Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2020786	10/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Erik Pasin, Md Inc	24321 Avenida De La Carlota H-7, Laguna Hills, CA	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation and interviews the laboratory failed to retain all cytology slide preparations for at least five years (refer to D3043).
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by:

	Based on observation and interviews the laboratory failed to retain all cytology slide preparations from 75 of 75 patient cases from October 2023 through May 2024 for at least five years. Findings include: 1. During a review of cytology slide preparations and the corresponding final test reports, the laboratory failed to locate and provide cytology slide preparations from 75 of 75 patient cases from October 2023 through May 2024. Slides include: -EP23-00426 -EP24-00024 -EP23-00427 -EP24-00025 -EP23-00428 -EP24-00027 -EP23-00429 -EP24-00029 -EP23-00430 -EP24-00030 -EP23-00431 -EP24-00031 -EP23-00432 -EP24-00032 -EP23-00435 -EP24-00033 -EP23-00437 -EP24-00034 -EP23-00439 -EP24-00035 -EP23-00440 -EP24-00036 -EP23-00463 -EP24-00037 -EP23-00464 -EP24-00039 -EP23-00466 -EP24-00040 -EP23-00470 -EP24-00041 -EP23-00471 -EP24-00043 -EP23-00472 -EP24-00044 -EP23-00473 -EP24-00046 -EP23-00474 -EP24-00047 -EP23-00476 -EP24-00048 -EP23-00477 -EP24-00049 -EP23-00478 -EP24-00053 -EP23-00479 -EP24-00079 -EP23-00480 -EP24-00080 -EP23-00481 -EP24-00081 -EP23-00482 -EP24-00082 -EP23-00483 -EP24-00083 -EP23-00484 -EP24-00084 -EP23-00487 -EP24-00085 -EP23-00488 -EP24-00086 -EP23-00489 -EP24-00090 -EP23-00490 -EP24-00091 -EP23-00491 -EP24-00092 -EP23-00492 -EP24-00094 -EP23-00493 -EP24-00095 -EP23-00494 -EP23-00495 -EP23-00496 -EP23-00501 -EP23-00503 2. During an interview on October 21, 2024 at 11:20 AM, the Office Manager and Staff A stated Facility B (CLIA 31D1026901) sent prepared cytology slide preparations to the Laboratory Director/Technical Supervisor's home residence for evaluation and reporting. The Laboratory Director/Technical Supervisor would "sporadically drop off" cytology slide preparations to the laboratory being surveyed for filing. 3. During an interview on October 22, 2024 at 11:55 AM, the Office Manager stated the Laboratory Director/Technical Supervisor reported that the Laboratory Director /Technical Supervisor did not have possession of any cytology slide preparations located outside of the laboratory. The Office Manager further stated the cytology slide preparations could not be located. 4. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
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 review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to ensure written policies and procedures were followed to assess the competency of the Technical Supervisor (refer to D5209); failed to follow two written policies and procedures (refer to D5401); failed to establish written policies and procedures for one laboratory test process (refer to D5403); failed to establish and follow written policies and procedures for an annual statistical evaluation of the required laboratory statistics (refer to D5629); failed to follow written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to establish and follow written policies and procedures to ensure that workload limits would be prorated when examining slides in less than eight hours (refer to D5641); failed to follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of

	hours spent examining slides per 24-hour period (refer to D5645); failed to establish written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory (refer to D5655); failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results (refer to D5657); failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems (refer to D5791); and failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic cytology systems (refer to D5891).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of competency assessment records and interview the laboratory failed to ensure written policies and procedures were followed to assess the competency of the Technical Supervisor. The laboratory failed to assess the competency of one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure JOB DESCRIPTION, which stated: "Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation." 2. The Survey Team requested and the laboratory failed to provide competency assessment records for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
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 review of 17 laboratory policies and procedures, lack of laboratory records and interviews the laboratory failed to follow two written policies and procedures. Findings include: 1. The laboratory failed to follow the procedure URINE CYTOLOGY THINPREP CONTROL SLIDES FOR THE EVALUATION OF QUALITY OF STAINING AND SPECIMEN PREPARATION - TC/PC CLIENTS,

	which stated: "It is the responsibility of the pathology director at the TC/PC site receiving the ThinPrep urine cytology control slide and the patient Thinprep urine cytology slides to document the quality of the staining and slide preparation on the Technical Quality Assurance and Slide Log form received with the ThinPrep slides and requisitions." a. The Survey Team requested and the laboratory failed to provide records titled TECHNICAL QUALITY ASSURANCE AND SLIDE LOG for 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 2. The laboratory failed to follow the procedure MICROSCOPE PREVENTATIVE MAINTENANCE, which stated: "Services of a certified company will be utilized for preventative maintenance on an annual basis." a. The Survey Team requested and the laboratory failed to provide microscope maintenance records for 2022, 2023 and January 1, 2024 to the date of the survey in 2024. b. During an interview on October 21, 2024 at 11:20 AM, the Office Manager stated the Laboratory Director/Technical Supervisor microscopically examined slides at a remote location (Laboratory Director/Technical Supervisor's home residence). c. During an interview on October 22, 2024 at 1:20 PM, the Office Manager stated the laboratory did not have any microscope maintenance records. 3. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
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 review of 17 laboratory policies and procedures and interview the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for reporting nongynecologic cytology test results into the laboratory information system (LIS). 2. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of statistical records and interview the laboratory failed to establish and follow written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. The laboratory failed to document three of three required annual nongynecologic statistics for 2022 and 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. Statistics include: - Number of nongynecologic cytology cases examined -Number of nongynecologic specimens processed by specimen type -Number of nongynecologic cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide records of the three required annual statistics for 2022 and 2023. 3. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
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 review of laboratory policies and procedures, lack of workload limit records and interview the laboratory failed to follow written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of cytology specimens. The Technical Supervisor failed to establish an individual maximum workload limit for one of one Technical Supervisors who performed primary screening in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure JOB DESCRIPTION, which stated: "In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)" "Must establish the workload limit for each individual examining slides" 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor established an individual maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on

	October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit reassessment records and interview the laboratory failed to follow written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of cytology specimens. The Technical Supervisor failed to reassess a maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure JOB DESCRIPTION, which stated: "In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)" "Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary" 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a maximum workload limit for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (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; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload records and interview the laboratory failed to establish and follow written policies and procedures to ensure workload limits for the Technical Supervisors would be prorated when examining slides in less than an eight-hour work day. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate workload limits for the Technical Supervisors when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor established an individual maximum workload limit for one of one Technical Supervisors. Refer to D5633, D5637 and D5647 3. The Survey Team requested and the laboratory failed to provide documentation of the total number of

	slides examined in each 24-hour period and the number of hours examining slides per 24-hour period for one of one Technical Supervisors in 2022, 2023 and January 2, 2024 to the date of the survey in 2024. Refer to D5645 4. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload records and interview the laboratory failed to follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined by each Technical Supervisor per 24-hour period and the number of hours the Technical Supervisors spent examining slides per 24-hour period. Findings include: 1. The laboratory failed to follow the procedure JOB DESCRIPTION, which stated: "In cytology, the technical supervisor or the individual qualified under 493.1449(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." 2. The Survey Team requested and the laboratory failed to provide records of the total number of slides examined in each 24-hour period and the number of hours spent examining slides per 24-hour period for one of one Technical Supervisors in 2022, 20233 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit records and interview the laboratory failed to establish and follow written policies and procedures to ensure records were available to document the workload limit for one of one Technical Supervisors who performed primary screening of cytology specimens in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisors who performed primary screening of cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for one of one Technical Supervisors who performed

	primary screening of cytology specimens in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisor includes: -Laboratory Director /Technical Supervisor 3. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview the laboratory failed to establish written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. The Survey Team reviewed 306 final test reports from January 2023 through May 2024 and identified 21 of 306 final test reports that failed to report test results within the diagnostic categories. Final test reports include: -EP23-00021 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings, the cytologic atypia is consistent with urothelial neoplasia. -EP23-00047 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings, the cytologic atypia is consistent with urothelial neoplasia. -EP23-00100 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or recurrent urothelial carcinoma -EP23-00102 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or recurrent urothelial carcinoma -EP23-00119 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or

	recurrent urothelial carcinoma -EP23-00148 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or recurrent urothelial carcinoma -EP23-00166 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings, the cytologic atypia is consistent with urothelial neoplasia. -EP23-00167 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings, the cytologic atypia is consistent with urothelial neoplasia. -EP23-00181 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings, the cytologic atypia is consistent with urothelial neoplasia. -EP23-00194 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or recurrent urothelial carcinoma -EP23-00198 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings, the cytologic atypia is consistent with urothelial neoplasia. -EP23-00203 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings, the cytologic atypia is consistent with urothelial neoplasia. -EP23-00245 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or recurrent urothelial carcinoma -EP23-00283 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or recurrent urothelial carcinoma -EP23-00303 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or recurrent urothelial carcinoma -EP23-00326 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or recurrent urothelial carcinoma -EP23-00342 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings, the cytologic atypia is consistent with urothelial neoplasia. -EP23-00344 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings, the cytologic atypia is consistent with urothelial neoplasia. -EP23-00359 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or recurrent urothelial carcinoma -EP23-00368 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings and history of bladder carcinoma, the cytologic atypia is consistent with residual or recurrent urothelial carcinoma -EP23-00409 Diagnosis: Atypical Cytology Comments: In the presence of abnormal UroVysion findings, the cytologic atypia is consistent with urothelial neoplasia. 3. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of quality assessment records and interview the laboratory failed to establish and follow written policies and

	procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems. The laboratory failed to document analytic quality assessment activities during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the analytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of analytic quality assessment activities during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. a. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the annual statistical evaluation of the required laboratory statistics. Refer to D5629 b. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the establishment and reassessment of workload limits. Refer to D5633, D5637 and D5647 c. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate workload records. Refer to D5641 and D5645 3. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) 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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of quality assessment records and interview the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic cytology systems. The laboratory failed to document postanalytic quality assessment activities during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory failed to follow the procedure RETROSPECTIVE QUALITY ASSURANCE, which stated: "Retrospective Quality Assurance will be performed on a bi-annual basis by a California licensed pathologist, for histology, cytology, clinical cytogenetics and documented on a Quality Assessment Evaluation Chart. 2. The Survey Team requested and the laboratory failed to provide records titled QUALITY ASSESSMENT EVALUATION CHART for 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 3. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on interviews the laboratory failed to have a Laboratory Director who provides

	overall management and direction in accordance with 493.1445 of this subpart. Findings include: 1. During an interview on October 21, 2024 at 11:20 AM, the Office Manager stated the laboratory failed to employ a Laboratory Director from May 1, 2024 to the date of the survey in 2024. As of May 1, 2024 the Laboratory Director was no longer employed by the laboratory. 2. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 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. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload records and interviews the laboratory failed to have a Technical Supervisor who meets the qualification requirements of 493.1451 of this subpart. The laboratory failed to employ an individual qualified by education and either training or experience to provide technical supervision for the subspecialty of cytology (refer to D6109).
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on interviews the laboratory failed to employ an individual qualified by education and either training or experience to provide technical supervision for the subspecialty of cytology. Findings include: 1. During an interview on October 21, 2024 at 11:20 AM, the Office Manager stated the laboratory failed to employ a Technical Supervisor from May 1, 2024 to the date of the survey in 2024. As of May 1, 2024 the Technical Supervisor was no longer employed by the laboratory. 2. During an interview on October 22, 2024 at 2:00 PM, these findings were confirmed with the Office Manager, Laboratory Owner and Staff A.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) 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. This STANDARD is not met as evidenced by:

	Based on the microscopic review of 210 random negative nongynecologic cytology cases/214 slides from January 2023 through October 2023 the Technical Supervisor failed to verify the accuracy of one nongynecologic cytology test. 1. EP23-00316 07 /11/23 Voided Urine LABORATORY DIAGNOSIS: Negative for High Grade Neoplasia SURVEY TEAM DIAGNOSIS: Suspicious for High Grade Urothelial Carcinoma
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.