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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 22D2227661 | (X3) Date Survey Completed 07/13/2022 |
| Name of Provider or Supplier Convenientmd Urgent Care - Ludlow | Street Address, City, State 471 Center St, Ludlow, 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 |
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| D0000 | An initial CLIA certification survey was conducted for the laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. |
| D6040 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>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.</p> <p>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 7/13/22 at 10:05 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 186 hematology tests annually. .</p> |
| D6049 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>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.</p> |

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 7/13/22 at 10:05 AM 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 186 hematology tests annually.