Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0251274	04/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Roper St Francis Physician Network	306 Station 22 1/2 Street, Sullivans 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: During an onsite recertification survey on 04/17/2019, based on American Academy of Family Practitioners (AAFP) proficiency testing record review, and testing personnel interview, the laboratory failed to review and evaluate proficiency testing results for 1 of 6 proficiency testing events reviewed from 2017 through 2019 (2017, Event C). Findings include: 1. Review of AAFP proficiency testing results revealed the following scores: a. 2017, Event C; 50% for vaginal wet prep identification There was no documentation of director review and evaluation or corrective action for the failure. 2. Testing personnel confirmed during onsite interview on 04/17/2019 at 02: 15pm, that the laboratory had failed to review and evaluate proficiency testing results.
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 survey on 04/17/2019, based on the ActTDiff 2 operator guide review, laboratory room temperature and humidity record review, and testing personnel interview, it was determined that the laboratory failed to maintain acceptable room temperatures and humidity values between June 1, 2018 through the day of the survey. Findings include: 1. The ActTDiff 2 operator guide had a required room temperature range of 16 to 35 degrees Celsius and a required room humidity between 20 and 85 percent. 2. Review of the laboratory's temperature and humidity records revealed that temperature and humidity values were not recorded from June 1, 2018 through the day of the survey. There was no corrective action for the missing values during this time period available for review. 3. Testing personnel confirmed during an onsite interview on 04/17/2019 at 2:15 pm that the laboratory had failed to maintain proper humidity values.
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 04/17/2019, based on the lack of documentation and testing personnel interview, the laboratory failed to develop and follow a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: patient age, sex, diagnosis or pertinent clinical data, distribution of patient test results, and relationship with other test parameters for 2 of 2 years reviewed (2017 and 2018). Findings include: 1. The laboratory's system to identify and assess patient test results that appear inconsistent with the following relevant criteria; patient age, sex, diagnosis or pertinent clinical data, distribution of patient test results, and relationship with other test parameters was unavailable for review on the day of the survey. Documentation of any routine review was unavailable on the day of the survey. 2. Testing personnel confirmed during an onsite interview on 04/17/2019 at 2:15pm that the laboratory had failed to ensure routine test result assessments were performed as required.
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 04/17/2019, based on the CMS 209 review, lack of documentation and testing personnel interview, the laboratory failed to ensure that testing personnel were evaluated annually after the first year of testing patient specimens for 8 of 8 testing personnel (employees 1 through 8 on CMS 209) for 2 of 2 years reviewed (2017 and 2018) . Findings include: 1. The laboratory listed 8 testing personnel on the CMS-209 on the day of the survey. 2. Documentation of an annual

	training and evaluation was unavailable for review on the day of the survey for 8 of 8 testing personnel (employees 1 through 8 on CMS 209) for two of two years reviewed (2017 and 2018) . 3. Testing personnel confirmed during an onsite interview that the laboratory had failed to ensure that testing personnel were evaluated at least annually after the first year of testing patient specimens.