

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2174164	(X3) Date Survey Completed 01/28/2021
Name of Provider or Supplier Convenientmd Urgent Care - Framingham	Street Address, City, State 236 Cochituate Rd, Framingham, MA	
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	An initial CLIA certification survey was conducted for the ConvenientMD Urgent Care Framingham laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493.
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and interview, the laboratory director failed to approve, sign, and date laboratory procedures as evidenced by the following: A review of the clinical laboratory procedure paper and on line procedure manual revealed that the current laboratory director had not reviewed and approved the laboratory policy and procedure manual. The physician assistant confirmed in an interview on 1/28/21 at 9:20 a.m. that documentation was not available to verify that the current laboratory director had reviewed and approved of laboratory procedures.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to perform complete validation studies for one (1) newly implemented test system prior to reporting out patient testing results as evidenced by the following: A review of validation studies for the Sysmex XP300 hematology analyzer. revealed that the laboratory failed to provide documentation to verify that accuracy and day to day precision studies had been completed as part of the validation for all six (6) of the complete blood count (CBC) measured test analytes being performed (white blood count, red blood count, hemoglobin, mean corpuscular volume, platelet count, and white cell differential) prior to utilizing the analyzer for patient testing and reporting. The physician assistant interviewed on 1/28/21 at 10:20 AM was not able to provide documentation at the time of the survey to confirm that the above validation parameters had been completed. The laboratory performs 7,423 CBCs annually. .

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on record review and interview, the technical consultant failed to fulfill the responsibility for verification of the laboratory's test performance characteristics as evidenced by the following: a) Documentation was not available to verify that the technical consultant reviewed and approved validation studies for the hematology analyzer prior to implementing the analyzer for patient testing and reporting for within run precision as well linearity (reportable range) studies. b) At the time of the survey documentation was not available to verify that accuracy as well as day to day precision studies were performed for the hematology analyzer prior to implementing the analyzer for patient testing and reporting c) The physician assistant and practice manager both confirmed in an interview on 1/28/21 at 10:15 AM that they were unable to find the above documentation. .

D6049

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

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on record review and interview, the technical consultant failed to evaluate competency of the staff through review of proficiency testing and quality control records as evidenced by the following: 1. A review of proficiency testing records for calendar year 2020 (three testing events)revealed that the technical consultant failed to document a review of proficiency testing results for hematology results for the first and third testing events. In addition, the technical consultant failed to document corrective actions in response to unsatisfactory proficiency testing results (chloride,

carbon dioxide, potassium, and sodium for the third testing event of 2020 in which the laboratory received zero percent for all four analytes) 2. A review of hematology quality control records from March to July 2020 was performed. Documentation was not available to verify that the technical consultant regularly reviewed quality control data to ensure that personnel were following established quality control policies and procedures and to ensure the accuracy and reliability of patient test results. 3. The physician assistant and practice manager confirmed in an interview on 1/28/21 at 10:05 AM. that reviews of proficiency testing and quality control results for hematology by the technical consultant were not being documented.