

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2166069	(X3) Date Survey Completed 06/17/2021
Name of Provider or Supplier Convenientmd Urgent Care Bellingham	Street Address, City, State 245 Hartford Ave, Bellingham, 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	A CLIA recertification survey was conducted for the ConveneientMD Urgent Care Bellingham laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibrations following the manufacturer's test system instructions as evidenced by the following: The manufacturer's certificate of calibration for calibration of the Sysmex XP 300 hematology analyzer indicated that calibration it expired on December 27, 2020. A review of calendar years 2019, 2020 and 2021 calibration records for the Sysmex XP 300 revealed that the last calibration in 2020 was performed on June 30, 2020 and the certificate for that calibration expired on December 27, 2020. The next documented calibration on the analyzer wasn't performed until 6/16/21, 12 months later. The director of operations confirmed in an email received on 6/23/21 that the calibration of the hematology analyzer had not been performed in December 2020. .</p>

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review, the laboratory failed to provide documentation to verify that the designated technical consultant met the qualification requirements of 493.1411 as evidenced by the following: At the time of the survey the laboratory failed to provide documentation to verify that the designated technical consultant had one year of training or experience, or both, in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (hematology).