Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D2103918	08/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Convenientmd, Llc	565 Amherst St, Nashua, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's procedure manual failed to include reportable ranges for Hematology testing. Findings include: 1) Review on 8 /21/2019 of the laboratory's procedure manual titled "CBC [complete blood count] Device Policy Manual" revealed no reportable ranges for complete blood count tests (white blood cell count, red blood cell count, hemoglobin, hematocrit, and platelet count). 2) Interview on 8/21/2019 at 11:15 a.m. with the Laboratory Director confirmed the CBC reportable ranges were not included in the "CBC Device Policy Manual" or any other procedure manual.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to label 3 Hematology control materials with expiration dates upon opening in August 2019. Findings include: 1) Review on 8/21/2019 of the package insert for complete blood count (CBC) control material revealed control materials expire 14 days after opening. 2) Observation on 8/21/2019 at 11:00 a.m. revealed 3 of 3 CBC control levels were labeled opened on 8/8/19 but were not labeled with the revised expiration date. 3) Interview on 8/19/2019 at 11:05 a.m. with the Laboratory Director confirmed the above findings.
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 record review and interview, the laboratory failed to verify precision performance specifications for Hematology testing in August 2019. Findings include: 1) Review on 8/21/2019 of laboratory instrument records revealed the manufacturer set up the Sysmex XP300 analyzer on 3/28/19. 2) Review on 8/21/2019 of the laboratory verification studies for complete blood count tests (CBC; includes white blood cell count, red blood cell count, hemoglobin, hematocrit, and platelet count) conducted 8/8/19 and 8/9/19 revealed no documentation (i.e. calculation of standard deviation, coefficient of variation, or 95% confidence interval) of precision studies. 3) Interview on 8/21/2019 at 12:00 p.m. with the Laboratory Director confirmed the laboratory did not analyze the verification study data for precision. The LD revealed an assessment of patient impact had been conducted for testing patients on the new analyzer prior to the laboratory conducting its own verification of performance specification studies. 4) The laboratory's annual patient CBC test volume is 2,628.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to only report patient Hematology results within the laboratory's reportable range in May 2019. Findings include: 1) Review of the Sysmex [XP300] reportable range limits revealed the reportable range for hematocrit (HCT) was 10.0 - 60.0 %. 2) Review on 8/21/2019 of patient results from April 2019 to August 21, 2019 revealed on May 27, 2019 the laboratory reported HCT as 67.2%. 3) Interview on 8/21/2019 at 11:45 a.m. with the Laboratory Director (LD) confirmed the above findings. The LD revealed the laboratory did not have a system in place to ensure the laboratory reported values within the reportable ranges.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to ensure Hematology quality assessment (QA) programs were established and maintained to identify failures in quality as they occur in 2019. Findings include: 1) Review on 8/21 /2019 of QA documentation revealed on 8/8/19 the laboratory discovered the use of expired complete blood cell count (CBC) quality control materials from 8/1/2019 to 8 /7/2019. On 8/15/19, the laboratory discovered on 5/17/19 and 5/18/19 the laboratory used expired CBC control materials. The laboratory reported 12 patient CBC reports on days the expired material had been used. 2) Review on 8/21/2019 of control records from April 2019 to August 21, 2019 revealed on 7/6/19 testing personnel failed to follow the laboratory's procedures for performing CBC control testing and troubleshooting CBC control testing failures. There was no documentation that QA activities had caught the Testing Personnel's failure to follow procedure. 3) Observation on 8/21/2019 at 11:00 a.m. of CBC control materials revealed the opened vials of control material were not labeled with revised expiration dates. Cross reference tag D5415. 4) Interview on 8/21/2019 at 12:00 p.m. with the Laboratory Director (LD) confirmed the above findings.