

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2249541	(X3) Date Survey Completed 11/14/2022
Name of Provider or Supplier Convenientmd Sanford	Street Address, City, State 1420 Main St, Sanford, ME	
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 record review and staff interview, it was determined that the laboratory director failed approve the laboratory CBC policy manual prior to use. Findings include: 1. Review of the "CBC Device Policy Manual" on 11/14/2022 revealed: a. The policy signature page to be signed by the Chief Medical Officer and not the laboratory director. b. The CBC policy first page to have a typed list of staff with the note: "Approved Date: 01/01/2100". 2. Staff interview with practice manager (PM) on 11/14/2022 at 9:30am confirmed the above findings. 3. The laboratory performs 486 tests annually in the specialty of Hematology.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on maintenance record review and interview with the practice manager (PM) the laboratory failed to document routine maintenance and function checks for laboratory equipment in the specialty of Hematology. Findings include: 1. Record review of the Sysmex XP-300, 2022 maintenance logs on 11/14/2022 revealed the laboratory failed to document quarterly maintenance and function checks for the</p>

following: a. June 2022 Quarterly "Clean Sample Rotor Valve (SRV)" b. September 2022 Quarterly "Clean Sample Rotor Valve (SRV)" 2. Record review on 11/14/2022 of the Sysmex XP-300 Automated Hematology Analyzer Quick Guide, Maintenance Section, Page 11, 3-Month Maintenance section revealed: a. "Clean the SRV" 3. Staff interview with the practice PM on 11/14/2022 at 10:00am confirmed the above findings. 4. The laboratory performs 486 tests annually in the specialty of Hematology.