

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  20D2165130	<b>(X3) Date Survey Completed</b>  10/19/2021
<b>Name of Provider or Supplier</b>  Convenientmd Urgent Care - Brunswick	<b>Street Address, City, State</b>  193 Bath Road, Brunswick, ME	
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>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and staff interview, the laboratory failed to test PT samples in the same manner as routine patient samples by testing personnel (TP) who routinely perform the testing in the specialty of Hematology. Findings include: 1. Record review on 10/19/2021 of the laboratory's 2020 American Proficiency Institute (API) Hematology/Coagulation PT attestation sheets revealed: a. 2020 API Hematology/Coagulation Event 1 - All samples were tested by TP1 b. 2020 API Hematology/Coagulation Event 2 - All samples were tested by TP2 c. 2020 API Hematology/Coagulation Event 3 - All samples were tested by TP3 d. No PT event samples were tested by TP4, TP5, TP6 and TP7 in 2020. 2. Staff interview with the practice manager on 10/19/2021 at 11:00 AM confirmed PT was not rotated amongst all TP. 3. The laboratory performs 864 tests per year in the specialty of Hematology.</p>
<b>D2128</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p>

This STANDARD is not met as evidenced by:  
 Based on review of the proficiency testing (PT) data report (CASPER Report 0155D), PT graded results from the American Proficiency Institute (API) and staff interview, the laboratory failed to investigate or take remedial action when unacceptable PT scores are received. Findings include: 1. Record review on 10/19/2021 of the CASPER Report 0155D, revealed the laboratory received an unacceptable PT score (93%) for 2021 Event 1 for the regulated analyte 0765 Cell ID or White Blood Count (WBC) Diff. 2. Record review on 10/19/2021 of the laboratory's 2021 API PT records revealed: a. Unacceptable test results (93%) for 2021 Event 1: Sample ID: HSY-03: Neut/Gran % in the WBC differential. b. Investigation or remedial action was not documented for the above unacceptable results. c. The PT event was signed as reviewed by the laboratory director. 3. Staff interview on 10/19/2021 at 11:00 AM with the practice manager confirmed the above findings. 4. The laboratory performs 864 Complete Blood Count tests annually in the specialty of Hematology.

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**  
 CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:  
 Based on record review and interview with the practice manager (PM), the laboratory failed to follow the written procedure to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's 2019, 2020 and 2021 employee competency records on 10/19/2021 revealed the laboratory did not have competency documentation for the Technical Consultant (TC). 2. Review of the laboratory's 'Competency Assessment' Policy on 10/19/2021 revealed: a. "Documented competency assessment shall be required for individuals fulfilling the following responsibilities outlined in Subpart M of the CLIA regulations: Clinical Consultant (CC), Technical Consultant (TC), Technical Supervisor (TS), General Supervisor (GS) and Testing Personnel (TP)." b. "CCs, TCs, TSs, and GSs who perform testing are required to have the six (6) required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities." 3. Staff interview with the practice manager on 10/19/2021 at 11:30 AM confirmed the laboratory did not follow the policy in place to assess the competency of the TC and they were not assessed. 4. The laboratory performs 864 moderate complexity tests annually in the specialty of Hematology.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
 CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:  
 Based on record review and staff interview, it was determined that the reference range

for Red Blood Cell (RBC) on the laboratory's final patient test report did not correlate with the reference range in the laboratory's procedure manual. Findings include: 1. Comparison of final patient test report's RBC reference range for patient #1 (male) and patient #2 (female) with the laboratory's procedure for Complete Blood Count (CBC), 'CBC Device Policy manual' on 10/19/2021 revealed the following: a. Final report: RBC 4.41 - 5.80  $10^6/uL$  b. CBC procedure: RBC 4.14 - 5.8  $10^6/mm^3$  2. Staff interview with the practice manager on 10/19/2021 at 11:00 AM confirmed the reference range for RBC male and female in the procedure referenced above did not correlate with the reference range on the final patient test report. 3. The laboratory performs 864 tests annually in the specialty of Hematology.