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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 29D0938030 | (X3) Date Survey Completed 07/21/2021 |
| Name of Provider or Supplier Sierra Pathology Associates Inc | Street Address, City, State 1155 Mill St, Reno, NV | |
| 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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| D5032 | <p>CYTOLOGY CFR(s): 493.1221</p> <p>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.</p> <p>This CONDITION 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 annual evaluation and comparison of one of six laboratory statistics (refer to D5629); failed to establish written policies and procedures to establish, reassess and document a workload limit for ten of ten Technical Supervisors and four of four Cytotechnologists (refer to D5633, D5637 and D5647); failed to establish written policies and procedures to ensure Cytotechnologist's workload limits were based on performance requirements and failed to document those workload requirements (refer to D5635); failed to establish written policies and procedures to prorate the workload limit for ten of ten Technical Supervisors when examining slides in less than an eight hour day (refer to D5641); and failed to establish written policies and procedures to specify on a corrected report the basis for correction (refer to D5659).</p> |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> |

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 and document the competency of ten of ten Technical Supervisors who performed microscopic evaluations and reporting of gynecologic and non-gynecologic cytology results for 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of ten of ten Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of the evaluation of the competency of ten of ten Technical Supervisors for 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 - Technical Supervisor #6 - Technical Supervisor #7 - Technical Supervisor #8 - Technical Supervisor #9 - Technical Supervisor #10 3. During an interview with the Survey Team at 10:45 AM on July 21, 2021 the Cytology Supervisor/Cytotechnologist #1 confirmed these findings.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(a)

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.

This STANDARD is not met as evidenced by:
 Based on review of manufacturer's instructions, laboratory records and interview it was determined that the laboratory failed to ensure nine of ten Technical Supervisors and three of four Cytotechnologists received the appropriate training to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test in accordance with the manufacturer's instructions for 2020 and to date of the survey in 2021. Findings include: 1. The HOLOGIC THINPREP PROCESSOR OPERATOR'S MANUAL states "Evaluation of microscope slides produced with the ThinPrep processor should be performed only by cytotechnologists and pathologists who have been trained to evaluate ThinPrep-prepared slides by Hologic or by organizations or individuals designated by Hologic." 2. The Survey Team requested and the laboratory failed to provide training records for nine of ten Technical Supervisors and three of four Cytotechnologists who performed diagnostic interpretations on Hologic ThinPrep Pap Tests in 2020 and to the date of the survey in 2021. Technical Supervisors include: - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 - Technical Supervisor #6 - Technical Supervisor #7 - Technical Supervisor #8 - Technical Supervisor #9 - Technical Supervisor #10 Cytotechnologists include: - Cytology Supervisor/Cytotechnologist #1 - Cytotechnologist #3 - Cytotechnologist #4 3. During an interview with the Survey Team at 10:50 AM on July 21, 2021 the Cytology Supervisor/Cytotechnologist #1 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, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of one of six laboratory statistics and failed to document one of six required annual statistics for 2019 and 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of the number of specimens processed by specimen type. 2. The Survey Team requested and the laboratory failed to provide one of six required annual statistics for 2019 and 2020. Statistics include: a. the number of specimens processed by specimen type. 3. During an interview with the Survey Team at 2:05 PM on July 19, 2021 the Cytology Supervisor/Cytotechnologist #1 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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that individual maximum workload limits were established for ten of ten Technical Supervisors and four of four Cytotechnologists during the years 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that individual maximum workload limits were established for ten of ten Technical Supervisors and four of four Cytotechnologists. 2. The Survey Team requested and the laboratory failed to provide an individual workload limit for ten of ten Technical Supervisors and four of four Cytotechnologists for 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 - Technical Supervisor #6 - Technical Supervisor #7 - Technical Supervisor #8 - Technical Supervisor #9 - Technical Supervisor #10 Cytotechnologists include: - Cytology Supervisor/Cytotechnologist #1 - Cytotechnologist #2 - Cytotechnologist #3 - Cytotechnologist #4 3. During an interview with the Survey Team at 11:45 AM on July 19, 2021 the Cytology Supervisor/Cytotechnologist #1 confirmed these findings.

D5635

CYTOLOGY

CFR(s): 493.1274(d)(1)(i)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(i) The workload limit is based on the individual's performance using evaluations of the following: (d)(1)(i)(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section. (d)(1)(i)(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section.

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 Cytotechnologist's workload limits would be based on the individual's performance. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the workload limit for Cytotechnologists would be based on individual capabilities to include evaluations of the following: a. A review of 10 percent of the Cytotechnologist's cases interpreted as negative and b. A comparison of the Cytotechnologist's interpretations with the Technical Supervisor's confirmations of patient slides. 2. The Survey Team requested and the laboratory failed to provide documentation that the workload limits were based on the individual's performance requirements. 3. During an interview with the Survey Team at 11:45 AM on July 19, 2021 the Cytology Supervisor/Cytotechnologist #1 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, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limit for ten of ten Technical Supervisors and four of four Cytotechnologists was reassessed and adjusted when necessary at least every six months during 2020 and to date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the reassessment and adjustment when necessary of workload limits at least every six months for ten of ten Technical Supervisors and four of four Cytotechnologists. 2. The Survey Team requested and the laboratory failed to provide reassessed workload limits for ten of ten Technical Supervisors and four of four Cytotechnologists during 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 - Technical Supervisor #6 - Technical Supervisor #7 - Technical Supervisor #8 - Technical Supervisor #9 - Technical Supervisor #10
Cytotechnologists include: - Cytology Supervisor/Cytotechnologist #1 - Cytotechnologist #2 - Cytotechnologist #3 - Cytotechnologist #4 3. During an

interview with the Survey Team at 11:45 AM on July 19, 2021 the Cytology Supervisor/Cytotechnologist #1 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 ten of ten Technical Supervisors would be prorated when examining slides in less than eight hours. The laboratory failed to document prorated workload limits for ten of ten Technical Supervisors when examining slides in less than an eight-hour day in 2020 and 2021 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for ten of ten Technical Supervisors 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 ten of ten Technical Supervisors when examining slides in less than eight hours. Technical Supervisors include: - Laboratory Director /Technical Supervisor #1 - Technical Supervisor #2 - Technical Supervisor #3 - Technical Supervisor #4 - Technical Supervisor #5 - Technical Supervisor #6 - Technical Supervisor #7 - Technical Supervisor #8 - Technical Supervisor #9 - Technical Supervisor #10 3. During an interview with the Survey Team at 11:45 AM on July 19, 2021 the Cytology Supervisor/Cytotechnologist #1 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 that records were available to document the workload limit for ten of ten Technical Supervisors and four of four Cytotechnologists for 2020 and to the date of the survey in 2021. Cross refer to D5633 and D5637

D5659

CYTOLOGY
CFR(s): 493.1274(e)(6)

(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.

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 for issuing a corrected report to include the basis for the correction.

Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for issuing a corrected report to include the basis for the correction. 2. The laboratory failed to include the basis for correction on one of two final revised/amended reports reviewed by the Survey Team from 2019 and 2020. Test report includes: - GY20-06648 3. During an interview with the Survey Team at 8:30 AM on July 20, 2021 the Cytology Supervisor/Cytotechnologist #1 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 the nature of the following deficient practices 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 nine of ten Technical Supervisors and three of four Cytotechnologists had received the appropriate morphology training and certification required by the manufacturer (refer to D6102); and failed to establish policies and procedures to evaluate the competency of ten of ten Technical Supervisors who performed microscopic evaluations and reporting of gynecologic and non-gynecologic cytology results for 2020 and to the date of the survey in 2021 (refer to D6103).

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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 reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

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| | <p>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 Director failed to be responsible for the overall operation and administration of the laboratory to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5629, D5633, D5637, D5641, D5645, D5647 and D5659.</p> |
| <p>D6102</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview, it was determined that the Laboratory Director failed to ensure that nine of ten Technical Supervisors and three of four Cytotechnologists that performed Hologic ThinPrep Pap Test evaluations during 2020 and to the date of the survey in 2021, had received the appropriate morphology training and certification in accordance with manufacturer's instructions. Cross refer to D5411</p> |
| <p>D6103</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that Laboratory Director/Technical Supervisor #1 failed to establish policies and procedures to evaluate the competency of ten of ten Technical Supervisors who performed microscopic evaluations and reporting of gynecologic and non-gynecologic cytology results for 2020 and to the date of the survey in 2021. Cross refer to D5209</p> |
| <p>D6115</p> | <p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p> <p>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.</p> |

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| | <p>This STANDARD is not met as evidenced by: Based on the microscopic review of 366 random negative gynecologic cses/376 negative gynecologic slides and the corresponding final test reports from October 2020 and confirmation by Laboratory Director/Technical Supervisor #1 on July 21, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. 1. GY20-06676 10/15/2020 Hologic Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance (ASCUS) SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion (LSIL) LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: LSIL 2. GY20-06353 10/05/2020 Hologic Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for evaluation due to Limited Cellularity LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for evaluation due to Limited Cellularity</p> |
| <p>D6130</p> | <p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3)</p> <p>(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.</p> <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 Laboratory Director/Technical Supervisor #1 failed to establish and reassess the workload limits at least every six months and make adjustments when necessary for ten of ten Technical Supervisors and four of four Cytotechnologists in 2020 and to the date of the survey in 2021. Cross refer to D5633 and D5637</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> |