Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2133352	01/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Instride Foot And Ankle Specialists,	14 Doctors Cir Sw #2, Supply, NC	

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 interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisor (refer to D5209): failed to follow written policies and procedures for the evaluation and comparison of annual statistics (refer to D5629); failed to follow written policies and procedures for the establishment of individual workload limits, failed to reassess workload limits at least every six months and failed to document a workload limit (refer to D5633, D5637 and D5647); and failed to maintain records of the total number of slides examined and the total number of hours spent examining slides (refer to D5645).
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 one of one Technical Supervisor. The

	laboratory failed to assess the competency of one of one Technical Supervisor 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 to assess the competency of the Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for one of one Technical Supervisor in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on January 10, 2022 at 2:45 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor and Laboratory Consultant.
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 17 laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the microscopic examination and reporting of nongynecologic cytology specimens, including the detection of inadequately prepared specimen slides. 2. During an interview on January 10, 2022 at 2:45 PM, these findings were confirmed by the Laboratory Director /Technical Supervisor and Laboratory Consultant.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were

	available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of one of three nongynecologic cytology statistics and failed to provide an annual statistical evaluation of two of three nongynecologic cytology statistics: Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of one of three nongynecologic cytology statistics: -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). 2. The Survey Team requested and the laboratory failed to provide an annual evaluation and comparison of two of three nongynecologic cytology statistics: -The number of specimens processed by specimen type; - The number of patient cases reported by diagnosis (including the number of reported as unsatisfactory for diagnostic interpretation). 3. During an interview on January 10, 2022 at 2:45 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor and Laboratory Consultant.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure maximum workload limits were established for one of one Technical Supervisor. Cross refer to D6130 Findings include: 1. The laboratory failed to follow the written procedure SLIDE SCREENING WORKLOAD LIMIT POLICY which stated: "A workload limit is established using the federally allowed number of cytology slides to be examined by the Pathologist (histology supervisor) within an 8 hour workday." 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor established a maximum workload limit for one of one Technical Supervisors who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on January 10, 2022 at 2:45 PM, the Laboratory Director/Technical Supervisor confirmed that a workload limit was not established.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure maximum workload limits were reassessed at least every six months for one of one Technical Supervisor. Cross refer to D6130 Findings include: 1. The laboratory failed to follow the written procedure SLIDE SCREENING WORKLOAD LIMIT POLICY which stated: "The laboratory Director will assess the workload limits for the pathologist at least every six months. Workload limits are re-established through a documented assessment of case reviews based on performance against the laboratory's overall statistics." 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for one of one Technical Supervisor who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on January 10, 2022 at 2:45 PM, the Laboratory Director /Technical Supervisor confirmed that workload limits were not reassessed based on performance.
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: 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 the laboratory would maintain records of the total number of slides examined by one of one Technical Supervisor and the total number of hours spent examining slides during each 24-hour period. Cross refer to D6133 Findings include: 1. The laboratory failed to follow the written procedure SLIDE SCREENING WORKLOAD LIMIT POLICY which stated: "Daily workload recording must be recorded in a the DAILY SLIDE SCREENING LOG (APPENDIX A), which will include the following information: a. Case identification. b. Type of slide. c. Record quality of stains. d. Record start time of examination of slides. e. Record end time of examination of slides." 2. The Survey Team requested and the laboratory failed to provide records of the total number of slides examined and the total number of hours one of one Technical Supervisor spent examining cytology specimen slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. 3. During an interview on January 10, 2022 at 2:45 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor and Laboratory Consultant.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure records were available to document the workload limit for one of one Technical Supervisor in 2020 and 2021. Findings include: 1. The laboratory failed to follow the written procedure SLIDE SCREENING WORKLOAD LIMIT POLICY which stated: "The laboratory Director will assess the workload limits for the pathologist at least every six months. a. The assessment is documented." 2. Laboratory records titled SEMI-ANNUAL WORKLOAD REVIEW from 2020 and 2021 failed to include an initial workload limit or a reassessed workload limit for one of one Technical Supervisor. 3. During an interview on January 10, 2022 at 2:45 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor and Laboratory Consultant.
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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. 2. During an interview on January 10, 2022 at 2:45 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor and Laboratory Consultant.
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: Based on review of laboratory records and interview it was determined that the Technical Supervisor failed to establish individual workload limits and failed to reassess workload limits at least every six months for one of one Technical Supervisor performing primary slide examinations in 2020, 2021 and to the date of the survey. Findings include: 1. The Survey Team requested and the Laboratory Director /Technical Supervisor failed to provide documentation that the Technical Supervisor established a maximum workload limit for one of one Technical Supervisors who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Technical Supervisor includes: - Laboratory Director/Technical Supervisor 2. The Survey Team requested and the Laboratory Director/Technical Supervisor failed

	to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for one of one Technical Supervisor who performed primary slide examinations in 2020, 2021 and to the date of the survey in 2022. Technical Supervisor includes: - Laboratory Director/Technical Supervisor 3. During an interview on January 10, 2022 at 2:45 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor and Laboratory Consultant.
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6) In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that one of one Technical Supervisor performing primary screening of cytology specimen slides failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period 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 records of the total number of slides screened and the total number of hours one of one Technical Supervisor devoted to screening cytology specimen slides during each 24-hour period in 2020, 2021 and to the date of the survey in 2022. Technical Supervisor includes: - Laboratory Director/Technical Supervisor 2. During an interview on January 10, 2022 at 2:45 PM: a. When asked if the records DAILY SLIDE SCREENING LOG and WORKLOAD LIMIT SUMMARY REPORT included the total number of slides evaluated on each cytology case, the Laboratory Director/Technical Supervisor replied, "no." b. When asked if the records DAILY SLIDE SCREENING LOG and WORKLOAD LIMIT SUMMARY REPORT included the actual time spent screening the slides on each cytology case, the Laboratory Director/Technical Supervisor replied, "no." c. When asked if the time documented on the records was accurate and who had completed the "start time" and "end time" and "total time", the Laboratory Director/Technical Supervisor replied, "staff at the front desk write in the time." d. These findings were confirmed by the Laboratory Director/Technical Supervisor and Laboratory Consultant.
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.