

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2137806	(X3) Date Survey Completed 07/31/2019
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
D0000	The laboratory at ConvenientMD Urgent Care - Portland, ME is not in compliance with the requirements of 42 CFR Part 493, Clinical Laboratory Improvement Amendments (CLIA). The following requirements have not been met:
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 Regional Manager (RM) and review of 2018 and 2019 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 07/31/19 of the Proficiency Testing (PT) data report (CASPER 0096) revealed no PT results were reported to CMS in 2018 and 2019 in Specialty of Hematology. 2. Record review conducted on 07/31/19 of 2018 and 2019 graded results from the PT organization American Proficiency Institute (API) revealed that the laboratory's CLIA identification number 20D2137806 was missing on all 2018 and 2019 performance evaluation reports. 3. The RM stated in an interview on 07/31/19 at 11:28 AM that the laboratory submitted the API PT enrollment form in 2018 without the laboratory's CLIA ID because the laboratory was awaiting their CLIA ID following their CLIA registration. The RM also stated that a second API PT enrollment form was submitted with the laboratory's CLIA ID after receiving it, but the enrollment form was submitted to API without the Laboratory Director's (LD) signature which caused the laboratory's CLIA number 20D2137806 to be missing from all 2018 PT result records. The RM further stated that the 2019 API PT enrollment form was submitted to API</p>

without the laboratory's CLIA ID 20D2137806 which resulted in laboratory's CLIA number to be missing from all 2019 PT result records. 4. The laboratory performed approximately 2000 Complete Blood Counts (CBCs) annually on the Sysmex XP-300 in 2018 and 2019.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on proficiency testing (PT) record review and staff interview with the Regional Manager (RM), the laboratory director (LD) failed to sign attestation statements documenting that proficiency testing (PT) samples were tested in the same manner as patient samples. Findings include: 1. Record review conducted on 07/31/19 2018 and 2019 PT records revealed the following: American Proficiency Institute (API) Hematology/Coagulation PT attestation statements: a) 1st and 2nd events in 2018 were missing the LD signature. b) 1st and 2nd events in 2019 were missing the LD signature. 2. Interview with the RM on 07/31/19 at 10:30 AM confirmed the above findings.

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 2018 and 2019 proficiency testing (PT) record review and staff interview with the Regional Manager (RM), the laboratory failed to perform and document remedial action for unacceptable PT performance in the American Proficiency Institute (API) Hematology/Coagulation 2nd Event in 2018. Findings include: 1. Record review conducted on 07/31/19 of the 2018 and 2019 American Proficiency Institute (API) Hematology/Coagulation result evaluation reports revealed the laboratory received a score of 0% for the 2nd Event in 2018. 2. Record review conducted on 07/31/19 of the 2018 Proficiency Institute (API) Hematology /Coagulation 2nd Event performance evaluation report revealed the Laboratory

Director (LD) signed the evaluation form, but did not document any remedial actions for the laboratory's unacceptable PT performance. 3. Interview with the RM on 07/31/19 at 10:45 AM confirmed the above findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) procedures, QC data, and Quality Assurance (QA) documentation, and interview with the Regional Manager (RM), the laboratory failed to follow QA procedures for running daily quality control on the Sysmex XP-300 in February 2018. Findings include: 1. Record review of the laboratory's approved CBC Device Policy Manual, Section 1: Control Verification of the CBC Analyzer: a. Step #3 stated, "If a control is not within range, the control must be repeated. If after the second attempt the control is not in range, a Maintenance Cleaning (concentrated or otherwise) must be completed and documented in the notes section the reason the control was re-run". b. Step #5 "Notation of the out of range control, any actions taken to resolve this issue and the results of these actions must be documented in the Notes section of the CBC or LIS software". 2. Record review conducted on 07/31/19 of the laboratory's Laboratory Quality Assurance Policy, effective October 19, 2015, Section 1, bullet 2 stated " In the event a quality control does not meet the laboratory's established acceptable criteria, the LeadRN must verify documentation regarding the out of range control was made in the Laboratory Problem Log. Documentation must include any actions taken to resolve the issue and the results of those actions". 3. Record review conducted on 07/31/19 of Sysmex XP-300 QC data for the period of 01/23/18 through 04/03/18 revealed daily QC was run and rejected at 8:25 AM, 8:27 AM, and 8:31 AM on 02/24/2018. 4. Record review conducted on 07/31/19 of the "Sysmex XP-300 Technical Services Record revealed no documentation noting that daily QC that was run and rejected three times on 02/24/18. 5. Interview with the RM on 07/31/19 at 11:45 AM confirmed the findings above.