Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0648073	09/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mercyone Dubuque Laboratory	250 Mercy Drive, Dubuque, 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 and interviews the laboratory failed to ensure one of two Technical Supervisors received the required morphology certification to perform diagnostic interpretations of Becton Dickinson (BD) SurePath Pap Tests (refer to D5411); failed to establish and follow written policies and procedures for the establishment and reassessment of individual workload limits (refer to D5633 and D5637); failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides per 24-hour period (refer to D5645); failed to establish and follow written policies and procedures to document workload limits (refer to D5647); and failed to ensure test reports indicated the name of the laboratory where the test was performed (refer to D5805).
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 the laboratory failed to follow written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of two of two Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The laboratory failed to follow the procedure COMPETENCY ASSESSMENT, which stated: "Competency Assessment is performed on an annual basis." 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for two of two Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on September 13, 2022 at 8:20 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interviews the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. The laboratory failed to document general laboratory quality assessment activities in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5209 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the general laboratory systems. 2. The Survey Team requested and the laboratory failed to provide documentation of general laboratory quality assessment activities in 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to document a system for monitoring and evaluating the competency of the Technical Supervisors. (Refer to D5209) 3. During an interview on September 13, 2022 at 11:05 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Pathology Support Services Supervisor.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic cytology systems. The laboratory failed to document preanalytic quality assessment activities in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written

	policies and procedures for an ongoing program to monitor, assess and correct problems identified in the preanalytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of preanalytic quality assessment activities in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on September 13, 2022 at 11:05 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Pathology Support Services Supervisor.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of 28 laboratory policies and procedures, laboratory records and interviews the laboratory failed to follow two written policies and procedures. Cross refer to D5805 Findings include: 1. The laboratory failed to follow the procedure CYTOLOGY REPORT FORMAT POLICY, which stated: "Copath cytopathology report format:" "Name and address of laboratory location where the test was performed (required element)." a. The Survey Team reviewed consecutive final test reports from June 2022 (range reviewed: GY22-3510 through GY22-3569). Seven of 60 final test reports failed to indicate the name of the laboratory where the test was performed. (Refer to D5805) 2. The laboratory failed to follow the procedure QUALITY, CYTOLOGY CAP PREPAREDNESS, which stated: "Semiannually, all hospital based fine-needle aspiration specimens will be reviewed for cytology /histology correlation, the results of which will be included in the annual anatomic pathology QC summary." a. The Survey Team requested and the laboratory failed to provide cytology/histology correlation records of fine-needle aspiration specimens for 2020, 2021 and to the date of the survey in 2022. b. During an interview on September 13, 2022 at 3:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in

	the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures for two laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's current process for documenting the nongynecologic stain quality assessment. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for entering test results into the laboratory information system. 3. During an interview on September 13, 2022 at 8:20 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor 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, laboratory records and interviews the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the BD SurePath Pap Test in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states: "Training on the preparation and evaluation of BD SurePath test slides is a product labeling requirement." 2. The Survey Team requested and the laboratory failed to provide the required morphology certification for one of two Technical Supervisors who performed diagnostic interpretations of BD SurePath Pap Tests in 2020, 2021 and to the date of the survey in 2022. Technical Supervisor includes: - Technical Supervisor B 3. During interviews on September 13, 2022 at 8:20 AM and September 14, 2022 at 3:10 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor 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 specimen slides the laboratory failed to follow written policies and procedures for a program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. The laboratory failed to identify one of nineteen cases from January 2021 through April 2022 as having a more significant lesion. Findings include: 1. The laboratory failed to follow the procedure CYTOLOGY/HISTOLOGY CORRELATIONS AND FOLLOW UP LETTERS, which stated: "Pathologist designates the reason for the discrepancy including any comments." 2. The Survey Team reviewed records titled CYTO-HISTO CORRELATIONS and the corresponding slides from January 2021 through April 2022. a. The Survey Team reviewed 19 discrepant cases and identified one of the 19 cases as having a more significant lesion than reported by the laboratory. The cause for the discrepancy was determined by the Survey Team as being a "diagnostic interpretation error." Case includes: -GY21-3238 b. On September 14, 2022, the Laboratory Director/Technical Supervisor A reviewed the case and 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: A. Based on review of laboratory policies and procedures, lack of laboratory records and interview the laboratory failed to follow written policies and procedures to ensure maximum workload limits were established for two of two Technical Supervisors who performed primary screening of nongynecologic cytology specimens. Findings include: 1. The laboratory failed to follow the written procedure WORKLOAD RECORDING POLICY, which stated: "The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target." 2. The Survey Team requested and the laboratory failed to provide an established maximum workload limit for two of two Technical Supervisors who performed primary slide screening in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on September 13, 2022 at 8:20 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to follow written policies and procedures to ensure maximum workload limits were established for one of two Cytotechnologists in 2022. Findings include: 1. The laboratory failed to follow the written procedure WORKLOAD RECORDING POLICY, which stated: "The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target." 2. The Survey Team requested and the laboratory failed to provide an established maximum workload limit for one of two Cytotechnologists in 2022. Cytotechnologist includes: - Cytotechnologist A 3. During an interview on September 13, 2022 at 8:20 AM, the Laboratory Director confirmed there was no documentation of a workload limit for Cytotechnologist A in 2022. 4. During an interview on September 13, 2022 at 12:10 PM, Cytotechnologist A

	stated that Cytotechnologist A began working at the laboratory in May 2022. The Survey Team asked Cytotechnologist A what Cytotechnologist A's workload limit was. Cytotechnologist A replied "I'm not sure. I think 60 or 80." 5. During an interview on September 14, 2022 at 8:20 AM, the Laboratory Director/Technical Supervisor A provided the Survey Team with records titled SEMIANNUAL CYTOTECHNOLOGIST PERFORMANCE REVIEW documenting the workload limit for Cytotechnologist A that was dated after the survey began.
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: A. Based on review of laboratory policies and procedures and interview the laboratory failed to establish written policies and procedures to reassess and adjust, when necessary, a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the Technical Supervisors' workload limits would be reassessed at least every six months and adjusted when necessary. 2. During an interview on September 13, 2022 at 8:20 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to follow written policies and procedures to reassess and adjust, when necessary, a maximum workload limit at least every six months for one of two Cytotechnologists. Findings include: 1. The laboratory failed to follow the procedure CT WORKLOAD LIMIT ASSESSMENT POLICY, which stated: "Each individual's workload limit is re-assessed at least every 6 months. 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor reassessed the workload limit at least every six months for one of two Cytotechnologists in 2022. Cytotechnologist includes: -Cytotechnologist B 3. During an interview on September 13, 2022 at 8:20 AM, the Laboratory Director confirmed there was no documentation of a workload limit reassessment for Cytotechnologist B in 2022.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures and interview the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records of the total number of slides the Technical Supervisors examined

	per 24-hour period and the number of hours spent examining slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides the Technical Supervisors examined per 24-hour period and the number of hours spent examining slides per 24-hour period. 2. During an interview on September 13, 2022 at 8:20 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. The Laboratory Director/Technical Supervisor A stated that the procedure WORKLOAD RECORDING POLICY failed to describe the Technical Supervisor's current process for documenting the total number slides examined per 24-hour period and the number of hours spent examining slides. B. Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to follow written policies and procedures to ensure that the laboratory maintained records of the number of hours one of two Cytotechnologists spent examining slides per 24-hour period from June through August 2022. Findings include: 1. The laboratory failed to follow the written procedure WORKLOAD RECORDING POLICY, which stated: "Each individual evaluating gynecologic preparations by manual method is responsible for accurately recording for each 24-hour period:" "Total number of hours spent examining slides in each 24-hour period: CT will complete the DAILY workload recording on the log sheet at the end of each shift." 2. The Survey Team reviewed records titled CT-DAILY WORKLOAD RECORDING LOG with handwritten entries from June through August 2022 for Cytotechnologist A. The records failed to document the number of hours spent examining slides for 34 of 34 dates that slides were examined. Dates include: June 2022: 13, 14, 20, 21, 22, 23, 27, 28, 29, 30 July 2022: 5, 6, 8, 11, 12, 13, 14, 18, 19, 20 August 2022: 1, 2, 3, 4, 8, 10, 12, 15, 16, 17, 18, 22, 23, 24 3. During an interview on September 13, 2022 at 12:10 PM, Cytotechnologist A described Cytotechnologist A's workload recording process from June through August 2022: -Cytotechnologist A did not complete the workload record on a daily basis. -Cytotechnologist A confirmed that Cytotechnologist A failed to document the number of hour spent examining slides when completing the handwritten entries. -At a later date Cytotechnologist A would transfer the handwritten entries into a record on the computer. At this time Cytotechnologist A would estimate the amount of time spent examining slides. -In September Cytotechnologist A began entering the number of slides examined and time spent examining slides directly into the record on the computer on a daily basis. 4. During an interview on September 13, 2022 at 2:05 PM, these findings were confirmed with the Pathology Support Services Supervisor. 5. During an interview on September 13, 2022 at 3:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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: A. Based on review of laboratory policies and procedures, lack of laboratory records and interview the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for two of two Technical Supervisors who performed primary screening of nongynecologic cytology specimens in 2020, 2021 and through the date of the survey in 2022. Findings include:

	1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisors who performed primary screening of nongynecologic cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of an established maximum workload limit for two of two Technical Supervisors in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on September 13, 2022 at 8:20 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for one of two Cytotechnologists. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the initial workload limit for Cytotechnologists upon hire. 2. The Survey Team requested and the laboratory failed to provide a record of an established maximum workload limit for one of two Cytotechnologists. Cytotechnologist includes: - Cytotechnologist A 3. During an interview on September 13, 2022 at 8:20 AM, the Laboratory Director confirmed there was no records of a workload limit for Cytotechnologist A in 2022.
D5805	TEST REPORT CFR(s): 493.1291(c) 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. This STANDARD is not met as evidenced by: Based on review of final test reports and interview seven of 60 final test reports from June 2022 failed to indicate the name of the laboratory where the test was performed. Findings include: 1. The Survey Team reviewed consecutive final test reports from June 2022 (range reviewed: GY22-3510 through GY22-3569). Seven of 60 final test reports failed to indicate the name of the laboratory where the test was performed. Test reports include: -GY22-3510 -GY22-3515 -GY22-3522 -GY22-3523 -GY22-3542 -GY22-3552 -GY22-3566 a. The seven final test reports required technical supervisory review. The final test reports failed to indicate the name of the laboratory where the final Technical Supervisor review occurred. 2. During an interview on September 13, 2022 at 8:20 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. The Laboratory Director/Technical Supervisor A stated that the name of the laboratory where the test was performed was linked to the Technical Supervisor's electronic signature and needed to be modified.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic cytology systems. The laboratory failed to document postanalytic quality assessment activities in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5805 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the postanalytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of postanalytic quality assessment activities in 2020, 2021 and to the date of the survey in 2022. a. The laboratory failed to document a system for monitoring and evaluating final test reports to ensure the reports contained the required information. (Refer to D5805) 3. During an interview on September 13, 2022 at 11:05 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Pathology Support Services Supervisor.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, specimen slides and interviews the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services and identify failures in quality as they occur (refer to D6094); failed to ensure that one of two Technical Supervisors had received the appropriate morphology training prior to reporting gynecologic patient specimens (refer to D6102); and failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of personnel performing cytology duties (refer to D6103).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services. The Laboratory Director failed

	to identify failures in quality as they occured in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5291, D5391 and D5891 Findings include: 1. The Laboratory Director failed to ensure the establishment of written policies and procedures for a quality assessment program. 2. The Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality as they occurred in 2020, 2021 and to the date of the survey in 2022.
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, laboratory records and interviews the Laboratory Director failed to ensure that one of two Technical Supervisors who performed BD SurePath Pap Test evaluations had received the appropriate morphology training prior to reporting patient specimens in 2020, 2021 and to the date of the survey in 2022. Cross refer to D5411 Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation of appropriate training to accurately report cytology test results prior to performing BD SurePath Pap Test evaluations.
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, lack of laboratory records and interviews it was determined that the Laboratory Director failed to ensure written policies and procedures were followed to assess, monitor and maintain the competency of the Technical Supervisors and personnel performing cytology duties. Cross refer to D5209 Findings include: 1. The Laboratory Director failed to ensure competency was assessed for two of two Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. (Refer to D5209) 2. The Laboratory Director failed to ensure the competency of two of two personnel performing cytology duties in 2020, 2021 and to the date of the survey in 2022. Personnel include: -Staff A -Staff B a. During an interview on September 15, 2022 at 8:30 AM, these findings were confirmed with the Pathology Support Services Supervisor. b. During an interview on September 15, 2022 at 11:00 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) 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. This STANDARD is not met as evidenced by: Based on microscopic review of 784 random negative gynecologic cases/slides and the corresponding final test reports from May through July 2022 and confirmation by the Laboratory Director/Technical Supervisor A on September 14 and September 15, 2022 the Technical Supervisor failed to verify the accuracy of three gynecologic cytology tests. Findings include: 1. GY22-3812 06/30/2022 SurePath Pap Test (SPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Atypical Glandular Cells LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: Atypical Glandular Cells 2. GY22-3940 07/06/2022 SPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Atypical Glandular Cells LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: Atypical Glandular Cells, Favor Reactive Endocervicals 3. GY22-3576 06/13/2022 SPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion LABORATORY DIRECTOR/TECHNICAL SUPERVISOR A DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: A. Based on the lack of laboratory records and interview the Technical Supervisor failed to establish individual workload limits and failed to reassess workload limits at least every six months for two of two Technical Supervisors performing primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the Technical Supervisor failed to provide documentation that the Technical Supervisor established a maximum workload limit for two of two Technical Supervisors who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B 2. The Survey Team requested and the Technical Supervisor failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for two of two Technical Supervisors who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on September 13, 2022 at 8:20 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on review of laboratory records and interviews the Technical Supervisor failed to establish individual workload limits and

	failed to reassess workload limits at least every six months for two of two Cytotechnologists in 2022. Findings include: 1. The Survey Team requested and the Technical Supervisor failed to provide documentation that the Technical Supervisor established a maximum workload limit for one of two Cytotechnologists in 2022. Cytotechnologist includes: - Cytotechnologist A a. During an interview on September 13, 2022 at 8:20 AM, the Laboratory Director confirmed there was no documentation of a workload limit for Cytotechnologist A in 2022. 2. The Survey Team requested and the Technical Supervisor failed to provide documentation that the Technical Supervisor reassessed the workload limit at least every six months for one of two Cytotechnologists in 2022. Cytotechnologists include: -Cytotechnologist B a. During an interview on September 13, 2022 at 8:20 AM, the Laboratory Director confirmed there was no documentation of a workload limit reassessment for Cytotechnologist B in 2022.
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.