

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0547058	(X3) Date Survey Completed 04/06/2022
Name of Provider or Supplier Protzel Pathology Laboratory	Street Address, City, State 9735 Wilshire Blvd Ste 241, Beverly 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish safety procedures to ensure protection from physical, chemical and electrical hazards, and necessary precautions to ensure safety from biohazardous materials. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure protection from physical, chemical and electrical hazards. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure precautions were taken during the handling of biohazardous cytology materials. 3. During an interview on April 4, 2022 at 11:30 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.</p>
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, cytology specimen slides and</p>

corresponding final cytology test reports and interview it was determined that the laboratory failed to establish written policies and procedures to retain copies of all cytology test reports for at least ten years after the date of reporting. The laboratory failed to retain a copy of six of 51 final cytology test reports from 2018 to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the laboratory's process of retaining copies of all final cytology test reports for at least ten years after the date of reporting. 2. During a review of cytology specimen slides and the corresponding final test reports, the Survey Team requested and the laboratory failed to provide six of 51 final cytology test reports. Final Test Reports include: -RP-981-18 -RP-981A-18 -RP-981B-18 -RP-981C-18 -RP-981D-18 -RP-981E-18 3. During an interview on April 5, 2022 at 11:00 AM, the Office Manager confirmed these findings and stated: "We don't have a computer to search for anything before 2019. I can't find the reports if they're not put back. Sometimes we pull a report out and just don't file it back."

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, cytology specimen slides and interviews it was determined that the laboratory failed to establish written policies and procedures for two laboratory test processes (refer to D5403); failed to establish written policies and procedures for the evaluation of three of three annual statistics (refer to D5629); failed to establish written policies and procedures for the establishment of individual workload limits, and failed to reassess workload limits at least every six months (refer to D5633 and D5637); failed to establish 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 establish written policies and procedures to ensure the laboratory maintained records of the total number of slides examined per 24-hour period, and maintain records of the total number of hours spent examining slides per 24-hour period (refer to D5645); failed to establish written policies and procedures to document the workload limit (refer to D5647); failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D5655); failed to establish 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 written policies and procedures to ensure corrected reports indicated the basis for the correction on the final cytology test report (refer to D5659); and failed to maintain a record system for positive patient identification and the date of specimen receipt (refer to D5787).

D5201

CONFIDENTIALITY OF PATIENT INFORMATION
CFR(s): 493.1231

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

This STANDARD is not met as evidenced by:
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 confidentiality of patient information. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the laboratory would ensure confidentiality of patient information. 2. During an interview on April 4, 2022 at 11:30 AM, the Office Manager and Laboratory Director /Technical Supervisor confirmed these findings.

D5205

COMPLAINT INVESTIGATIONS
CFR(s): 493.1233

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the documentation of complaints and problems reported to the laboratory for 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for investigating and documenting complaints and problems reported to the laboratory. 2. The Survey Team requested and the laboratory failed to provide documentation of complaints and problems reported to the laboratory. 3. During an interview on April 5, 2022 at 8:45 AM, the Office Manager and the Laboratory Director/Technical Supervisor confirmed these findings.

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 laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of the Laboratory Director/Technical Supervisor. The laboratory failed to assess the competency of the one of one Laboratory Director /Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process to assess the competency of the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for the one of one Laboratory Director/Technical Supervisor during 2020, 2021 and to the date of the survey in 2022. Laboratory Director/Technical Supervisor Includes: -Laboratory Director/Technical Supervisor 3. During an interview on April 4, 2022 at 11:30 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, cytology specimen slides 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 identified in the general laboratory systems. The laboratory failed to document general laboratory quality assessment activities during 2020, 2021 and to the date of the survey in 2022. Cross refer to D5201, D5205 and D5209 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 general laboratory systems. 2. The Survey Team requested and the laboratory failed to provide documentation of general laboratory quality assessment activities during 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to document a system for monitoring and evaluating confidentiality of patient information. (See D5201) b. The laboratory failed to document a system for monitoring and evaluating complaints and problems reported to the laboratory. (See D5205) c. The laboratory failed to document a system for monitoring and evaluating the competency of the Laboratory Director/Technical Supervisor. (See D5209) 3. The laboratory failed to document a system for monitoring and evaluating the completeness of specimen requisitions. a. Four of 44 patient specimen requisitions from 2018 to the date of the survey failed to include the date of specimen collection. Patient Specimen Requisitions include: -RP-2244-19 -RP-2723-21 -RP-0041-22 -RP-0448-22 b. Three of 44 patient specimen requisitions from 2018 to the date of the survey failed to include the specimen source. Patient Specimen Requisitions include: -RP-1194-18 -RP-1467-18 -RP-0690-19 4. During interviews on April 5, 2022 at 8:20 AM and 8:45 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

D5309

TEST REQUEST

CFR(s): 493.1241(e)

If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

This STANDARD is not met as evidenced by:

Based on review of laboratory records it was determined that the laboratory failed to ensure that patient specimen information was transcribed accurately into the final cytology test report for five of 44 specimens sampled from 2018 to the date of the survey in 2022. Findings include: 1. The Survey Team reviewed 44 final cytology test reports with the corresponding laboratory records. a. Five of 44 final cytology test reports failed to have accurate patient specimen information transcribed into the final cytology test report. Patient Specimens include: -RP-1996-19 Test Report Information: Date Collected 8-21-19 Specimen Requisition Information: Date

Collected 8-2-19 Test Report Information: First Name "Barora" Specimen Requisition Information: First Name "Barbora" -RP-0041-22 Test Report Information: First Name "Phillip" Specimen Requisition Information: First Name "Philipp" -RP-2059-18 Test Report Description: Interpretation states "Papanicolaou stained smears and cell block sections prepared from left breast seroma fluid are bright. "Bright" is a data entry error and the intended diagnostic description is unknown. Specimen Requisition Information: "Bright" is not documented. -RP-2588-18 Test Report Information: Date Collected 10-30-2018 and Date Received 10-03-2018 Specimen Requisition Information: Date Collected 10-30-2018 and Date Received not provided -RP-2799-18 Test Report Information: Gross Description to include the number of slides was not transcribed

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, interviews and observation of cytology specimen slides it was determined that the laboratory failed to establish written policies and procedures to describe the laboratory's requirements for specimen collection, specimen labeling, specimen storage and preservation, specimen transportation, specimen processing and accessioning, specimen acceptability and rejection and specimen referral. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's requirements for the following: -specimen collection -specimen labeling -specimen storage and preservation -specimen transportation -specimen processing and accessioning -specimen acceptability and rejection -specimen referral a. During an interview on April 4, 2022 at 11:30 AM, the Office Manager and Laboratory Director /Technical Supervisor confirmed these findings 2. The laboratory failed to ensure instruction were provided for labeling on 54 of 54 cytology specimen slides from 2018 to the date of the survey in 2022, prior to the application of an assigned accession number. a. The Survey Team observed cytology specimen slides that were received as unlabeled direct smears from physicians offices. b. The cytology specimen slides were assigned an accession number upon receipt and accessioning in the laboratory. The assigned accession number was not on the cytology specimen slides from the time of collection through the preanalytic phase of testing. Specimen Case and # of Slides include: -RP-0509-18 4 slides -RP-0675-18 4 slides -RP-1312-18 2 slides -RP-1467-18 2 slides -RP-2185-18 2 slides -RP-2380-18 2 slides -RP-2716-18 3 slides -RP-0179-19 2 slides -RP-0811-19 2 slides -RP-0889-19 4 slides -RP-0890-19 4 slides -RP-1906-19 2 slides -RP-0139-21 1 slide -RP-0624-20 2 slides -RP-0714-21 2 slides -RP-0726-20 6 slides -RP-0851-21 2 slides -RP-2723-21 4 slides -RP-2933-21 2 slides -RP-0041-22 2 slides 3. During an interview on April 4, 2022 at 2:30 PM, when asked how the cytology specimen slides were labeled prior to being assigned the accession number, the Office Manager replied: -"They get the number when they come in and before we send them out. The offices send a paper request slip with them so we know." When asked if the laboratory provided instructions or

required a patient name or other identifier to be written on the slide, the Office Manager replied that the laboratory assigns the next accession number. The Office Manager confirmed that the cytology specimen slides failed to include a patient name or any other unique identifier prior to the assignment of the accession number.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, cytology specimen slides 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 identified in the preanalytic systems. The laboratory failed to document preanalytic quality assessment activities during 2020, 2021 and to the date of the survey in 2022. Cross refer to D5309 and D5311 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 preanalytic laboratory systems. 2. The Survey Team requested and the laboratory failed to provide documentation of preanalytic laboratory quality assessment activities during 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to have an ongoing mechanism to ensure the accuracy of transcription from patient records to the final cytology test report. (See D5309) b. The laboratory failed to have an ongoing mechanism to identify problems with specimen collection, specimen labeling, specimen storage and preservation, specimen transportation, specimen processing and accessioning, specimen acceptability and specimen referral. (See D5311) 3. During an interview on April 5, 2022 at 8:20 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

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 laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for two laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's requirements for microscopic examination, including the detection of inadequately prepared slides. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's system for entering results in the patient record and reporting patient results. 3. During an interview on April 4, 2022 at 11:30 AM, the Office Manager and Laboratory Director /Technical Supervisor confirmed these findings.

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 laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology statistics. The laboratory failed to document three of three required nongynecologic statistics for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology statistics. Statistics include: -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 2. The Survey Team requested and the laboratory failed to provide the three required nongynecologic annual statistics for 2020 and 2021. Statistics include: -The number of cases examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 3. During an interview on April 4, 2022 at 11:30 AM, the Office Manager and Laboratory Director /Technical Supervisor confirmed these findings.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure individual maximum workload limits were established for the Laboratory Director/Technical Supervisor who performed primary screening of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the Laboratory Director/Technical Supervisor established individual maximum workload limits for the Laboratory Director/Technical Supervisor who performed primary screening of nongynecologic cytology specimens. 2. During an interview on April 4, 2022 at 10:00 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to reassess and adjust when necessary a maximum workload limit at least every six months for the Laboratory Director/Technical Supervisor who performed primary screening of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Laboratory Director/Technical Supervisor's workload limits would be reassessed at least every six months and adjusted when necessary. 2. During an interview on April 4, 2022 at 10:00 AM, the Office Manager and Laboratory Director /Technical Supervisor confirmed these findings.

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 laboratory records and interview it was determined that the laboratory failed to establish written policies and

procedures to ensure that the workload limits for the Laboratory Director/Technical Supervisor 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 the workload limits for the Laboratory Director/Technical Supervisor when examining slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for one of one Laboratory Director /Technical Supervisor when examining slides in less than an eight-hour work day. Laboratory Director/Technical Supervisor Includes: -Laboratory Director/Technical Supervisor 3. During an interview on April 4, 2022 at 10:00 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records of the total number of slides the Laboratory Director/Technical Supervisor examined per 24-hour period and the number of hours spent examining slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides the Laboratory Director/Technical Supervisor examined per 24-hour period and the number of hours spent examining slides per 24-hour period. 2. During an interview on April 4, 2022 at 10:00 AM, the Office Manager and Laboratory Director /Technical Supervisor confirmed these findings.

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 laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for one of one Laboratory Director/Technical Supervisor who performed primary screening of nongynecologic cytology specimens in 2020, 2021 and through the date of the survey in 2022. 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 Laboratory Director/Technical Supervisor who performed primary screening of nongynecologic cytology specimens. 2. The Survey Team

	<p>requested and the laboratory failed to provide records of individual workload limits for one of one Laboratory Director/Technical Supervisor who performed primary screening of nongynecologic cytology specimens in 2020, 2021 and to the date of the survey in 2022. Laboratory Director/Technical Supervisor Includes: -Laboratory Director/Technical Supervisor 3. During an interview on April 4, 2022 at 10:00 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.</p>
<p>D5655</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(4)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: 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 unsatisfactory 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 that unsatisfactory slide preparations were identified and reported as unsatisfactory for evaluation. 2. During an interview on April 4, 2022 at 10:00 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.</p>
<p>D5657</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(5)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: 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 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. During an interview on April 4, 2022 at 11:30 AM, these findings were confirmed by the Office Manager and the Laboratory Director/Technical Supervisor.</p>
<p>D5659</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(6)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. The laboratory failed to state the basis for the correction on one of one corrected cytology test report from 2019. 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. The laboratory failed to indicate the basis for the correction on one of one corrected cytology test report from 2019. Test Report Includes: -RP-2244-19 3. During an interview on April 5, 2022 at 10:00 AM, the Office Manager confirmed these findings.

D5663

CYTOLOGY
CFR(s): 493.1274(f)(4)

(f) Record and slide retention. (f)(4) All slides must be retrievable upon request.

This STANDARD is not met as evidenced by:
Based on review of cytology specimen slides and corresponding final test reports and interview it was determined that the laboratory failed ensure 18 of 27 cytology specimen slides from 2018 to the date of the survey in 2022 were retrievable upon request. Findings include: 1. During a review of cytology specimen slides and the corresponding test reports, the laboratory failed to locate and provide 18 of 27 cytology specimen slides from seven patient cases. Case # # Slides/Case # Slides Not Retrieved -RP-0372-18 5 3 -RP-0533-18 5 3 -RP-2716-18 3 2 -RP-2910-18 5 4 -RP-2578-21 3 2 -RP-2435 (3)-19 3 2 -RP-2435 (4)-19 3 2 2. During an interview on April 6, 2022 at 10:00 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of cytology specimen slides and the corresponding laboratory records and interviews it was determined that the laboratory failed to maintain a system for positive identification of patient specimens. The laboratory failed to maintain a system for the date of specimen receipt into the laboratory. Findings include: 1. The laboratory failed to maintain a system for positive identification of patient specimens. a. During the review of cytology specimen slides and the corresponding final cytology test reports, the Survey Team identified one specimen slide in Patient Specimen Case # RP-2723-21 that did not belong to the patient. b. During an interview on April 5, 2022 at 10:30 AM, the Office Manager confirmed that the specimen slide was mislabeled and belonged to Patient Case #RP-2721-21. 2.

The laboratory failed to maintain a system to document the date of specimen receipt into the laboratory. a. During an interview on April 5, 2022 at 10:30 AM, the Office Manager stated that the date a specimen was received into the laboratory was written on the specimen test requisition the day of receipt. b. The laboratory failed to document the date a specimen was received on 35 of 42 specimen test requisitions from 2018 to the date of the survey 2022. Specimens include: -RP-0372-18 -RP-0533-18 -RP-1194-18 -RP-1276-18 -RP-1312-18 -RP-1647-18 -RP-2185-18 -RP-2380-18 -RP-2588-18 -RP-2799-18 -RP-2910-18 -RP-3165-18 -RP-0179-19 -RP-0690-19 -RP-0691-19 -RP-0811-19 -RP-0812-19 -RP-0889-19 -RP-0890-19 -RP-1906-19 -RP-1996-19 -RP-2244-19 -RP-2435-19 -RP-0139-20 -RP-0624-20 -RP-0714-20 -RP-0758-20 -RP-0706-21 -RP-0726-21 -RP-0851-21 -RP-2578-21 -RP-2723-21 -RP-2933-21 -RP-0041-22 -RP-0448-22 3. During an interview on April 5, 2022 at 10:30 AM, the Office Manager confirmed these findings.

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, 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 identified in the analytic cytology systems. The laboratory failed to document analytic quality assessment activities in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5629, D5657, D5659, D5663 and D5787 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 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to document a system for monitoring and evaluating annual statistics (See D5629). b. The laboratory failed to document a system for monitoring and evaluating final test reports for nomenclature (See D5657). c. The laboratory failed to document a system for monitoring and evaluating the basis for correction on final test reports (See D5659). d. The laboratory failed to document a system for monitoring and evaluating the retrievability of specimen slides (See D5663). e. The laboratory failed to document a system for monitoring and evaluating a system to ensure positive patient specimen identification (See D5787). 3. During an interview on April 5, 2022 at 8:20 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

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 laboratory records and interview it was determined that the laboratory failed to establish 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 in 2020, 2021 and to the date of the survey in 2022. 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 postanalytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of postanalytic quality assessment activities during 2020, 2021 and to the date of the survey in 2022. 3. During an interview on April 5, 2022 at 8:20 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

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 review of laboratory policies and procedures, laboratory records, cytology specimen slides 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 ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur (refer to D6093); failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur (refer to D6094); and failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of the Laboratory Director/Technical Supervisor and Office Manager performing cytology duties (refer to D6103).

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director failed to ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur. Cross refer to D5629 Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide records of an established quality control program and failed to identify failures in quality as they occur. 2. During an interview on April 5, 2022 at 8:20 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, cytology specimen slides and interviews it was determined that the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5291, D5391, D5791 and D5891 Findings include: 1. The Survey Team requested and the Laboratory Director failed to ensure the establishment of written policies and procedures for a quality assessment program for all phases of cytology testing. 2. The Survey Team requested and the Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality as they occurred in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on April 5, 2022 at 8:45 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

D6098

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(8)

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, final cytology test reports and interviews it was determined that the Laboratory Director failed to ensure that seven of 51 final cytology test reports from 2018 to the date of the survey in 2022 included pertinent information required for test result interpretation. Cross refer to D5655 and D5657 Findings include: 1. The Survey Team reviewed 51 random final cytology test reports from 2018 to the date of the survey in 2022. Seven of 51 final test reports failed to indicate the test result interpretation. Test Reports Include: -RP-0675-18 -RP-1312-18 -RP-0811-19 -RP-0812-19 -RP-1906-19 -RP-0139-21 -RP-2723-21 2. The Laboratory Director failed to ensure a system of descriptive nomenclature was used by the laboratory to consistently use diagnostic categories and criteria to report nongynecologic cytology test results. (See D5655 and D5657)

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

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.

This STANDARD is not met as evidenced by:
 Based on review of laboratory policies and procedures, laboratory records, review of specimen slides and corresponding final cytology test reports and interviews 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 one of one Office Manager performing cytology duties. Cross refer to D5209 Findings include: 1. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess the competency of the Laboratory Director/Technical Supervisor, and when necessary identify methods to improve the skills of the Laboratory Director /Technical Supervisor. a. The Survey Team requested and the Laboratory Director failed to provide documentation of competency assessments for one of one Laboratory Director/Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. Laboratory Director/Technical Supervisor Includes: -Laboratory Director/Technical Supervisor b. The Laboratory Director/Technical Supervisor failed to accurately report the type of neoplasm on one of three malignant cytology cases reported in 2018 and 2019. On April 6, 2022 at 10:00 AM, the Laboratory Director/Technical Supervisor confirmed these findings. Case includes: -RP-1467-18 Laboratory Director /Technical Supervisor Interpretation: Metastatic High Grade Squamous Cell Carcinoma Survey Team Interpretation: Malignant Lymphoma Concurrent Biopsy Interpretation: Diffuse B-Cell Lymphoma 2. The Survey Team requested and the Laboratory Director failed to provide written policies and procedures to assess the competency of the Office Manager, and when necessary identify methods to improve the skills of the Office Manager. a. The Survey Team requested and the Laboratory Director failed to provide documentation of competency assessments for one of one Office Manager in 2020, 2021 and to the date of the survey in 2022. Office Manager Includes: -Office Manager b. During an interview on April 4, 2022 at 11:30 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.

D6130

TECHNICAL SUPERVISOR RESPONSIBILITIES
 CFR(s): 493.1451(c)(2)(3)

(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.

This STANDARD is not met as evidenced by:
 Based on review of laboratory polices and procedures, lack of laboratory records and interviews it was determined that the Technical Supervisor failed to establish an individual workload limit and failed to reassess workload limits at least every six months for one of one Laboratory Director/Technical Supervisor performing primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor established a maximum workload limit for one of one Laboratory Director/Technical Supervisor who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Laboratory Director/Technical Supervisor includes: - Laboratory Director /Technical Supervisor 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor reassessed a workload limit at

	<p>least every six months for one of one Laboratory Director/Technical Supervisor who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Laboratory Director/Technical Supervisor includes: - Laboratory Director /Technical Supervisor 3. During an interview on April 4, 2022 at 11:30 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.</p>
<p>D6133</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures, lack of laboratory records and interviews it was determined that one of one Laboratory Director/Technical Supervisor performing primary screening of cytology specimen slides failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5645 Findings include: 1. The Survey Team requested and the laboratory failed to provide records of the total number of slides screened and the total number of hours one of one Laboratory Director/Technical Supervisor devoted to screening cytology specimen slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Laboratory Director/Technical Supervisor includes: - Laboratory Director/Technical Supervisor 2. During an interview on April 4, 2022 at 11:30 AM, the Office Manager and Laboratory Director/Technical Supervisor confirmed these findings.</p>
<p>D9999</p>	<p>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.</p>