Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 42D2053859	**(X3) Date Survey Completed** 02/22/2018
Name of Provider or Supplier Liberty Doctors Dba South Strand Urgent Care	**Street Address, City, State** 11405 Ocean Highway, Pawleys Island, SC	
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**
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: During an onsite recertification certification survey on 02/22/2018, based on the Drew 3 hematology analyzer operator's guide, laboratory temperature records, and testing personnel interview, the laboratory failed to document an acceptable room temperature for 81 out of 730 days reviewed in 2016 and 2017. Findings include: 1. The Drew 3 hematology analyzer operator's guide stated that the instrument should be operated in an ambient room temperature of 64.4 to 89.6 degrees fahrenheit. 2. Review of the laboratory's temperature records revealed 81 out of 730 days in 2016 and 2017 during which room temperature was recorded below 64.4 degrees Fahrenheit. There was no corrective action for the out of range temperature. 3. Testing personnel confirmed during an onsite interview on 02/22/2018 at 2:00pm that the laboratory failed to document an acceptable room temperature for 81 out of 730 days reviewed in 2016 and 2017.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: During an onsite recertification survey on 02/22/18, based on the Drew 3 hematology analyzer operator's guide, laboratory record review, and testing personnel interview, the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for 2 of 2 years reviewed (2016 and 2017). Findings include: 1. Review of the Drew 3 hematology analyzer operator's guide revealed that the syringe pistons should be lubricated every six months. 2. Review of laboratory records revealed there was no documentation of six month maintenance for the syringe pistons available for review for 2016 or 2017. 3. Testing personnel confirmed during an onsite interview on 02/22 /2018 at 2:00pm that the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.
D5777	COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c) (b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: During an onsite recertification survey on 02/22/2018, based on laboratory procedure manual review, lack of documentation, and testing personnel interview, the laboratory failed to ensure that a system to identify and assess patient test results that appear inconsistent was followed in the laboratory for 2 of 2 years reviewed (2016 and 2017). Findings include: 1. The laboratory's procedure manual stated that 5 random patient reports would be selected quarterly and evaluated for consistency with the following criteria: a: Patient age. b: Sex. c: Diagnosis or pertinent clinical data. d: Distribution of patient test results. e: Relationship with other test parameters 2. Documentation of the laboratory's system to identify and assess patient test results that appear inconsistent with the stated criteria for the years 2016 and 2017 was unavailable for review on the day of the survey. 3. Testing personnel confirmed during an onsite interview on 02/22/2018 at 2:00pm that the laboratory had failed to ensure that a system to identify and assess patient test results that appear inconsistent with the relevant criteria was followed in the laboratory for 2 of 2 years reviewed (2016 and 2017).
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by:

	During an onsite recertification survey on 02/22/2018, based on CMS 209 review, testing personnel record review, and testing personnel interview, the laboratory failed to document annual competency evaluations for 2 of 4 testing personnel responsible for moderate complexity hematology testing for 2 of 2 years reviewed (2016 and 2017). Finding include: 1. The laboratory listed 4 testing personnel for moderately hematology complex testing on the CMS 209 on the day of the survey. 2. Review of testing personnel records revealed that employees 1 and 4 did not have documented annual competency evaluations for the years 2016 or 2017 available for review on the day of the survey. 3. Testing personnel confirmed during an onsite interview on 02/22 /2018 at 2:00pm that the laboratory failed to document annual competency evaluations for 2 of 4 testing personnel responsible for moderate hematology complexity testing for the years 2016 and 2017.