Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0923243	01/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Stormont Vail Health Ob/Gyn-Lincoln Center,	800 Sw Lincoln St, Topeka, KS	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a lack of proficiency testing (PT) attestation documentation from the provider American Proficiency Institute (API) performed after August 29, 2018 until date of survey and interview, the laboratory failed to attest on four of four testing events that proficiency testing samples were handled in the same manner as patient samples. Findings: 1. Attestation documentation for four of four proficiency testing events (listed below) from August 29, 2018 to January 13, 2020 was requested but none were availible at the time of survey. a. API 2018 Microbiology, 3rd Event. b. API 2019 Microbiology, 1st, 2nd, and 3rd Events 2. Interview with Technical Consultant (TC) #2 on January 13, 2020 at 1:35 p.m. confirmed, the laboratory failed to attest on four of four testing events that proficiency testing samples were handled in the same manner as patient samples.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on the review of manufacturer's test procedure requirements, lack of documentation, and interview, the laboratory failed to establish and perform a function check on their timer and two of two thermometers. Findings: 1. Review of the Affirm VP III Microbial Indentification test procedure revealed an incubation step that required the use of a timer. 2. Request was made to review the timer function check protocol and records. No documentation was available at the time of survey. 3. Request was made for two of two thermometer function check protocol and records. No documentation was available at the time of survey. 4. Interview with the TC #2 on January 13, 2020 at 1:15 p.m. confirmed, the laboratory failed to establish and perform a function check on their timer and two of two thermometers.