Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D1076651	12/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Iowa Clinic Pathology Laboratory, The	5950 University Avenue, West Des Moines, IA	

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
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, observation and interviews it was determined the laboratory failed to follow written policies and procedures to ensure positive patient identification on gynecologic specimen vials (refer to D5203); failed to establish written policies and procedures to assess the competency of the Technical Supervisors, Cytotechnologists, and Pathology Technician (refer to D5209); failed to establish written policies and procedures for three laboratory test processes (refer to D5403); failed to follow manufacturer's instructions (refer to D5411); failed to test staining materials for intended reactivity (refer to D5473); failed to follow written policies and procedures to determine the cause of discrepancy between cytology cases and the histopathology diagnosis (refer to D5623); failed to follow written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five years was documented (refer to D5625 and D5627); failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory (refer to D5657); failed to establish written policies and procedures to ensure corrected test reports indicated the basis for the correction (refer to D5659); and failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the analytic phases of cytology testing (refer to D5791).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232

	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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, observation and interview it was determined that the laboratory failed to follow written policies and procedures to ensure positive patient identification at the time of receipt into the laboratory. The laboratory failed to ensure that the patient identification on specimen vials matched the patient identification on the corresponding requisitions for three of three gynecologic specimens from December 7, 2021. Findings include: 1. The procedure titled PROCESSING PROCEDURE FOR THINPREP PAP TEST stated: "1. Unload - remove containers and requisitions from individual bio-hazard bags and check to be sure patient IDs match." 2. The Survey Team observed the Pathology Technician unpack and accession three gynecologic specimens on December 7, 2021 at 8:30 AM. The Pathology Technician failed to ensure that the patient identification on the specimen vials matched the patient identification on the corresponding requisitions for three of three specimens. Specimens include: -G21-13161 -G21-13165 -G21-13191 3. During an interview on December 7, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A.
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 Technical Supervisors and Cytotechnologists. The laboratory failed to provide records of competency assessment for two of two Technical Supervisors and one of three Cytotechnologists in 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 Technical Supervisors and Cytotechnologists. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for two of two Technical Supervisors in 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director /Technical Supervisor A -Technical Supervisor B 3. The Survey Team requested and the laboratory failed to provide records of competency assessment for one of one Cytotechnologist in 2020 and to the date of the survey in 2021. Cytotechnologist includes: -Cytotechnologist C 4. During an interview on December 8, 2021 at 1:45 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Technical Supervisor B.
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 45 laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for three laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for cytology proficiency testing enrollment and participation of personnel that perform gynecologic cytology testing. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for the removal of collection devices from Hologic ThinPrep vials. a. The Survey Team observed the Pathology Technician remove collection devices from one Hologic ThinPrep vial during processing for one of one case on December 7, 2021 at 8:30 AM. Case includes: -G21-13191 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for testing staining materials for intended reactivity of the Papanicolaou stain used for gynecologic slide preparations for each day of use. 4. During an interview on December 7, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Cytotechnologist A.
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, lack of laboratory records and interview it was determined that the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the HOLOGIC THINPREP Pap Test in 2020 and to the date of the survey in 2021. Cross refer to D6102 Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM

	OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 2000 SYSTEM 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 the required morphology certification for two of two Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2020 and to the date of the survey in 2021. 3. The Survey Team requested and the laboratory failed to provide the required morphology certification for two of three Cytotechnologists who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2020 and to the date of the survey in 2021. 4. During an interview on December 7, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B and Cytotechnologist A.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of laboratory records and interview it was determined that the laboratory failed to test staining materials for intended reactivity of the Papanicolaou stain used for gynecologic slide preparations for each day of use in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the Papanicolaou stain used for gynecologic slide preparations were assessed each day of use in 2019, 2020 and to the date of the survey in 2021. 2. During an interview on December 6, 2021 at 3:00 PM these findings were confirmed by Cytotechnologist A.
D5623	CYTOLOGY CFR(s): 493.1274(c)(2) (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) (2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies. 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 follow written policies and procedures to determine the cause of discrepancy between gynecologic cytology cases with a diagnosis of high grade squamous intraepithelial lesion [HSIL] or malignancy and the histopathology diagnosis in four of four cases from January 2021 to

	September 2021. Findings include: 1. The procedure titled PROTOCOL FOR CORRELATIONS stated: "Review and correlation of specimens with patients' current tissue samples is done to complete assessment of patients' conditions and to insure proper care." 2. The Survey Team reviewed records titled ABNORMAL PAP REPORT. The laboratory failed to document the cause of discrepancy between the cytology cases with a diagnosis of HSIL with the histopathology diagnosis of Negative for four of four cases from January 2021 to September 2021. Cases include: -G21-00608 -G21-05911 -G21-08123 -G21-09241 3. During an interview on December 7, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Technical Supervisor B who both stated that previous gynecologic cytology slides with a diagnosis of high grade squamous intraepithelial lesion are not reviewed to determine the cause of discrepancy when the current histopathology diagnosis is negative.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (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. This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures to ensure that the search for prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of high grade squamous intraepithelial lesion [HSIL] or malignancy was documented. The laboratory failed to document the search for prior negative gynecologic cases for twenty of forty HSIL or malignant cases from January 2021 to November 2021. Findings include: 1. The procedure titled DOCUMENTATION OF PREVIOUS CASE REVIEW ON CURRENT HSIL+ stated: "Record the following on the Excel spreadsheet titled "PCR on HSIL Documentation": Date, Current case # and CT initials, Current Case Diagnosis. If no previous negative cases are available (mark cell with an X)" 2. The Survey Team reviewed records titled 2021 PCR ON HSIL. The laboratory failed to document the search for prior negative gynecologic cases for twenty of forty HSIL or malignant cases from January 2021 to November 2021. Cases include: -G21-00608 -G21-01473 -G21-01766 -G21-01951 -G21-02455 -G21-02505 -G21-02741 -G21-03012 -G21-03054 -G21-03253 -G21-05911 -G21-08123 -G21-09049 -G21-09423 -G21-09700 -G21-10218 -G21-10530 -G21-11180 -G21-11846 -G21-12025 3. During an interview on December 6, 2021 at 12:10 PM Cytotechnologist A stated that when there are only prior abnormal cases for a current HSIL or malignant case, the search is not documented. 4. During an interview on December 7, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Cytotechnologist A and Cytotechnologist B. B. Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that the review of prior negative gynecologic cases received

	within the previous five years for each patient with a current diagnosis of high grade squamous intraepithelial lesion [HSIL] or malignancy was documented in the final test reports. The laboratory failed to include the phrase "previous case(s) reviewed" in eight of nine test reports for which previous cases were reviewed from January 2021 to November 2021. Findings include: 1. The procedure titled DOCUMENTATION OF PREVIOUS CASE REVIEW ON CURRENT HSIL+ stated: "In the current case report include the phrase "previous case(s) reviewed" in the Other Findings section." 2. The Survey Team reviewed final test reports for nine cases with a diagnosis of HSIL or malignant from 2021 for which previous cases were reviewed. The laboratory failed to include the phrase "previous case(s) reviewed" in the test reports for eight of nine cases from January 2021 to November 2021. Cases include: -G21-00637 -G21-03143 -G21-05962 -G21-06576 -G21-09241 -G21-09356 -G21-12663 -G21-12794 3. During an interview on December 7, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Cytotechnologist A and Cytotechnologist B.
D5627	CYTOLOGY CFR(s): 493.1274(c)(4) Records of initial examinations and all rescreening results must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that the laboratory failed to document the rescreen results for six of twenty-two previous negative cases on current cases with a diagnosis of high grade squamous intraepithelial lesion [HSIL] or malignancy from January 2020 to the date of the survey in 2021. Findings include: 1. The Survey Team reviewed records titled 2020 PCR ON HSIL and 2021 PCR ON HSIL. The laboratory failed to document the rescreen results for six of twenty-two previous negative cases on current cases with a diagnosis of HSIL or malignancy from January 2020 to the date of the survey in 2021. Cases include: -G17-02331 -G17-02602 -G17-08044 -G17-09240 -G17-10110 -G18-13157 2. During an interview on December 7, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Cytotechnologist A and Cytotechnologist B.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on the 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 gynecologic and 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 gynecologic cytology test results. 2. 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. 3. During an interview on December 7, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Cytotechnologist A and Cytotechnologist B.
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 to ensure corrected test reports indicated the basis for the correction on the test report. One of two corrected test reports from July 2021 to August 2021 failed to state the basis for the correction. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report. 2. The Survey Team reviewed two corrected test reports from July 2021 to August 2021. One of two test reports failed to state the basis for correction. Test report includes: -N21-1104 3. During an interview on December 8, 2021 at 11:00 AM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Technical Supervisor B.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of 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 in the analytic phases of cytology testing. Cross refer to D5403, D5473, D5623, D5625, D5627 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with the quality assessment of the Papanicolaou stain used for gynecologic slide preparations. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with the correlation of gynecologic cases with a diagnosis of high grade squamous intraepithelial lesion or malignancy with histopathology results. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with the search and review of prior negative gynecologic cases from cases with a current diagnosis of high grade squamous intraepithelial lesion or malignancy. 4. During an interview on

	December 8, 2021 at 1:45 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Technical Supervisor B.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) 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. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, lack of laboratory records and interview it was determined that the Laboratory Director/Technical Supervisor A failed to ensure that two of two Technical Supervisors and two of three Cytotechnologists who performed Hologic ThinPrep Pap Test evaluations had received the appropriate morphology training prior to reporting patient specimens in 2020 and to the 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 two of two Technical Supervisors who performed Hologic ThinPrep Pap Test evaluations in 2020 and to the date of the survey in 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. The Survey Team requested and the laboratory failed to provide training records for two of three Cytotechnologists who performed Hologic ThinPrep Pap Test evaluations in 2020 and to the date of the survey in 2021. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist C 4. The Survey Team reviewed laboratory annual statistics for 2020 and 2021. The records stated the following numbers of Hologic ThinPrep Pap Tests were evaluated and reported by the laboratory prior to receiving the required morphology training: -2020 total of Hologic ThinPrep Pap Tests: 9,849 tests -January through November 2021 total of Hologic ThinPrep Pap Tests: 10,846 tests 5. During an interview on December 7, 2021 at 3:00 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A, Technical Supervisor B and Cytotechnologist A.
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 and

	interview it was determined that the Laboratory Director/Technical Supervisor A failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of Technical Supervisors, Cytotechnologists and Pathology Technicians performing cytology test procedures. Cross refer to D5209 Findings include: 1. The Survey Team requested and the laboratory failed to provide records to assess the competency of one of one Pathology Technician in 2020 and to the date of the survey in 2021. Pathology Technician includes: -Pathology Technician 2. During an interview on December 8, 2021 at 1:45 PM these findings were confirmed by the Laboratory Director/Technical Supervisor A and Technical Supervisor B.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory personnel records and confirmed by laboratory personnel identifier #2 at approximately 1:45 pm on 12/08/21, the laboratory failed to meet the testing personnel requirements by ensuring testing personnel performing high complexity testing meet the educational qualification requirements as specified in standard D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2) (ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b) (4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved

	by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and the Laboratory Test List & Annual Volume form and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:45 pm on 12/8/2021, the laboratory failed to ensure that one out of eight testing personnel (identifier #3) met the educational requirements for performing high complexity testing. The findings include: 1. The Laboratory Test List & Annual Volume form stated the laboratory used the Ventana test system to perform immunohistochemical stains. 2. The Ventana test system is categorized as a high complexity test system. 3. At the time of the survey, test personnel #3 did not meet the high complexity testing personnel qualifications.
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.