Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0671282	01/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
John R Zaso Do Pc	2073 Newbridge Road, Bellmore, 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 the surveyor's review of the laboratory's Quality Control (QC) records and interview with the laboratory supervisor and the laboratory administrator, the laboratory failed to follow the manufacturer's instructions for performing external positive and negative controls with each new lot of Henry Schein Influenza A&B kit, each new lot of Henry Schein Rapid Strep kit and with each new lot of Binax RSV kit. FINDINGS: 1. On 1/10/2018 at approximately 11:00 AM the laboratory supervisor and the laboratory administrator confirmed surveyor's findings that although the laboratory documented the lot numbers, expiration dates and the received dates, there were no records of external positive and negative controls for each new lot of Henry Schein Influenza A&B, each new lot of Henry Schein Rapid Strep and with each new lot of Binax RSV from September 2017 through the survey date. 2. Approximately 60 patient specimens were tested and reported for Influenza A&B, RSV and for Rapid Strep during the above time frame.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Assessment (QA) polices /procedures and an interview with and confirmed by the laboratory supervisor and the laboratory administrator, the laboratory failed to follow the laboratory's written QA policy and perform general laboratory systems QA reviews yearly for bacteriology testing in calendar years 2016 and 2017.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's findings and interview with the laboratory supervisor and the laboratory administrator, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. maintained the plan of correction from the survey conducted on October 11, 2016; and, 2. maintained the laboratory's QA program for bacteriology; refer to D6021.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor's review of the Quality Assessment (QA) policy and an interview with the laboratory supervisor and the laboratory administrator, the laboratory director failed to ensure that the general laboratory systems QA reviews were performed annually, as required by their QA policy, in calendar years 2016 and 2017. PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY OF OCTOBER 11, 2016.