

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2087936	(X3) Date Survey Completed 09/25/2018
Name of Provider or Supplier Convenientmd Urgent Care - Dover	Street Address, City, State 14 Webb Pl, Dover, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the current procedures for hematology testing was not signed and dated for approval by the current laboratory director. Findings include: 1) Review on 9/25, 2018 of all procedures for complete blood cell count (CBC) testing revealed the current laboratory director had not signed and dated them for approval. 2) Interview on 9/25/2018 at 2:30 p.m. with the director of quality assurance and compliance confirmed the CBC procedures were not signed and dated for approval by the current laboratory director.</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, results of hematology control materials failed to meet the laboratory's criteria for acceptability prior to reporting patient hematology test results in 2018. Findings include: 1) Review on 9/25/2018 of the laboratory's procedure titled "Hematology Quality Control Guidelines" revised 3/25 /2016, revealed three levels (low, normal and high) of controls for complete blood count (CBC) testing must be performed every day and all three levels must be within</p>

each level's acceptable ranges. Control levels with results not within acceptable ranges are to be repeated and further troubleshooting needed if still out of range. If, after troubleshooting, control results are still out of acceptable range then the analyzer is to be taken out of service and no patient specimens are to be tested. 2) Review on 9/25/2018 of CBC control records from 2/23/2018 through 9/25/2018 revealed on 6/23/2018, 8/25/2018 and 9/10/2018 the high control failed to meet acceptable criteria and was not resolved. 3) Review on 9/25/2018 of patient records from June 2018, August 2018 and September 2018 revealed one patient CBC test had been assayed on 6/23/2018, one patient CBC test had been assayed on 8/25/2018, and one patient CBC tests had been assayed on 9/10/2018. 4) Interview on 9/25/2018 at 2:30 p.m. with the director of quality assurance and compliance confirmed the above findings.