Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2152251	12/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Norton Immediate Care Center - Dupont	901 Dupont Rd, Suite 100, Louisville, KY	

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	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review, review of the policy and procedure manual, and staff interview on 12/05/2018, the laboratory failed to ensure the policy for the performance of Complete Blood Cell counts performed on the AcT Diff 2 hematology analyzer was approved, signed, and dated by the laboratory director prior to patient testing and reporting results. Findings include: Review of records for the hematology analyzer revealed the instrument was initially used for patient testing and reporting 10 /19/2018. Review of the policy and procedure for the hematology analyzer failed to include the laboratory director's review and approval prior to 10/19/2018. Interview with staff at 12:45 PM on 12/05/2018, revealed the laboratory failed to have a policy in place to ensure all procedures were reviewed, approved, signed, and dated prior to patient testing and reporting.
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 staff interview on 12/05/2018, the laboratory failed to ensure the laboratory director/technical consultant review, approve, sign, and date the performance specifications for the AcT Diff 2 hematology analyzer prior to routine patient testing. Findings include: Record review revealed performance specifications (precision, accuracy, reportable range verification, reference range verification) were established for the AcT Diff 2 hematology analyzer 10/18/2018. There was no documentation of review by the laboratory director/technical consultant prior to patient testing on 10/19/2018. Interview with staff at 12:45 PM on 12/05/2018, revealed the laboratory failed to have a policy in place to ensure all performance specifications for each nonwaived unmodified test system were reviewed, approved, signed, and dated prior to reporting patient test results.