PM that there were no written procedures for Cytology workload limits.</p> |
| <p>D5645</p> | <p>CYTOLOGY CFR(s): 493.1274(d)(3)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to maintain records of Cytology workload limits evidenced by the following: On the day of the survey, surveyors asked the surgical director to produce Cytology workload limit records. The surgical director confirmed in an interview on 11/27/18 at 12:30 PM that there were no Cytology workload limits recorded for 2017 and 2018.</p> |
| <p>D6076</p> | <p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> |

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| | <p>This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the laboratory director failed to provide overall management and direction in accordance with 493.1445 of this subpart as evidenced by the following: -Refer to D6093: The laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. -Refer to D6094: The laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. -Refer to D6106: The laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process</p> |
| <p>D6093</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to establish and maintain quality control programs to assure the quality of laboratory services provided evidenced by the following: a. Six (6) patient biopsy requisitions and final reports were reviewed on 11/27/18 at 12:35 PM. Two (2) prostate biopsy requisitions indicated orders for immunohistochemical (IHC) stains. b. There was no documentation of the reactions of the control slide with each IHC stain. c. The surgical director confirmed in an interview on 11/27/18 at 12:35 PM that the results of the IHC control slide were being reviewed by the Pathologists but the results were not being documented. (Refer to D5601)</p> |
| <p>D6094</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to establish and maintain quality assessment programs to assure the quality of laboratory services provided as evidenced by the following: a. The laboratory added Histopathology and Cytology testing on 6/20/17. b. The practice's surgical director confirmed through interview on 11/27/18 at 12:00 PM that the laboratory failed to establish policies and to maintain quality assessment of Histopathology and Cytology testing in 2017 and 2018. c. The laboratory performs 5,348 Histopathology and Cytology tests per year. (Refer to D2003 & D5217)</p> |
| <p>D6106</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> |

This STANDARD is not met as evidenced by:

Based on observation and interview, the laboratory director failed to have a written approved procedure manual in place available to all personnel responsible for any aspect of the testing process as evidenced by the following: On the day of the survey, surveyors asked the surgical director to review policies and procedures for Histopathology and Cytology testing. The surgical director confirmed in an interview on 11/27/18 at 12:15 PM that there were no written procedures available for Histopathology and Cytology testing. (Refer to D5401& D5403)