Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1009337	01/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
John R Zaso Do Pc	611 Merrick Avenue, East Meadow, 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 surveyor's review of the manufacturer's packet insert for OSOM Genzyme Influenza A&B and Binax NOW RSV and interview with the laboratory supervisor /testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new kit of Influenza A&B and Binax NOW RSV opened. FINDINGS: 1. The laboratory is using the OSOM Genzyme Influenza A&B and Binax NOW RSV kits. The manufacturer of the OSOM Genzyme and The Binax require that external positive and negative controls (provided in the kits) be performed with each new lot number/shipment. 2. On January 28, 2019 at approximately 11:00 AM the laboratory supervisor confirmed surveyor's findings that documentation for the required external control testing was not available at survey for calendar year 2017. 3. Approximately 50 patient specimens were tested and reported for Influenza A&B and RSV testing during the above time frames.
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 hematology quality Control (QC) records and an interview with the laboratory supervisor/testing person, the laboratory failed to discontinue the use of expired hematology quality control materials. FINDINGS: 1. On January 28, 2019 at approximately 11:00 AM the laboratory supervisor confirmed surveyor's findings that the laboratory used 3 levels of expired QC for hematology testing lot numbers:068300, 078300 and 088300 expired 2/15/18 for Quality controls low, normal and high respectively from 2/16/18 through 2/28/18. 2. The laboratory used 3 levels of expired QC for hematology testing lot numbers: 068800, 078800 and 088800 expired 5/8/17 for Quality controls low, normal and high respectively from 5/9 /17 through 5/27/17. 3. Approximately 60 patients were tested for hematology using the expired quality control materials during the above time frames.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor's review of the bacteriology Quality Control (QC) documentation and an interview with the laboratory supervisor/testing person, the laboratory failed to check each new batch, lot number and shipment of 0.04 bacitracin disc for positive and negative reactivity in calendar year 2017. FINDINGS: 1. On January 28, 2019 at approximately 10:30 AM the laboratory supervisor/testing person confirmed surveyor's findings that the laboratory failed to check each new batch, lot number and shipment of the bacitracin disc for positive and negative reactivity in calendar year 2017. 2. The laboratory failed to record the lot number/expiration date for the shipment of bacitracin disc received in the lab in calendar year 2017. 3. Approximately 1500 patients specimens were tested and reported for throat culture during this time period.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the surveyor's review of Quality Control (QC) records and confirmed, during this onsite survey with the laboratory supervisor/testing person, the laboratory director failed to ensure that the QC program for hematology and bacteriology testing

	was maintained to assure quality of laboratory services. Refer to: D1001, D5417, D5471