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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 20D2137805 | (X3) Date Survey Completed 07/31/2019 |
| 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 |
|---------------------------|---|
| D0000 | The laboratory at ConvenientMD Urgent Care - Westbrook 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 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 20D2137805 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 20D2137805 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 20D2137805 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 record review and staff interview, the laboratory failed to maintain copies of American Proficiency Institute (API) Proficiency Testing (PT) records for the 1st Event of 2019 for two years from the date of the PT testing event. Missing records included raw data from the Sysmex XP-300 Hematology analyzer documenting that PT samples were tested in the same manner as patient specimens. Findings include: 1. Record review of 2018 and 2019 PT records conducted on 07/31/2019, revealed that the raw data from Sysmex XP-300 Hematology analyzer for the PT 2019 Event 1 results reported to American Proficiency Institute (API) was not maintained by the laboratory. 2. Interview with the Regional Manager (RM) at approximately 1:45 PM confirmed the finding above.