| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 15D0360052 | 02/14/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Urology Associates, Llc | 2525 W University Ave Suite 504, Muncie, IN | |

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 complaint survey was completed on February 14, 2020. On February 24, 2020, it was determined that Immediate Jeopardy (IJ) existed for the following Condition-level deficiencies: Cytology: 42 CFR 493.1221 Laboratory Director: 42 CFR 493.1441 Laboratory Techincal Supervisor: 42 CFR 493.1447 |
| **D3013** | FACILITIES<br>CFR(s): 493.1101(e)<br><br>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview it was determined that eight of 223 urine cytology cases were not maintained and stored with the glass slide preparations intact. Findings include: 1. Eight of 223 urine cytology cases in a slide file drawer labeled "C19-00041 through C19-00263" were observed with broken glass slide preparations which were not repaired. Case #: # of Slides Broken in Case: -C19-00139 2 of 2 -C19-00151 1 of 2 -C19-00188 2 of 2 -C19-00189 2 of 2 -C19-00190 2 of 2 -C19-00191 2 of 2 -C19-00192 2 of 2 -C19-00206 1 of 2 2. During an interview on February 12, 2020 at 11:15 AM Histotechnologist A confirmed the slides were broken and stated "I didn't do that. I would never file them that way." |
| **D5032** | CYTOLOGY<br>CFR(s): 493.1221<br><br>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. |

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| | This CONDITION is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records, glass slide preparations, observation and interviews it was determined the laboratory failed to establish policies and procedures (refer to D5403); failed to perform the NuView System testing on urine cytology specimens according to the manufacturer's instructions (refer to D5411); failed to ensure the NuPrep solution was not used beyond the expiration date (refer to D5417); failed to establish performance specifications when the laboratory modified the NuView Test System manufacturer's instructions with an alternate method of processing urine cytology specimens (refer to D5423); failed to test Papanicolaou staining materials for intended reactivity each day of use (refer to D5473); failed to establish policies and procedures for the annual evaluation and comparison of three of three laboratory statistics (refer to D5629); failed to establish and reassess a workload limit for one of one Laboratory Director /Technical Supervisor (refer to D5633, D5637); failed to establish policies and procedures to ensure the workload limit for one of one Laboratory Director/Technical Supervisor would be prorated to determine the number of slides that may be examined (refer to D5641); failed to establish policies and procedures to ensure that the laboratory would maintain records of the total number of slides examined and hours spent examining slides (refer to D5645); failed to establish policies and procedures to ensure that unsatisfactory urine cytology slide preparations were identified and reported as unsatisfactory (refer to D5655); and failed to establish policies and procedures to ensure urine cytology test reports contained narrative descriptive nomenclature (refer to D5657). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology. |
| **D5203** | SPECIMEN IDENTIFICATION AND INTEGRITY<br>CFR(s): 493.1232<br><br>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, observation, interview and review of glass slide preparations it was determined that the laboratory failed to follow written policies and procedures to ensure positive patient identification during specimen processing, staining and reporting of test results. Findings include: 1. The laboratory failed to follow the procedure SPECIMEN HANDLING PROCEDURE: PREANALYTIC SYSTEM which stated: "10. Write the accession number on the requisition and on the matching tissue container. 11. This number will be the permanent identifying number for this tissue. (Cytology will be a C series). 12. Label 'C-year-case number' for cytology." 2. During observation of specimen processing on January 28, 2020 at 8:45 AM, Histotechnologist A failed to label three of three specimen containers and corresponding specimen slides with the complete patient identifier accession number. Cases include: Accession #: # Written on Specimen: -C20-000047 47 -C20-000048 48 -C20-000049 49 a. During further observation it was determined that the laboratory failed to label five of five previously processed specimen centrifuge tubes with the complete patient identifier accession number. Cases include: Accession #: # Written on Specimen: -C20-000038 38 -C20-000039 39 -C20-000040 40 -C20-000041 41 -C20-000042 42 b. During an interview on January |

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| | 28, 2020 at 10:00 AM, Histotechnologist A stated that the slide label with the complete patient identifier accession number was not placed on the specimen slide until after the slide staining process. 3. During microscopic review of urine cytology case #C19-000170 it was observed that one of three slides in the case was not labeled with the complete patient identifier accession number. The slide was labeled as "170." and did not have an attached slide label with a patient identifier accession number. 4. During microscopic review of urine cytology case #C18-00359 it was observed that two of two slide labels in the case did not have the complete patient identifier accession number. The slide was labeled as "C-00359." |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, lack of competency assessment records and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of one of one Laboratory Director/Technical Supervisor who performed cytology testing and reporting of test results in 2018, 2019 and to the date of the survey in 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the competency of the Laboratory Director /Technical Supervisor who performed cytology testing. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for the Laboratory Director/Technical Supervisor in 2018, 2019 and to the date of the survey in 2020. 3. During an interview on January 28, 2020 at 2:40 PM, the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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 general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. Cross refer to D5203 and D5209 Findings include: 1. The laboratory failed to follow the procedure QUALITY ASSURANCE PLAN: PRE-ANALYTIC which stated: "Exception Criteria: The patients unique ID number does not match the ID number on the specimen container or slide. Responsible Staff: The specimen processor compares the test requisition form with the container and/or slide. Any inconsistencies shall be recorded in the Remedial Action Log and worked up as problems." 2. The Survey Team reviewed the QUALITY ASSURANCE LOG from 2019. a. The laboratory failed to record any |

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| | discrepancies between the test requisition and the corresponding cytology specimen slides on 13 cases in 2019, as part of the quality assessment preanalytic review program. b. The Survey Team reviewed the same cytology cases to check for completeness of the patients unique identification number on the slides. Thirteen of 13 cases did not have the complete patient identification number written on the slide, prior to the application of the slide label. Cases include: -C19-00003 -C19-00082 -C19-00120 -C19-00139 -C19-00168 -C19-00249 -C19-00264 -C19-00277 -C19-00318 -C19-00449 -C19-00516 -C19-00588 -C19-00633 |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of 27 laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for six laboratory processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the microscopic examination of urine cytology specimens, including the detection of inadequately prepared specimen slides. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures for entering patient specimen information into the laboratory information system and the reporting of patient test results. a. The written procedure REPORTING OF PATIENT RESULTS stated "Final reports are issued by the pathologist/Laboratory Director from the AP Easy Pathology Reporting System." The procedure failed to detail how to enter specimen information and cytology test results. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the stains and solutions in the Papanicolaou stain process would be maintained, to include detailing the laboratory's utilization of QC records titled PAP NON-GYN STAINING SOLUTIONS. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's stain quality assessment process for the Papanicolaou stain. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for coverslipping specimen slides. 6. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process to repair broken or |

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| | damaged specimen slides. 7. During an interview on January 28, 2020 at 2:40 PM, the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records, observation and interviews it was determined that the laboratory failed to perform the NuView System testing on urine cytology specimens according to the manufacturer's instructions. Findings include: 1. The laboratory failed to follow the manufacturer's instruction SPECIMEN PREPARATION FOR URINE-NUVIEW SYSTEM FOR NON-GYN CYTOLOGY which stated: -"Using a pipette, place 1-2 drops of cell suspension on to glass slide provided." a. During urine specimen processing on January 28, 2020 at 8:45 AM Histotechnologist A was observed not using the specimen slides provided in a kit by the manufacturer. b. Histotechnologist A stated that the laboratory used their own slides, which were prepared and dipped in albumin, utilizing the product "Stay-On." 2. The laboratory record SPECIMEN PREPARATION FOR URINE-NUVIEW SYSTEM FOR NON-GYN CYTOLOGY stated: "-Allow the slides to dry. Speed the process by placing slides near a fan blowing warm air or in an oven for 10 minutes." a. During an interview on January 28, 2019 at 9:50 AM Histotechnologist A stated slides were placed in the oven for 25 minutes. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview it was determined that the laboratory failed to ensure the NuPrep solution used to process urine cytology specimens was not used beyond the expiration date. Findings include: 1. During an observation of the cytology processing area on January 28, 2020 at 9:50 AM the Survey Team identified the following expired reagent: - one bottle of NuPrep (expired 11/2019) 2. During an interview on January 28, 2020 at 9:50 AM Histotechnologist A stated the bottle "was the last of the gallon." |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer |

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| | must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions and observation it was determined that the laboratory failed to establish performance specifications when the laboratory modified the NuView System manufacturer's instructions with an alternate method of processing urine cytology specimens. Cross refer to D5411 Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy, precision, analytical sensitivity and specificity of the modified procedure, reportable range of test results or any other performance characteristic was adequate to provide accurate diagnostic interpretations. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records and interview it was determined that the laboratory failed to test Papanicolaou staining materials for intended reactivity to ensure predictable staining characteristics each day of use in 2019 and January 1-28, 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide stain assessment records for the Papanicolaou stain from January 2019 through January 28, 2020. 2. During an interview on January 28, 2020 at 9:35 AM Histotechnologist A stated that the CYTOLOGY STAIN QC LOG was used for more than one stain process and confirmed it was not specific to the results of the Papanicolaou staining materials. |
| **D5629** | CYTOLOGY<br>CFR(s): 493.1274(c)(5)<br><br>(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 |

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| | lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation of three of three annual nongynecologic statistics. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation of three of three annual nongynecologic statistics. -The number of cytology cases examined; -The number of specimens processed by specimen type; -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). 2. During an interview on January 28, 2020 at 2:40 PM Histotechnologist A and the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D5633** | CYTOLOGY<br>CFR(s): 493.1274(d)(1)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Technical Supervisor for one of one Laboratory Director/Technical Supervisor who performed primary slide screening in 2018, 2019 and to the date of the survey in 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that a maximum workload limit was established for the Laboratory Director/Technical Supervisor when performing primary screening of nongynecologic specimen slides. 2. The Survey Team requested and the laboratory failed to provide documentation of an established workload limit for the Laboratory Director/Technical Supervisor in 2018, 2019 and to the date of the survey in 2020. 3. During interviews on January 27, 2020 at 9:30 AM and January 28, 2020 at 2:40 PM the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D5637** | CYTOLOGY<br>CFR(s): 493.1274(d)(1)(ii)<br><br>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to reassess a maximum workload limit at least every six months for one of one Laboratory Director/Technical Supervisor in 2018 and 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure a maximum workload limit was reassessed at least every six |

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| | months for the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of a workload reassessment for the Laboratory Director/Technical Supervisor in 2018 and 2019. 3. During interviews on January 27, 2020 at 9:30 AM and January 28, 2020 at 2:40 PM the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D5641** | CYTOLOGY<br>CFR(s): 493.1274(d)(2)(ii)<br><br>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure the workload limit for one of one Laboratory Director/Technical Supervisor, when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to determine how to prorate the workload limit for the one of one Laboratory Director/Technical Supervisor when time was spent on duties other than slide examination or when examining slides in less than an 8-hour day. 2. During interviews on January 27, 2020 at 9:30 AM and January 28, 2020 at 2:40 PM the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D5643** | CYTOLOGY<br>CFR(s): 493.1274(d)(2)(iii)<br><br>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and (d)(2)(iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures to designate how nongynecologic NuView slide preparations were counted for workload recording purposes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to designate how nongynecologic NuView liquid-based slide preparations (cell dispersion over one-half |

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| | or less of slide) were counted for workload recording. 2. During interviews on January 27, 2020 at 9:30 AM and January 28, 2020 at 2:40 PM the Laboratory Director /Technical Supervisor confirmed these findings. |
| **D5645** | CYTOLOGY<br>CFR(s): 493.1274(d)(3)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory would maintain records for one of one Laboratory Director/Technical Supervisor of the total number of slides examined and the number of hours spent examining slides during each 24-hour period in 2018, 2019 and through January 24, 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how records would be maintained of the total number of slides examined and the number of hours the Laboratory Director/Technical Supervisor spent examining slides during each 24-hour period. 2. The Survey Team requested and the Laboratory Director/Technical Supervisor failed to provide records to document the total number of slides examined and the number of hours spent examining the slides.. The number of slides examined per specimen case was unknown and not provided by the laboratory. Cases include: a. 684 of 684 cases examined from January 1-December 31, 2018 Case #'s: C18-00001 through C18-00684 b. 648 of 648 cases examined from January 1-December 31, 2019 Case #'s: C19-00001 through C19-00648 c. 40 of 40 cases examined from January 1 to 24, 2020 Case #'s: C20-00001 through C20-00040 3. During an interview on January 27, 2020 at 9:30 AM the Laboratory Director/Technical Supervisor stated, "I don't keep workload. I was told at another site I don't need to because of low volume." 4. During an interview on January 27, 2020 at 10:30 AM Histotechnologist A stated that the Laboratory Director/Technical Supervisor "does screen cytology at other sites." 5. During interviews on January 27, 2020 at 9:30 AM and January 28, 2020 at 2:40 PM the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D5655** | CYTOLOGY<br>CFR(s): 493.1274(e)(4)<br><br>(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, negative urine cytology slide preparations and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that urine cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report 11 of 11 unsatisfactory urine cytology cases from January 1, 2018 through December |

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| | 31, 2019 as being "Unsatisfactory for Evaluation." Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory urine cytology slide preparations were identified and reported as unsatisfactory. 2. The Survey Team identified and the Survey Team Pathologist confirmed on February 14, 2020 eleven (11) urine cytology cases as "Unsatisfactory for Evaluation" that were originally reported as "Negative" by the laboratory. Cases include: -C18-00130 -C18-00139 -C18-00149 -C18-00231 -C18-00449 -C18-00473 -C18-00537 -C18-00545 -C19-00112 -C19-00220 -C19-00233 3. During an interview on January 27, 2020 at 9:40 AM the Laboratory Director /Technical Supervisor stated "I am not using the Paris System yet. I say limited, but not unsatisfactory." 4. During an interview on January 28, 2020 at 2:40 PM the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D5657** | CYTOLOGY<br>CFR(s): 493.1274(e)(5)<br><br>(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure nongynecologic urine cytology test reports contained narrative descriptive nomenclature. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's nomenclature system for reporting nongynecologic urine cytology test results. 2. During an interview on January 28, 2020 at 2:40 PM the Laboratory Director /Technical Supervisor confirmed these findings. |
| **D5659** | CYTOLOGY<br>CFR(s): 493.1274(e)(6)<br><br>(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. 2. During an interview on January 28, 2020 at 2:40 PM Histotechnologist A and the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an |

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| | ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the analytic phases of cytology testing. Cross refer to D5403, D5411, D5417, D5423, D5473, D5629, D5633, D5637, D5641, D5645, D5655, D5657, D5659, D6115<br>Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for a program to monitor and assess the accuracy of urine cytology diagnostic interpretations. a. The Survey Team requested and the laboratory failed to provide documentation of any quality assessment activities to monitor the accuracy of diagnostic interpretations during 2018, 2019 and to the date of the survey in 2020. b. The Survey Team reviewed 1372 cases/2728 slides and the corresponding laboratory records and observed the following: -2018 TOTAL URINE CASES: 684 -2018 Total Suspicious//Malignant Cases: 28 -Laboratory Identified Cases: 21 -Additional Cases Identified by Survey Team: 7 -25% of Total Suspicious /Malignant Cases not Identified by the Laboratory (7 of 28) -2019 TOTAL URINE CASES: 648 -2019 Total Suspicious//Malignant Cases: 23 -Laboratory Identified Cases: 13 -Additional Cases Identified by Survey Team: 10 -43% of Total Suspicious /Malignant Cases not Identified by the Laboratory (10 of 23) -2020 TOTAL URINE CASES: 40 -2020 Total Suspicious//Malignant Cases: 01 -Laboratory Identified Cases: 00 -Additional Cases Identified by Survey Team: 01 -100% of Total Suspicious /Malignant Cases not Identified by the Laboratory (1 of 1) 2. The laboratory procedure QUALITY ASSURANCE/QUALITY CONTROL PROCEDURE FOR PATHOLOGY SPECIMENS stated: "Pathologist's consultations of surgical, prostate and Cytopathology is to be done on a daily basis or as needed as a valuable tool to improve specific patient care, to educate, and to be more sensitive in identifying those cases in which external consultation for second opinions should be obtained. The Pathologist who is reading the cases selects specific cases for consultation as follows: 1. All cases of malignancy. 2. Difficult or unusual cases. 3. Cases with discrepancies between diagnosis and patient history." a. The Survey Team requested and the laboratory failed to provide documentation of Cytopathology consultations during 2018, 2019 and to the date of the survey in 2020. 3. During an interview on January 27, 2020 at 2:40 PM the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of final cytology test reports and interview it was determined that one of 648 final cytology test reports from 2019 failed to include the test result. Findings include: 1. The Survey Team reviewed 648 consecutive final cytology test reports from January 1 through December 31, 2019. Test Reports Include: -C19-00001 through C19-00648. a. One of 648 test reports failed to indicate the test result: -Case #C19-000421 2. During an interview on January 28, 2020 at 2:40 PM Histotechnologist A and the Laboratory Director/Technical Supervisor confirmed these findings. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records, cytology slide preparations, observation and interviews it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure that quality assessment programs were established and maintained (refer to D6094); and failed to ensure written policies and procedures were established to assess the competency of staff who performed cytology testing (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart. |
| **D6079** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(a)(b)<br><br>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records, cytology slide preparations, observation and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and |

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| | ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5203, D5403, D5411, D5417, D5423, D5473, D5633, D5637, D5641, D5645, D5655, D5657 |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records, cytology slide preparations and interviews it was determined that the Laboratory Director failed to ensure that analytic quality assessment programs were established and maintaind to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5291 and D5791 |
| **D6103** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(13)<br><br>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory polices and procedures, laboratory records and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of one of one Laboratory Director/Technical Supervisor and three of three Histotechnologists who performed preanalytic, analytic and postanalytic cytology test procedures in 2018, 2019 and to the date of the survey in 2020. Cross refer to D5209 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the competency of the Histotechnologists who performed cytology testing. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for three of three Histotechnologists who performed cytology processing. Histotechnologists include: -Histotechnologist A -Histotechnologist B - Histotechnologist C 3. During an interview on January 28, 2020 at 2:40 PM the Laboratory Director/Technical Supervisor confirmed these findings. Based on review of laboratory polices and procedures, laboratory records and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of one of one Laboratory Director/Technical Supervisor and three of three Histotechnologists who performed cytology test procedures. |
| **D6108** | LABORATORY TECHNICAL SUPERVISOR<br>CFR(s): 493.1447 |

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| | The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of 1228 negative urine cytology specimen cases/2448 slides and corresponding final test reports it was determined that the Technical Supervisor failed to verify the accuracy of 34 urine cytology test reports (refer to D6115). The cumulative effect of these practices resulted in the Technical Supervisor's inability to provide technical supervision requirements of 493.1451 of this subpart. |
| **D6115** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(2)<br><br>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.<br><br>This STANDARD is not met as evidenced by:<br>Based on the microscopic review of 1228 negative urine cytology cases/2448 slides from 2018, 2019 and to the date of the survey in 2020 and confirmation by the Survey Team Pathologist on February 14, 2020 it was determined that the Technical Supervisor failed to verify the accuracy of 34 urine cytology tests. 1. C20-00007 01/07 /20 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 2. C19-00102 02/26/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 3. C19-00172 04/08/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 4. C19-00224 04/30/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 5. C19-00384 08/14 /19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 6. C19-00415 08/27/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 7. C19-00458 09/16/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 8. C19-00495 10/04/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 9. C19-00500 10/04 /19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 10. C19-00583 11/19/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 11. C19-00642 12/24/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Squamous Cell Carcinoma 12. C18-00320 06/19/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 13. C18-00334 06/25/18 NuView Prep Urine |

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| | LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 14. C18-00371 07/13 /18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma Possible Polyoma Virus Changes 15. C18-00380 07/24/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 16. C18-00383 07/20 /18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: High Grade Urothelial Carcinoma 17. C18-00505 09 /09/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Urothelial Cells-Papillary Clusters-? Neoplastic 18. C18-00682 12/28/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma 19. C19-00112 03/05/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-evaluable due to obscuring inflammation 20. C19-00220 04/30/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-diagnostic due to scant cellularity 21. C19-00233 05/03/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-evaluable due to obscuring inflammation 22. C18-00130 03/09/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-evaluable due to obscuring inflammation 23. C18-00139 03/13/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-evaluable due to scant cellularity 24. C18-00149 03/20/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-evaluable due to obscuring inflammation 25. C18-00231 05/10/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-evaluable due to obscuring inflammation 26. C18-00449 08/21/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-evaluable due to obscuring inflammation 27. C18-00473 08/28/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-evaluable due to obscuring inflammation 28. C18-00537 10/04/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-evaluable due to obscuring inflammation 29. C18-00545 10/08/18 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Non-evaluable due to obscuring inflammation 30. C19-00043 01/31/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Changes Suggestive of Polyoma Virus Infection 31. C19-00242 05/08/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Urothelial Cells Present Note: Cellular Changes Present Suggestive of Polyoma Virus Infection 32. C19-00463 09/16/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Urothelial Cells Present Note: Cellular Changes Present Suggestive of Polyoma Virus Infection 33. C19-00525 10/18/19 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Urothelial Cells Present Note: Cellular Changes Present Suggestive of Polyoma Virus Infection 34. C18-00103 02/27/8 NuView Prep Urine LABORATORY DIAGNOSIS: Negative SURVEY TEAM PATHOLOGIST DIAGNOSIS: Consistent with Polyoma Virus Changes |
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| **D6130** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(c)(2)(3)<br><br>(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of laboratory records and interviews it was determined that the Technical Supervisor failed to establish and reassess workload limits at least every six months for one of one Laboratory Director/Technical Supervisor in 2018, 2019 and to the date of the survey in 2020. Cross refer to D5633 and D5637 |
| **D6133** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(c)(6)<br><br>In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of laboratory records and interviews it was determined that one of one Laboratory Director/Technical Supervisor failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period in 2018, 2019 and to the date of the survey in 2020. Cross refer to D5645 |
| **D9999** | By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only. |