Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2227673	07/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Convenientmd Urgent Care - Westborough	139 Turnpike Rd, Westborough, 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 - Westborough laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 of the Sysmex XP300 hematology analyzer for accuracy, linearity (reportable range), as well as day to day and within run precision prior to implementing the analyzer for patient testing and reporting. b) The director of operations confirmed in an interview on 7/28/22 at 9:15 AM that the designated technical consultant was only overseeing the competency of the staff performing laboratory testing, not approving validation studies for new methods or instrumentation. c) The laboratory performs approximately 150 hematology tests annually. .
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 include a documented review of quality control records and proficiency testing as part of the evaluation of the competency of the staff as evidenced by the following: a) A review of quality control and proficiency testing records for hematology for calendar year 2022 (5 months of laboratory operation) revealed that the technical consultant had not documented a review of hematology quality control or proficiency testing records. b) The Director of Operations confirmed in an interview on 7/27/22 at 9:15AM that the technical consultant was mainly responsible for the competency of the staff performing testing but this aspect of quality control and proficiency testing reviews had not been included. c) The laboratory performs approximately 150 hematology tests annually.