

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  30D2103918	<b>(X3) Date Survey Completed</b>  10/07/2021
<b>Name of Provider or Supplier</b>  Convenientmd, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to label 3 of 3 hematology control materials with the revised expiration date upon opening. Findings include: 1. Observation on 10/7/2021 at 10:05 a.m. of the 3 control materials used for complete blood counts (CBC) revealed no revised expiration date on the 3 vials of control material. The 3 CBC control material vials were opened on 9/28/2021. 2. Interview on 10/7/2021 at 10:05 a.m. with the technical consultant (TC) confirmed the 3 opened vials of control material were not labeled with the expiration date upon opening. The TC revealed the CBC control material has a 14 day expiration when opened. This is a repeat deficiency from the recertification survey completed on 8/21/2019.</p>
<b>D6021</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:  
Based on record review, observation and staff interview, the laboratory director (LD) failed to ensure quality assessment programs implemented as a result of previous deficiency citations are maintained to assure the quality of hematology testing in 2019, 2020, and 2021. Findings include: 1) The laboratory failed to label control materials used for complete blood counts (CBC) in 2021; refer to tag D5415. This is a repeat deficiency from the recertification survey completed on 8/21/2019. 2) The technical consultant failed to ensure competency assessments were performed in 2019, 2020, and 2021; refer to tag D6053. This is a repeat deficiency from the recertification survey completed on 8/21/2017.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the technical consultant (TC) failed to ensure 3 of 3 new testing personnel were evaluated for competency semiannually in their first year of performing hematology testing in 2019, 2020, and 2021. Findings include: 1) Review on 10/7/2021 of testing personnel records revealed 4 new testing personnel trained to perform complete blood count (CBC) testing. Further review revealed 3 out of the 4 testing personnel have been trained greater than 1 year and 2 (TP #1, TP #2) out of these 3 testing personnel failed to have evaluations for competency semiannually in their first year, and 1 (TP #3) out of the 3 failed to be evaluated for competency in the first year. Competencies performed in the first year are: TP #1 - trained 7/2019, annual assessment 7/2020. TP #2 - trained 3/2020, annual assessment 6/2021. TP #3 - trained 7/2020, no competency assessments performed. 2) Interview on 10/7/2021 at 9:30 a.m. with the TC confirmed the above finding. This is a repeat deficiency from the recertification survey completed 8/21/2017.