Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2166070	12/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Convenientmd Urgent Care Plainville	86 Taunton St, Plainville, 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 Plainville laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 document a review of quality control records as evidenced by the following: a) A review of quality control records for hematology for calendar year 2019 (5 months of laboratory operation) revealed that the technical consultant had not documented a review of hematology quality control records. b) The regional manager confirmed in an interview on 12/4/19 at 9:53 AM that she and the technical consultant regularly reviewed hematology quality control but these reviews were not documented. .
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not

	limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. The laboratory did not provide, upon request, all information and data needed by the CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part as evidenced by the following: a) A review of validation studies on for the Sysmex XP300 hematology analyzer on 12/4/19 at 9:30 AM revealed that day to day and within run precision studies were not available on the day of the inspection b) The regional manager confirmed in an interview on 12/4 /19 at 9:35 AM that the precision studies had been performed but were not available on site to review.