Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0154840	05/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
William H Simon Md	2940 Lincoln Avenue, Suite 201, Oceanside, NY	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a surveyor's review of the manufacturer's packet inserts for the Alere i Rapid Strep A, Alere i Influenza A&B and an interview with the laboratory supervisor /testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls for waived testing from February 2018 through the survey date. FINDINGS: 1. The laboratory performs Rapid Strep A and Influenza A&B testing. The manufacturer of the Alere i Rapid Strep A and Alere i Influenza A&B require that external positive and negative controls, included in each test kit, be performed for each kit opened prior to use for patient testing. 2. On May 21, 2019 at approximately 11:30 AM, the laboratory supervisor/testing person confirmed surveyor's findings that the required external positive and negative quality controls were not performed for the Rapid Strep A and for the Influenza A&B kits with each new kit opened from February 2018 through the survey date. 3. Approximately 50 patients specimens were tested and reported for Rapid Strep and influenza A&B testing from February 2018 through the survey date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on surveyor's review of the quality Control (QC) records and an interview with the laboratory supervisor/testing person, the laboratory failed to discontinue the use of expired testing materials. FINDINGS: On May 21, 2019 at approximately 11:30 AM the laboratory supervisor confirmed surveyor's findings that the laboratory used an expired Alere i Rapid Strep kit lot # 099986 expiration date 3/19/19 to test Rapid Strep for one patient on 4/1/19 and used expired Rapid Strep kit on one patient on 4/3 /19.