Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 30D2170918	**(X3) Date Survey Completed** 03/12/2020
Name of Provider or Supplier Convenientmd Urgent Care - Littleton	**Street Address, City, State** 551 Meadow St, Littleton, NH	
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**
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of hematology instrument validation records and staff interview, the laboratory failed to verify performance specifications for accuracy, reportable range and precision in December 2019 before reporting patient results. Findings include: 1) Review of validation records for the Sysmex XP-300 complete blood cell count (CBC) analyzer revealed studies for reportable range had been conducted in 11/13/2019. Testing for precision the study had been performed but statistical parameters were not calculated, evaluated, and approved. Accuracy was not included in the reportable range study and there was no other documentation that accuracy had been verified. There was no documentation the laboratory director reviewed and approved the reportable range study. 2) Interview with Testing Personnel (TP1) on 3/12/2020 at 12:05 p.m. confirmed the above finding. TP1 revealed the laboratory began CBC testing on 12/17/2019.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test

	results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, patient results, and staff interview the laboratory failed to perform hematology QC testing prior to performing and reporting patient test results on 2/14/2020. Findings include: 1) Review of complete blood cell count (CBC) QC records from February 2020 revealed on 2/14/2020 the laboratory performed three levels of CBC QC after 4:00 p.m. 2) Review of CBC patient results for 2/14/2020 revealed 2 patient CBC results (sample ID 1208855, and 1208867) had been reported at 1:46 p.m. and 1:53 p.m., respectively. 3) Interview with Testing Personnel (TP1) on 3/12/2020 at 11:00 a.m. confirmed the above finding. TP1 revealed weekly quality assurance checks of CBC QC does not include review of time stamps to ensure QC is performed and acceptable prior to reporting patient results.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of personnel records and staff interview, the laboratory director failed to ensure 1 of 4 hematology testing personnel met educational qualification requirements. Findings include: 1) Review of the laboratory's policy titled "Competency Assessment" last revised 2/1/2020 revealed on page 2 "Lab competency assessments will be performed on individuals who met the education/training criteria. Lab Directors will review these before competency is done on the individual." 2) Review of personnel initial competency assessments revealed 3 of 4 testing personnel's initial CBC competency assessments failed to document that "Educational requirements have been met for testing personnel" on the initial competency form. 3) Review of personnel qualification records revealed 1 of 4 (TP2) testing personnel's records failed to include educational qualifications; refer to tag D6065. 4) Interview with Testing Personnel (TP1) on 3/12/2020 at 12:30 p.m. confirmed the above findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are

	adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of validation studies for the hematology analyzer and staff interview, the laboratory director failed to ensure verification of performance specifications for accuracy and precision had been performed and failed to review and approve the reportable range study. Refer to tag D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC), patient records and staff interview, the laboratory director failed to ensure testing personnel perform and accept hematology QC prior to reporting patient results in February 2020. Refer to tag D5481.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records and staff interview, 1 of 4 testing personnel failed to meet educational qualification requirements. Refer to tag D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

	This STANDARD is not met as evidenced by: Based on review of personnel records and staff interview, 1 of 4 hematology testing personnel failed to meet qualification requirements. Findings include: 1) Review of personnel records revealed 1 of 4 (TP2) testing personnel's records failed to include educational qualifications. Further review revealed TP2 completed complete blood cell count training and began patient testing on 2/28/2020. 2) Interview with Testing Personnel (TP1) on 3/12/2020 at 12:30 p.m. confirmed the above finding.