

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2137806	(X3) Date Survey Completed 01/11/2022
Name of Provider or Supplier Convenientmd Portland	Street Address, City, State 191 Marginal Way, Portland, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview with the practice manager (PM), the laboratory director (LD) failed to sign the attestation sheet for the American Proficiency Institute (API) proficiency testing (PT) samples in the specialty of Hematology. Findings include: 1. Record review on 1/11/2022 of the laboratory's PT attestation sheet for API Hematology/Coagulation 2020 event 3 revealed the LD did not sign the attestation sheet. 2. Staff interview on 1/11/2022 at 2:00 PM with the PM confirmed the above findings. 3. The laboratory performs 5,250 tests annually in the specialty of Hematology.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the practice manager (PM), the laboratory failed to follow the written procedure to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's 2020 and 2021 employee competency records on 1/11/2022 revealed the laboratory did not have competency</p>

documentation for the Technical Consultant (TC) for his/her CLIA federal regulatory responsibilities. 2. Review on 1/11/2022 of the laboratory's 'Competency Assessment' Policy revealed: a. "Documented competency assessment shall be required for individuals fulfilling the following responsibilities outlined in Subpart M of the CLIA regulations: Clinical Consultant (CC), Technical Consultant (TC), Technical Supervisor (TS), General Supervisor (GS) and Testing Personnel (TP)." b. "CCs, TCs, TSs, and GSs who perform testing are required to have the six (6) required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities." 3. Staff interview with the PM on 1/11/2022 at 2:00 PM confirmed the laboratory did not follow the policy in place to assess the competency of the TC and they were not assessed. 4. The laboratory performs 5,250 tests annually in the specialty of Hematology.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

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.

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, 2020 and 2021 maintenance logs on 1/11/2022 revealed the laboratory failed to document weekly maintenance and function checks for the following: a. Eight of 52 weeks in 2020. b. Five of 52 weeks in 2021. 2. Record review on 1/11/2022 of the laboratory's 'Laboratory Quality Assurance' policy revealed: a. "The designated team member with assistance of the PM must review laboratory equipment maintenance on a weekly basis." b. "Documentation of this review must be made on the weekly Practice Manager dashboard and notation must be made noting the last date of maintenance. Laboratory maintenance includes: CBC device weekly maintenance." 3. Record review on 1/11/2022 of the Sysmex XP-300 Automated Hematology Analyzer Quick Guide, Maintenance Section, Page 9, Weekly maintenance revealed: a. "Clean the SRV tray." 4. Record Review on 1/11/2022 of the 2020 and 2021 plumbed eyewash maintenance records revealed: a. Eyewash maintenance and function checks were not documented for 12 of 12 months in 2020. b. Eyewash maintenance and function checks were tested monthly instead of weekly in 2021. 5. Record review on 1/11/2022 of the The American National Standards Institute (ANSI) standards for plumbed eyewashes revealed: a. Plumbed flushing equipment "shall be activated weekly for a period long enough to verify operation and ensure that flushing fluid is available." 6. Staff interview with the practice PM on 1/11/2022 at 2:00 PM confirmed the above findings. 7. The laboratory performs 5,250 tests annually in the specialty of Hematology.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the proficiency testing (PT) data report (CASPER Report 0155D), PT graded results from the American Proficiency Institute (API) and staff interview, the laboratory failed to investigate or take remedial action when PT scores of less than 100% are received. Findings include: 1. Record review on 1/11/2022 of the CASPER Report 0155D, revealed the laboratory received a PT score of 80% for the regulated analyte 0785 HCT for 2020 Event 1. 2. Record review on 1/11/2022 of the laboratory's 2020 API PT records revealed: a. HCT score of 80% for 2020 Event 1 Hematology/Coagulation. b. MCHC score of 80% for 2020 Event 2 Hematology/Coagulation. c. Investigation or remedial action was not documented for the above PT results. d. 2020 Hematology/Coagulation event 3 PT results were not reviewed or signed by the LD. e. 2021 Hematology/Coagulation event 2 PT results were not reviewed or signed by the LD. 3. Staff interview on 1/11/2022 at 2:00 PM with the practice manager confirmed the above findings. 4. The laboratory performs 5,250 tests annually in the specialty of Hematology.