

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2103917	(X3) Date Survey Completed 07/17/2019
Name of Provider or Supplier Convenientmd Urgent Care - Keene	Street Address, City, State 351 Winchester St, Keene, 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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to demonstrate that it can obtain performance specifications comparable to the manufacturer for accuracy, precision, and reportable range for a new hematology analyzer in April 2019. Findings include: 1) Review on 7/17/2019 of verification of performance specification records for the Sysmex XP 300 hematology analyzer revealed the manufacturer representative set up the new instrument and performed studies for accuracy, precision, reportable range, and a correlation study for complete blood cell counts (CBC) on 4/11/2019. Further review revealed no documentation that laboratory personnel performed testing to verify the manufacturer's performance specifications for accuracy, precision and reportable range for measured CBC analytes (white blood cell count, red blood cell count, hemoglobin, hematocrit, and platelet count) on the new instrument. 2) Review on 7/17/2019 of the laboratory's policy titled "Establishment and Verification of Performance Specifications" effective 7/13/2019, revealed instruction for the laboratory to obtain a commercially available kit and to perform the testing for verification of the manufacturer's performance specifications. 3) Interview on 7/17/2019 at 10:30 a.m. with the two technical consultants confirmed the laboratory did not perform its own studies to verify the manufacturer's performance specifications for accuracy, precision, and reportable range for the new Sysmex XP 300 hematology</p>

analyzer. It was revealed that the laboratory has performed and reported 133 CBC results since beginning testing in April 2019 using the new analyzer.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(2)

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview on 6/30/15, the technical consultant failed to ensure the laboratory verified test performance characteristics for the Sysmex XP 300 instrument. Cross reference tag D5421.