

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0469942	(X3) Date Survey Completed 01/24/2018
Name of Provider or Supplier Pathology Consultation Services Inc	Street Address, City, State 501 Alameda, Suite B, Norman, OK	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, observation, review of glass slides and interviews it was determined that the laboratory failed to follow written policies and procedures to ensure the positive identification of 116 of 179 gynecologic cytology glass slides sampled from 10/2/17 to 1/24/18. Findings include: 1. The procedure titled ACCESSIONING OF CYTOLOGY SPECIMENS stated "LABELING SLIDES. Gynecologic and Non Gynecologic slides are labeled with permanent black pens with the corresponding accession number". 2. The procedure titled THINPREP PROCEDURE stated "3. PCS (P) number and patient name is written on the corresponding ThinPrep slide". 3. On 1/23/18 at 10:35 AM the Survey Team observed that the slides were not labeled with a unique identifier (accession number) to ensure positive patient identification. 4. The Survey Team identified 116 of 179 slides that failed to have a unique identifier on the patient slide: Accession Number on Labeling on the the Test Requisition Glass Slide P17-3292 3292 P17-4371 4371 P17-4684 4684 P17-4700 4700 P17-4701 4701 P17-4703 4703 P17-4706 4706 P17-4707 4707 P17-4709 4709 P17-4711 4711 P17-4712 4712 P17-4717 4717 P17-4720 4720 P17-4721 4721 P17-4730 4730 P17-4732 4732 P17-5052 5052 P17-5056 5056 P17-5057 5057 P17-5059 5059 P17-5061 5061 P17-5065 5065 P17-5067 5067 P17-5070 5070 P17-5072 5072 P17-5073 5073 P17-5076 5076 P17-5078 5078 P17-5079 5079 P17-5080 5080 P17-5082 5082 P17-5085 5085 P17-5086 5086 P17-5090 5090 P17-5135 5135 P17-5136 5136 P17-5138 5138 P17-5141 5141 P17-5142 5142 P17-5420 5420 P17-5421 5421 P17-5428 5428 P17-5429 5429 P17-5474 5474 P17-5480 5480 P17-</p>

5481 5481 P17-5484 5484 P17-5490 5490 P17-5491 5491 P17-5494 5494 P17-5496 5496 P17-5504 5504 P17-5506 5506 P17-5548 5548 P17-5549 5549 P17-5551 5551 P17-5554 5554 P17-5924 5924 P17-5926 5926 P17-5927 5927 P17-5932 5932 P17-5933 5933 P17-5936 5936 P17-5943 5943 P17-5944 5944 P17-5946 5946 P17-5951 5951 P17-5952 5952 P17-5953 5953 P17-5959 5959 P17-5982 5982 P17-5987 5987 P17-5989 5989 P17-5993 5993 P17-5995 5995 P17-5996 5996 P17-6000 6000 P18-0005 5 P18-0006 6 P18-0010 10 P18-0013 13 P18-0014 14 P18-0016 16 P18-0022 22 P18-0025 25 P18-0027 27 P18-0031 31 P18-0032 32 P18-0036 36 P18-0042 42 P18-0043 43 P18-0044 44 P18-0078 78 P18-0080 80 P18-0081 81 P18-0087 87 P18-0180 180 P18-0182 182 P18-0184 184 P18-0185 185 P18-0186 186 P18-0191 191 P18-0192 192 P18-0194 194 P18-0195 195 P18-0200 200 P18-0201 201 P18-0202 202 P18-0205 205 P18-0206 206 P18-0208 208 P18-0210 210 P18-0212 212 P18-0214 214 P18-0215 215 P18-0217 217 4. These findings were confirmed by Cytotechnologist A on 1/23/18 at 3:30 PM.

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 fifty-eight laboratory procedures, laboratory records and interview it was determined that the laboratory failed to have two written policies and procedures. Findings include: 1. The survey team requested and the laboratory failed to provide a written policy or procedure to describe the laboratory's gynecologic cytology proficiency testing program. a. The procedure titled "CLIA APPROVED PROFICIENCY TESTING PROGRAMS" stated "College of American Pathologists (CAP), American Society for Clinical Pathology (ASCP)". There were no further details of the laboratory's proficiency testing program in gynecologic cytology. b. This finding was confirmed by Cytotechnologist A during an interview on 1/23/18 at 3:30 PM. 2. The survey team requested and the laboratory failed to provide a written policy or procedure to describe the laboratory's process for identifying and maintaining discontinued procedures. a. This finding was confirmed by Cytotechnologist A during an interview on 1/24/18 at 1:05 PM.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory procedure manual and interview it was determined that the laboratory failed to ensure that three of fifty-eight procedures were signed and dated by the Laboratory Director prior to implementation. Findings include: 1. The following three procedures were not signed and dated by the Laboratory Director: a. QUALITY ASSURANCE PATHOLOGY - CYTOLOGY; b. CLIA APPROVED PROFICIENCY TESTING PROGRAM; c. STATE HEALTH DEPARTMENT. 2. These findings were confirmed by the Laboratory Director and Cytotechnologist A during an interview on 1/23/18 at 3:30 PM.

D5409

PROCEDURE MANUAL

CFR(s): 493.1251(e)

The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures and interview it was determined that the laboratory failed to identify and document the date of discontinuance on two of fifty-eight procedures and failed to document the date of discontinuance on three of thirty-three discontinued procedures. Findings include: 1. The Survey Team identified two procedures in the laboratory procedure manual titled CYTOTECHNOLOGIST COMPETENCY ASSESSMENT POLICY. One of the procedures was last signed and dated by the Laboratory Director on 1/23/17 and the other on 1/19/15. a. The Survey team showed these two procedures to Cytotechnologist A on 1/22/18 at 4:00 PM. Cytotechnologist A confirmed that the procedure last signed and dated by the Laboratory Director on 1/23/17 was the current procedure and the other should have been discontinued. There was no date of discontinuance documented anywhere on the procedure. 2. During an interview on 1/23/18 at 3:30 PM, the Survey Team asked if the procedure titled QUALITY ASSURANCE PATHOLOGY - CYTOLOGY was current. Cytotechnologist A confirmed that the procedure was not current. There was no date of discontinuance documented anywhere on the procedure. 3. The Survey Team reviewed a black binder with a cover page titled "PCS LABORATORY OBSOLETE" that contained thirty-three discontinued cytology procedures. There was no date of discontinuance on the following three of the thirty-three procedures: - QUALITY CONTROL DESCRIPTION (last review date 6/2/16) - QUALITY CONTROL OF CYTOLOGY INTERPRETATION (last review date 9/6/12) - CYTOLOGY INTERPRETATION (last review date 1/19/15) 4. These findings were confirmed by Cytotechnologist A during an interview on 1/24/18 at 1:05 PM.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)

Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on the review of laboratory procedures, observation and interview it was determined that the laboratory failed to ensure that thirty of thirty staining dishes were labeled to identify their content. Findings include: 1. The procedure PAPANICOLAOU STAINING AND COVERSLIPPING PROCEDURES stated "All dishes and lids are to be clearly labeled". 2. The Survey Team observed the nongynecologic staining dishes on 1/23/18 at 2:15 PM and observed that none of the dishes used in the staining process were labeled to identify the stains and reagents in the dishes. 3. These findings were confirmed by Cytotechnologist A during an interview on 1/23/18 at 3:30 PM.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on the review of laboratory procedures, maintenance records and interview it was determined that the laboratory failed to ensure that the required weekly maintenance on the ThinPrep 2000 Processor was performed for seven of thirteen weeks during October, November and December 2017. Findings include: 1. The procedure titled "THINPREP 2000 PROCESSOR MAINTENANCE" stated that the Pneumatic System Test was to be performed weekly. It further stated "The above maintenance schedule will be followed and documented on the ThinPrep 2000 Maintenance Schedule for the Month." 2. The Survey Team reviewed the ThinPrep 2000 maintenance records from October, November and December 2017. The laboratory failed to document that the weekly pneumatic system test was performed for three of four weeks in October, three of five weeks in November and one of four weeks in December. The dates are as follows: October 2017: 2-6, 9-13, 23-27 November 2017: 1-3, 13-17, 20-22 December 2017: 4-8 3. This finding was confirmed by Cytotechnologist A during an interview on 1/24/18 at 1:05 PM.

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 the review of laboratory procedures, workload records and interview it was

determined that the laboratory failed to establish a written policy and procedure to prorate the number of slides allowed to be evaluated using the individual workload limits for two of two Cytotechnologists when examining slides in less than an 8-hour workday. Findings include: 1. The procedure titled CYTOLOGY WORKLOAD PROCEDURE stated "Primary Screeners examining Gyn and Non Gyn slides in less than an 8 hour day, the technical supervisor will use the formula of number of hours examining slides X 100/8 to determine maximum slide volume." 2. The SEMI ANNUAL PERFORMANCE REVIEW records signed by the Laboratory Director /Technical Supervisor on 7/10/17 and 1/18/18 showed that Cytotechnologist A's daily workload limit was set at 85 slides per day and Cytotechnologist B's was 80 slides per day. Based on these workload limits Cytotechnologist A's prorated workload was 10.6 slides per hour and Cytotechnologist B's 10 slides per hour. 3. The Survey Team reviewed the TOTAL SLIDES AND TIME records for Cytotechnologist A and B from December 2017. a. Cytotechnologist A exceeded the prorated workload limit on seven of seventeen days. 12/6/17 Time spent evaluating slides: 5 hours Number of slides evaluated: 60 Maximum number of slides allowed: 54 12/7/17 Time spent evaluating slides: 3.5 hours Number of slides evaluated: 42.5 Maximum number of slides allowed: 38 12/14/17 Time spent evaluating slides: 1.75 hours Number of slides evaluated: 21.5 Maximum number of slides allowed: 19 12/15/17 Time spent evaluating slides: 4 hours Number of slides evaluated: 49 Maximum number of slides allowed: 43 12/18/17 Time spent evaluating slides: 4.25 hours Number of slides evaluated: 51.5 Maximum number of slides allowed: 46 12/21/17 Time spent evaluating slides: 2.5 hours Number of slides evaluated: 30 Maximum number of slides allowed: 27 12/27/17 Time spent evaluating slides: 2 hours Number of slides evaluated: 24.5 Maximum number of slides allowed: 22 b. Cytotechnologist B exceeded the prorated workload limit on nine of nine days. 12/1/17 Time spent evaluating slides: 4 hours Number of slides evaluated: 47 Maximum number of slides allowed: 40 12/4/17 Time spent evaluating slides: 1.25 hours Number of slides evaluated: 15 Maximum number of slides allowed: 13 12/5/17 Time spent evaluating slides: 2 hours Number of slides evaluated: 25 Maximum number of slides allowed: 20 12/7/17 Time spent evaluating slides: 1.75 hours Number of slides evaluated: 20.5 Maximum number of slides allowed: 18 12/12/17 Time spent evaluating slides: 2.75 hours Number of slides evaluated: 31.5 Maximum number of slides allowed: 28 12/14/17 Time spent evaluating slides: 2.25 hours Number of slides evaluated: 27.5 Maximum number of slides allowed: 23 12/19/17 Time spent evaluating slides: 2.25 hours Number of slides evaluated: 27.5 Maximum number of slides allowed: 23 12/21/17 Time spent evaluating slides: 2 Number of slides evaluated: 22.5 Maximum number of slides allowed: 20 12/28/17 Time spent evaluating slides: 1.5 Number of slides evaluated: 18 Maximum number of slides allowed: 15 4. These findings were confirmed by the Laboratory Director and Cytotechnologist A during an interview on 1/23/18 at 3:30 PM.

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 the review of laboratory procedures, maintenance records and interview it was determined that the laboratory failed to maintain the identity of the personnel who performed the maintenance checks on the ThinPrep 2000 Processor for twenty-two of twenty-two days in October 2017, twenty of twenty days in November 2017 and twenty of twenty days in December 2017. Findings include: 1. The procedure titled THINPREP 2000 PROCESSOR MAINTENANCE stated "The above maintenance schedule will be followed and documented on the ThinPrep 2000 Maintenance Schedule for the Month". 2. The Survey Team reviewed the ThinPrep 2000 maintenance records for October, November, and December 2017. The laboratory failed to document the identity of the laboratory personnel who performed the maintenance for twenty-two of twenty-two days in October, twenty of twenty days in November and twenty of twenty days in December. The dates are as follows: October 2017: 2, 3, 4, 5, 6, 9, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24, 25, 26, 27, 30, 31. November 2017: 1, 2, 3, 6, 7, 8, 9, 10, 13, 14, 15, 16, 17, 20, 21, 22, 27, 28, 29, 30. December 2017: 1, 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 22, 26, 27, 28, 29. 3. This finding was confirmed by Cytotechnologist A during an interview on 1/24/18 at 1:05 PM.

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.

This STANDARD is not met as evidenced by:
 Based on the review of the laboratory procedures, review of laboratory records, review of cytology slides, observation and interviews it was determined that the Laboratory Director who is also the Technical Supervisor, failed to be responsible for the overall operation and administration of the laboratory including assuring compliance with applicable regulations by having cytology procedures and programs established and followed. Cross Refer to D5203, D5403, D5407, D5409, D5415, D5429, D5641, D5787

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.