

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1046389	(X3) Date Survey Completed 02/26/2025
Name of Provider or Supplier Georgia Cell And Tissue Diagnostic Center Inc	Street Address, City, State 902 7th Street North, Lower Level, Cordele, GA	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of ten laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish and follow 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 to describe the laboratory's system for entering results in the laboratory</p>

information system and reporting patient results. 2. During an interview on February 26, 2025 at 11:30 AM these findings were confirmed by the Laboratory Director /Technical Supervisor.

D5637

CYTOLOGY
CFR(s): 493.1274(d)(1)(ii)

(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, lack of reassessed workload limits and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish and follow written policies and procedures to detail how the Technical Supervisor's workload limit would be reassessed and adjusted when necessary at least every six months. The laboratory failed to ensure the workload limit was reassessed and adjusted when necessary at least every six months for one of one Technical Supervisor in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor's workload limit would be reassessed and adjusted when necessary at least every six months. 2. The Survey Team requested and the laboratory failed to provide reassessed workload limits for one of one Technical Supervisor in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on February 26, 2025 at 11:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.

D5641

CYTOLOGY
CFR(s): 493.1274(d)(2)(ii)

(d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of prorated workload limits and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish and follow written policies and procedures to prorate the workload limit for the Technical Supervisor when examining slides in less than an 8-hour workday. The laboratory failed to ensure the workload limit for one of one Technical Supervisor was prorated when examining slides in less than an 8-hour workday in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limit for the Technical Supervisor when examining slides in less than an 8-hour workday. 2. The Survey Team requested and the laboratory failed to provide a prorated workload limit for one of one Technical Supervisor when examining slides in less than an 8-hour workday in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Technical Supervisor includes: -

	<p>Technical Supervisor 3. During an interview on February 26, 2025 at 11:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
D5645	<p>CYTOLOGY CFR(s): 493.1274(d)(3)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, workload records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish and follow written policies and procedures to ensure records were maintained of the total number of hours spent examining slides per 24-hour period. The laboratory failed to maintain records of the total number of hours spent examining slides per 24-hour period for one of one Technical Supervisor in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the laboratory maintained records of the total number of hours spent examining slides per 24-hour period. 2. The Survey Team reviewed records titled GEORGIA CELL AND TISSUE CYTOLOGY SCREENING. a. The laboratory failed to maintain records of the total number of hours spent examining slides per 24-hour period, to include the time spent examining slides at Facility B, for one of one Technical Supervisor in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Technical Supervisor includes: -Technical Supervisor 3. During an interview on February 26, 2025 at 11:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
D5657	<p>CYTOLOGY CFR(s): 493.1274(e)(5)</p> <p>(e)(5) The report contains narrative descriptive nomenclature for all results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report 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 nongynecologic cytology test results. 2. During an interview on February 26, 2025 at 11:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
D6130	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3)</p> <p>(c)(2) Must establish the workload limit for each individual examining slides; (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;</p>

	<p>This STANDARD is not met as evidenced by: Based on lack of reassessed workload limits and interview with the Laboratory Director/Technical Supervisor the Technical Supervisor failed to reassess and adjust when necessary the workload limit at least every six months for the Technical Supervisor who performed primary screening of cytology slides. The Technical Supervisor failed to reassess the workload limit for one of one Technical Supervisor in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the Technical Supervisor failed to provide reassessed workload limits for one of one Technical Supervisor in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. (Refer to D5637) 2. During an interview on February 26, 2025 at 11:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
<p>D6133</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6)</p> <p>(c)(6) 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of workload records and interview with the Laboratory Director /Technical Supervisor the Technical Supervisor failed to document the total number of hours spent examining slides in each 24-hour period. Technical Supervisor failed to provide records of the total number of hours spent examining slides in each 24-hour period in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. Technical Supervisor failed to document the number of hours spent examining slides in each 24-hour period in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. (Refer to D5645) 2. During an interview on February 26, 2025 at 11:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
<p>D9999</p>	<p>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.</p>