| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 35D0408903 | 10/23/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pathology Consultants Pc Main Laboratory | 3502 Franklin Ave, Bismarck, ND | |

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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| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory records and interviews it was determined that the laboratory (Facility A-CLIA#35D0408903) failed to meet the specified requirements for testing of samples for the gynecologic cytology proficiency test (PT) program by engaging in inter-laboratory communications with Facility B (CLIA 35D2002387) prior to the date the PT results were reported to the program (refer to D2011); failed to examine cytology PT samples received from the PT program in the manner required by the PT provider; and failed to meet the specified requirements in accordance with 493.801(b)(4) to include PT referral and the failure to avoid sending PT slides and test results to another laboratory during PT events in 2017 and 2018 (refer to D2013). The cumulative effect of this systemic problem resulted in the laboratory's failure to meet certification requirements to accurately and reliably evaluate patients gynecologic cytology specimen slides for 2017 and 2018. |
| **D2011** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(3)<br><br>Laboratories that perform tests on proficiency testing samples must not engage in any |

inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interviews it was determined that Facility A failed to meet the specified requirements for testing of samples for the gynecologic cytology PT program by engaging in inter-laboratory communications with Facility B prior to the date the proficiency testing results were reported to the program in 2017 and 2018. Findings include: 1. The Survey Team received PT documents for Facility A from 2017, which were provided by Cytotechnologist A on 10/21/19. PT documents provided included: -College of American Pathologists (CAP) Proctor Examination 2017 -CAP PAP PT Proctor Evaluation 2017 -CAP PAP PT Slideset Verification and Attestation Forms 2017 -CAP PAP PT Individual Result Forms 2017 a. The Survey Team reviewed PT testing records from 2017 for six Technical Supervisors from Facility B that took the PT test event at Facility B. The PT testing records stated the CLIA number was for Facility A. i. Three of six Technical Supervisors tested on slideset #34426. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor C - Technical Supervisor E ii. Three of six Technical Supervisors tested on slideset #34423. Technical Supervisors include: - Technical Supervisor B - Technical Supervisor D - Technical Supervisor F 2. The Survey Team received PT documents for Facility A from 2018, which were provided by Cytotechnologist A on 10/21/19. PT documents provided included: -CAP PAP PT Proctor Evaluation 2018 -CAP PAP PT Slideset Verification and Attestation Forms 2018 -CAP PAP PT Individual Result Forms 2018 a. The Survey Team reviewed PT testing records from 2018 for five Technical Supervisors from Facility B that took the PT test event at Facility B. The PT testing records stated the CLIA number was for Facility A. i. Three of five Technical Supervisors tested on slideset #33989. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor C - Technical Supervisor D ii. Two of five Technical Supervisors tested on slideset #34006. Technical Supervisors include: - Technical Supervisor B - Technical Supervisor E 3. During an interview on 10/21/19 at 1:15 PM, Cytotechnologist A stated: "We have two cytotechs who do all screening at this location and send all non-gyn and abnormal gyn slides to the hospital (Facility B) for the pathologists to finalize. The pathologists don't screen or sign out cases here. All pathologist work is done at the hospital. We had been sending the PT slides to the hospital for pathologists to review after the cytotechs take the test and mark them here. We thought it was OK with CAP and something must have changed and we weren't notified. We always did it that way and it wasn't a problem. We just found out during our CAP inspection in July that we couldn't send the slides to the hospital, so we corrected it for our next test in November. There will be a separate test for the pathologists at the hospital and the techs will do a courtesy screen before they take it." a. During an interview on 10/21 /19 at 1:45 PM, the Laboratory Director/Technical Supervisor confirmed this process. 4. During an interview on 10/22/19 at 11:00 AM, Cytology Assistant A confirmed that Cytology Assistant A performed all proctoring duties for the PT events in 2017 and 2018. Cytology Assistant A further stated: "The techs take their test here before the pathologists. I make sure they take the tests alone at separate times in their offices. After they take it, I would go to the hospital and take the slides to proctor for the

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| | pathologists. The slides were marked ahead of time by the techs, then the pathologists take it at the hospital. Sometimes the techs would screen the slides at the hospital, too. Either here or the there, but the pathologists did the test at their offices at the hospital." 5. During an interview on 10/23/19 at 12:20 PM, the Laboratory Director /Technical Supervisor and Cytotechnologist A confirmed these findings. |
| **D2013** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(4)<br><br>The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory records and interviews it was determined that Facility A failed to avoid sending PT slides and test results to another laboratory (Facility B-CLIA#35D2002387). Facility A sent cytology PT slides and corresponding cytotechnologist slide results to Facility B for analysis by six of six Technical Supervisors from Facility B during PT events in 2017 and five of five Technical Supervisors from Facility B during PT events in 2018. Cross refer to D2011 |
| **D5032** | CYTOLOGY<br>CFR(s): 493.1221<br><br>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish policies and procedures for staining nongynecologic specimens that have a high potential for cross-contamination (refer to D5619); failed to establish policies and procedures for a review of at least 10 percent of negative gynecologic specimens (refer to D5621); failed to establish policies and procedures for the search and review of all prior negative gynecologic specimens received within the previous five years and failed to document the review of 12 of 42 prior negative specimens (refer to D5625); failed to establish policies and procedures to maintain and annually evaluate four of four required statistics (refer to D5629); failed to establish policies and procedures for |

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| | documenting the number of slides examined and hours spent examining slides (D5645); and failed to establish policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory (refer to D5655). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to assess the competency of two of two Cytotechnologists in 2017 and 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures to determine how competency is assessed for Cytotechnologists. 2. The Survey Team reviewed laboratory records titled CYTOTECHNOLOGIST COMPETENCY ASSESSMENT and COMPETENCY ASSESSMENT CHECKLIST for two of two Cytotechnologists who performed cytology testing in 2017 and 2018. a. During an interview on 10/23/19 at 9:30 AM, Cytotechnologist A confirmed that the laboratory did not have policies or procedures for assessing Cytotechnologist competency. 3. During an interview on 10/23/19 at 12: 20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed these findings. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure documentation for transport of cytology slides from Facility A to Facility B for 2017, 2018 and to the date of the survey in October 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the transport of cytology slides to Facility B was documented. 2. The Survey Team requested and the laboratory failed to provide transport records for slides between Facility A and Facility B for 2017, 2018 and to the date of the survey in October 2019. 3. During an interview on 10/23/19 at 9:30 |

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| | AM, Cytotechnologist A confirmed there was no documentation for transport of slides between facilities. 4. During an interview on 10/23/19 at 12:20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed these findings. |
| **D5619** | CYTOLOGY<br>CFR(s): 493.1274(b)(3)<br><br>(b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, observation and interviews it was determined that the laboratory failed to establish written policies and procedures to prevent cross-contamination during Papanicolaou staining of nongynecologic specimens that have a high potential for cross-contamination. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prevent cross-contamination of nongynecologic specimens that have a high potential for cross-contamination with other nongynecologic specimens during the Papanicolaou staining process. 2. The Survey Team observed Cytology Assistant B perform nongynecologic specimen staining on 10/22/19 at 8:30 AM. a. The Survey Team interviewed the Cytology Assistant B and asked if there was a protocol for staining nongynecologic specimen slides with a high potential for cross-contamination separately. Cytology Assistant B replied "not really, maybe with a history or cancer." 3. The Survey Team interviewed Cytotechnologist A on 10/22/19 at 4:15 PM and asked if there was a protocol for preventing cross-contamination for nongynecologic specimens. Cytotechnologist A stated the laboratory policy is to "prepare all specimens as Thin Prep slides to minimize the risk" and confirmed that the process is not stated in a policy or procedure. 4. During an interview on 10/23/19 at 12:20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed these findings. |
| **D5621** | CYTOLOGY<br>CFR(s): 493.1274(c)(1)<br><br>(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under 493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section). (c)(1)(i) The review must be performed by an individual who meets one of the following qualifications: (c)(1)(i)(A) A technical supervisor qualified under 493.1449(b) or (k). (c)(1)(i)(B) A cytology general supervisor qualified under 493.1469. (c)(1)(i)(C) A cytotechnologist qualified under 493.1483 who has the experience specified in 493.1469(b)(2). (c)(1)(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information. (c)(1)(iii) The review of those cases selected must be completed before reporting patient results. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures to detail how at least 10 percent of the gynecologic cases interpreted to be negative would be randomly selected for review. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures to detail how at least 10 percent of the gynecologic cases interpreted to be negative for epithelial cell abnormalities would be randomly selected for review. 2. During an interview on 10/22/19 at 9:45 AM, the Survey Team asked Cytotechnologist B how at least 10 percent of negative cases are selected for review. Cytotechnologist B explained that most cases are manually selected based on patient history of abnormal gynecologic testing and "if there aren't enough, we just pick a couple of slides from the tray to get to 10 percent" for review. a. During an interview on 10/22/19 at 4:15 PM, Cytotechnologist A confirmed this practice. When asked if the laboratory information system (LIS) is capable of randomly selecting 10 percent of cases for review, Cytotechnologist A replied "no." 3. During an interview on 10/23/19 at 12:20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed these findings. |
| **D5625** | CYTOLOGY<br>CFR(s): 493.1274(c)(3)<br><br>(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, interviews and laboratory records it was determined that the laboratory failed to establish written policies and procedures for the review of all negative gynecologic specimens received within the previous five years for each patient with a current high-grade squamous intraepithelial lesion (HSIL) or malignancy. The laboratory failed to document the search for prior negative specimens on 1 of 42 current HSIL specimens and failed to document the results of the search for prior negative specimens on 11 of 42 current HSIL specimens from January through June 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures for the review of negative specimens received within the previous five years for current HSIL specimens. 2. During an interview on 10/21/19 at 1:15 PM, Cytotechnologist A stated that cytotechnologists at the laboratory (Facility A) were responsible for the search and review of previous negative specimens for all HSIL specimens signed out at Facility B. a. Cytotechnologist A confirmed that the laboratory did not have policies or procedures to reflect this process. 3. The Survey Team reviewed laboratory records titled REVIEW OF PRIOR NEGATIVE SPECIMENS and GYN CYTOLOGY REQUEST FORM for 42 cytology specimens with a current HSIL from January through June 2019. a. The records failed to document the search for prior negative |

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| | specimens on one of 42 current HSIL specimens. Cases include: -GYN19-3472 b. The records failed to document the results of the search for prior negative specimens on 11 of 42 current HSIL specimens. Cases include: -GYN19-753 -GYN19-834 -GYN19-1247 -GYN19-2254 -GYN19-2309 -GYN19-2967 -GYN19-2993 -GYN19-5585 -GYN19-5817 -GYN19-6145 -GYN19-6399 c. During an interview on 10/22/19 at 4: 15 PM, Cytotechnologist A confirmed that the records did not indicate the results of the search for prior negative specimens. 4. During an interview on 10/23/19 at 12:20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed these findings. |
| **D5629** | CYTOLOGY<br>CFR(s): 493.1274(c)(5)<br><br>(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of four of four laboratory statistics, and failed to document four of four required annual statistics for 2017 and 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of four required laboratory statistics. 2. The Survey Team requested and the laboratory failed to provide records for four of four required annual statistics for 2017 and 2018: -The number of cytology cases examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) -The number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma, or other malignant neoplasm 3. During an interview on 10/23 /19 at 12:20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed these findings. |
| **D5645** | CYTOLOGY<br>CFR(s): 493.1274(d)(3)<br><br>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records of the total number of slides examined and the number of hours spent examining slides in each 24-hour period for two of two Cytotechnologists in 2017, 2018 and to the date of the survey in 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures to detail how the total number of slides examined and the number of hours spent examining slides are recorded each day. 2. The Survey Team reviewed laboratory records titled WEEKLY CYTO STATS for two of two Cytotechnologists who performed cytology testing in 2017, 2018 and to the date of the survey in 2019. a. During an interview on 10/23/19 at 9:30 AM, Cytotechnologist A confirmed that the laboratory did not have policies or procedures for this process. 3. During an interview on 10/23/19 at 12:20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed these findings. |
| **D5655** | CYTOLOGY<br>CFR(s): 493.1274(e)(4)<br><br>(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory gynecologic slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide policies and procedures to ensure that unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. During an interview on 10/22/19 at 9:45 AM, Cytotechnologist B stated the laboratory "has no exact way of determining" unsatisfactory slide preparations and the Cytotechnologists "just estimate if there is enough." 3. During an interview on 10/23 /19 at 9:30 AM, Cytotechnologist A stated the Cytotechnologists "just use judgement" to determine if a slide preparation is unsatisfactory. 4. During an interview on 10/23 /19 at 12:20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed that the laboratory did not have policies or procedures specifying the criteria for an unsatisfactory gynecologic slide. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of final test reports and interview it was determined that the laboratory failed to ensure that 35 of 35 final test reports from May 2019 indicated the address of the laboratory location where the test was performed. Findings include: 1. The Survey Team reviewed 35 final test reports reported in May 2019. Thirty-five of 35 final test reports did not indicate the address of the laboratory where the test was performed. Reports include: -GYN19-4867 -GYN19-4879 -GYN19-4880 -GYN19-4886 -GYN19-4887 -GYN19-4888 -GYN19-4891 -GYN19-4892 -GYN19-4893 -GYN19-4894 -GYN19-4895 -GYN19-4896 -GYN19-4915 -GYN19-4916 -GYN19-4918 -GYN19-4919 -GYN19-4920 -GYN19-4921 -GYN19-4922 -GYN19-4924 -GYN19-4925 -GYN19-4926 -GYN19-4927 -GYN19-4928 -GYN19-4930 -GYN19-4931 -GYN19-4932 -GYN19-4933 -GYN19-4935 -GYN19-4936 -GYN19-4937 -GYN19-4938 -GYN19-4939 -GYN19-4940 -GYN19-4941 2. During an interview on 10/23/19 at 12:20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed these findings. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance and oversight with applicable regulations (refer to D6079); failed to ensure that testing of samples for the gynecologic cytology PT program was not referred to another laboratory for testing (refer to D6089); and failed to ensure procedures were established to assess the competency of the Cytotechnologists and Cytology Assistants (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart. |
| **D6079** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(a)(b)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory 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 D5311, D5621, D5625, D5629, D5655 and D5805 |
| **D6089** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(i)<br><br>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of PT records and interviews it was determined that the Laboratory Director failed to ensure that testing of samples for the gynecologic cytology PT program in 2017 and 2018 was in accordance with 493.801(b)(4), which prohibits the sending of PT samples (slides) to another laboratory. Cross refer to D2013 |
| **D6103** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(13)<br><br>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess the competency of two of two Cytotechnologists and two of two Cytology Assistants in 2017 and 2018. Cross refer to D5209 A. 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 to assess the competency of two of two Cytology Assistants and one of one Cytotechnologist performing cytology processing in 2017 and 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures to determine how cytopreparatory competency is assessed for Cytology staff. 2. The Survey Team reviewed laboratory records titled CYTOLOGY PREPARATION ASSISTANT TASK COMPETENCY ASSESSMENT for two of two Cytology Assistants and one of one Cytotechnologist who performed cytology preparatory processing in 2017 and 2018. a. During an interview on 10/23/19 at 9:30 AM, Cytotechnologist A confirmed that the laboratory did not have policies or procedures for assessing cytopreparatory competency. 3. During an interview on 10/23/19 at 12:20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed these findings. B. Based on review of laboratory policies and procedures, laboratory records and interviews it was |

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| | determined that the laboratory failed to establish written policies and procedures to assess the competency of two of two Cytology Assistants who performed data entry in 2017 and 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures to determine how data entry competency is assessed for Cytology staff. 2. The Survey Team reviewed laboratory records titled CYTOLOGY DAILY DEMOGRAPHIC INPUT COMPETENCY ASSESSMENT, CYTOLOGY NONGYN DEMOGRAPHIC INPUT COMPETENCY ASSESSMENT for two of two Cytology Assistants who performed data entry in 2017 and 2018. a. During an interview on 10/23/19 at 9:30 AM, Cytotechnologist A confirmed that the laboratory did not have policies or procedures for assessing data entry competency. 3. During an interview on 10/23/19 at 12:20 PM, the Laboratory Director/Technical Supervisor and Cytotechnologist A confirmed these findings. |
| **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. |