

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D2099470	(X3) Date Survey Completed 02/07/2024
Name of Provider or Supplier Green Clinics Laboratory	Street Address, City, State 1633 Sorghum Mill Road, Dover, DE	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of 20 laboratory policies and procedures and interviews with the Laboratory Director/Technical Supervisor, the laboratory failed to ensure that 20 of 20 written procedures were approved, signed and dated by the Laboratory Director. Findings include: 1. The Laboratory Director failed to sign and date 20 of 20 laboratory procedures. Procedures include: - Instructions for Submitting Fine Needle Aspiration Cytology Specimens - Instructions for Submitting Urologic Cytology Specimens - Specimen Acceptance and Rejection - Quick/Full Accessioning Protocol - Reference Lab Protocol - FNA Adequacy Protocol - ThinPrep 2000 Non-Gyn - Cytology Slides and Blocks Retention - Papanicolaou Stain - Centrifuge Operation /Cleaning and Maintenance - Cytology Records and Reports - Cytology Workload - Pathologist - Post Analytic Quality Assurance - Pre-Analytic Daily QA - Verification of Performance Specifications - Procedure of Creation, Review and Approval of Standard Operation Procedures - Quality Assurance and Quality Management - Quarterly Statistical Laboratory Evaluation - Standard Operating Procedure (SOP) CellSolutions F50 Non-Gyn Protocol 2. During interviews on February 5, 2024 at 10:45 AM and 1:00 PM, these findings were confirmed by the Laboratory Director /Technical Supervisor.</p>
D9999	<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>