Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0095270	04/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Shoreline Ob-Gyn	4 Shaws Cove, Suite 204, New London, CT	

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: Based on record review and staff interview, the laboratory failed to ensure proper temperature of reagents and PACs prior to use. Findings include: 1. Record review on 4/30/18 of the laboratory's temperature logs from 6/15/16 to 4/30/18 revealed: a) Acceptable room temperature range is 22-28 degrees Celsius (C). b) Recorded room temperature was out of range 51 of 135 working days from 6/15/16 to 12/30/16. c) Recorded room temperature was out of range for 115 of 248 working days in 2017. d) Recorded room temperature was out of range for 67 of 80 working days in from 1/1 /18 to 4/30/18. e) Corrective action was not documented when temperatures were out of range. f) Temperature charts were signed as reviewed. 2. Record review on 4/30/18 of the Affirm VPIII package insert revealed, "All reagents and PACs must be at 22 to 28 degrees C prior to use." 3. Record review on 4/30/18 of the laboratory's 'Monthly QA Checklists from January 2017 to April 2018 revealed, the line item titled, "When humidity or temperature checks are out of acceptable range, corrective action was taken and documented," was checked off as completed. 4. Staff Interview with the practice administrator on 4/30/18 at 11:30 AM confirmed the above. 5. The laboratory performs 1,170 tests annually in the specialty of microbiology
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure all testing personnel (TP) tested unknown samples to demonstrate competency in performing laboratory tests in the specialty of microbiology. Findings Include: 1. Record review of the 2016, 2017 and 1st event of 2018 American Proficiency Institute attestation sheets for the BD Affirm on 4/30/18 revealed, 1 of 1 new TP did not examine proficiency testing material to accurately assess their skills. 2. Record review on 4/30 /18 of the 2016 and 2017 employee competency records, revealed: a) 1 of 1 new TP did not examine previously analyzed specimens, internal blind testing samples or external proficiency testing samples to accurately assess their skills prior to performing patient testing. b) 2 of 5 testing personnel did not examine previously analyzed specimens, internal blind testing samples or external proficiency testing samples to accurately assess their skills in 2017. 3. Staff interview with the practice administrator on 4/30/18 at 11:01 AM confirmed the above. 4. The laboratory performs 1,170 tests annually in the specialty of microbiology.