

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2172369	(X3) Date Survey Completed 10/19/2021
Name of Provider or Supplier Convenientmd Saco	Street Address, City, State 506 Main Street, Saco, 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
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on interview with the Practice Manager (PM) and review of 2020 and 2021 proficiency testing (PT) records, the laboratory failed to authorize the PT program to release PT results to the Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS). Findings include: 1. Record review conducted on 10/19/2021 of the Proficiency Testing (PT) data report (CASPER 0096) revealed no PT results were reported to CMS in 2020 and 2021 in Specialty of Hematology. 2. Record review conducted on 10/19/2021 of 2020 and 2021 graded results from the PT organization American Proficiency Institute (API) revealed that the laboratory's CLIA identification number 20D2172369 was missing on all 2020 and 2021 performance evaluation reports. 3. The PM stated in an interview on 10/19/2021 at 1:28 PM that he /she was not sure if the laboratory authorized the PT program to release PT results to the HHS, CMS because another department is responsible for setting up and ordering the PT. 4. The laboratory performs 1,656 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>

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 2019, 2020 and 2021 employee competency records on 10/19/2021 revealed the laboratory did not have competency documentation for the Technical Consultant (TC). 2. Review on 10/19/2021 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 10/19/2021 at 2:30 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 1,656 moderate complexity 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, Serial # B5558, 2020 and 2021 maintenance logs on 10/19/2021 revealed the laboratory failed to document weekly maintenance and function checks for the following: a. Three of 52 weeks in 2020. b. 13 weeks from 1/1/2021 through 10/19/2021. 2. Staff interview with the practice PM on 10/19/2021 at 2:00 PM confirmed the above findings. 3. The laboratory performs 1,656 tests annually in the specialty of Hematology.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on record review and interview with the practice manager (PM), it was determined that the reference range for Red Blood Cell (RBC) on the laboratory's final patient test report did not correlate with the reference range in the laboratory's procedure manual. Findings include: 1. Comparison of final patient test report's RBC reference range for patient #1 (male) and patient #2 (female) with the laboratory's

procedure for Complete Blood Count (CBC), 'CBC Device Policy manual' on 10/19/2021 revealed the following: a. Final report: RBC 4.41 - 5.80 $10^6/\mu\text{L}$ b. CBC procedure: RBC 4.14 - 5.8 $10^6/\text{mm}^3$ 2. Staff interview with the PM on 10/19/2021 at 1:30 PM confirmed the reference range for RBC male and female in the procedure referenced above did not correlate with the reference range on the final patient test report. 3. The laboratory performs 1,656 tests annually in the specialty of Hematology.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on record review and interview with the practice manager (PM), the laboratory failed to evaluate the competency of all testing personnel (TP) to perform moderate complexity testing in the specialty of Hematology. Findings include: 1. Record review on 10/19/2021 of the laboratory's 2020 and 2021 TP competency records revealed 2 of 12 moderate complexity TP did not have competency records. Specifically: a. TP#3, hired on 9/1/2020 did not have any documented competency records. b. TP#4, hired on 12/2/2019 did not have any documented competency records. 2. Record review on 10/19/2021 of the laboratory's 'Competency Assessment' policy revealed the procedure stated, "Documented competency assessment shall be required for individuals fulfilling the following staff responsibilities outlined in Subpart M of the CLIA regulations: Testing Personnel (TP)." 3. Staff interview with the PM on 10/19/2021 at 2:00 PM confirmed the above findings. 4. The laboratory performs 1,656 tests annually in the specialty of Hematology.