

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2137805	(X3) Date Survey Completed 01/11/2022
Name of Provider or Supplier Convenientmd Westbrook	Street Address, City, State 950 Main Street, Westbrook, 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 11:45 AM with the PM confirmed the above findings. 3. The laboratory performs 5,250 tests annually in the specialty of Hematology.</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>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 attain a score of at least 80% for the regulated analyte WBC in the specialty of Hematology. Findings include: 1. Record review on 1/11/2022 of the CASPER Report 0155D, revealed: a. The laboratory received an unsatisfactory PT</p>

score of 40% for the regulated analyte 0805 WBC for 2020 Event 3. 2. Record review on 1/11/2022 of the laboratory's 2020 API PT records revealed: a. Unsatisfactory PT score of 40% for the regulated analyte 0805 WBC for 2020 Event 3. b. Investigation or remedial action was not documented for the above unacceptable result. 3. Staff interview on 1/11/2022 at 11:45 AM with the practice manager confirmed the above findings. 4. The laboratory performs 5,250 tests annually in the specialty of Hematology.

D2128

HEMATOLOGY

CFR(s): 493.851(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

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 unsatisfactory or unacceptable PT scores are received. Findings include: 1. Record review on 1/11/2022 of the CASPER Report 0155D, revealed: a. The laboratory received an unsatisfactory PT score of 40% for the regulated analyte 0805 WBC for 2020 Event 3. 2. Record review on 1/11/2022 of the laboratory's 2020 API PT records revealed: a. Unsatisfactory PT score of 40% for the regulated analyte 0805 WBC for 2020 Event 3. b. Investigation or remedial action was not documented for the above unacceptable result. 3. Staff interview on 1/11/2022 at 11:45 AM with the practice manager confirmed the above findings. 4. The laboratory performs 5,250 tests annually in the specialty of Hematology.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

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 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 11:45 AM 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. 16 of 52 weeks in 2020. b. 8 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 Practice Manager 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 52 of 52 weeks in 2020. b. Eyewash maintenance and function checks were not documented for 42 of 52 weeks 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 11:45 AM confirmed the above findings. 7. The laboratory performs 5,250 tests annually in the specialty of Hematology.

D6019

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

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

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 director (LD) 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: a. The laboratory received a PT score of 87% for the regulated analyte 0765 CELL I.D. OR WBC DIFF for 2020 Event 1. b. The laboratory received a PT score of 40% for the regulated analyte 0805 WBC for 2020 Event 3. c. The laboratory received a PT score of 93% for the regulated analyte 0765 CELL I.D. OR WBC DIFF for 2021 Event 2. 2. Record review on 1/11/2022 of the laboratory's Hematology/Coagulation 2020 and 2021 API PT records revealed: 2020 Event 1 a. An unacceptable PT result for HSY-03 Monocytes% resulting in a score of 87%. b. Results signed by the LD with a note, "No corrective action needed." c. An investigation and action plan for the unacceptable score was not documented. 2020 Event 3 a. Unsatisfactory PT results for HSY-12, HSY-13, and HSY-14 White Cell Count (WBC) resulting in a score of 40%. b. Results signed by the technical consultant with a comment, "Reran samples HSY-12, HSY-13, HSY-14. Came back in acceptable range." c. An investigation and action plan for the unsatisfactory score was not documented. 2021 Event 2 a. An unacceptable PT result for HSY-08 Monocytes% resulting in a score of 93% for CELL ID or WBC DIFF. b. Results signed by the LD with a comment, Monocytes for HSY-08 unacceptable. Reran sample with acceptable results of 11.8%. JS MA." c. An investigation and action plan for the unacceptable score was not documented. 3. Staff interview on 1/11/2022 at 11:45 AM with the practice manager confirmed the above findings. 4. The laboratory performs 5,250 tests annually in the specialty of Hematology.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the practice manager (PM) the laboratory director (LD) failed to document new moderate complexity testing personnel (TP) training prior to testing patient samples in the specialty of Hematology. Findings include: 1. Record review on 1/11/2022 of the laboratory's TP records revealed, TP1 was hired on 2/4/2021. 2. No documentation was found from 2/4/2021 through the date of the survey (1/11/2022) that TP1 was trained prior to reporting CBC test results on patient samples 3. During interview on 1/11/2022 at 11:45 AM, the PM confirmed: a. TP1 began testing patient samples and reporting CBC patient results on 5/5/2021. b. Training prior to reporting CBC test results on patients was not documented. 4. The laboratory performs 5,250 tests annually in the specialty of Hematology.