Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0883452	04/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Patricia Ford Md Faap	71 Oak Street, Amityville, 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
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 a surveyor's review of the of laboratory's Quality Assurance (QA) policy and confirmed in an interview with the laboratory director/testing person at the time of this survey, the laboratory failed to follow their established written QA policy and identify issues and correct the problems in the calendar years 2017, 2018 and up to survey date. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON APRIL 21, 2017.
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 a surveyor's review of laboratory temperature records and an interview with

	the laboratory director/testing person, the laboratory failed to follow the manufacturer's instructions for monitoring and maintaining incubator temperatures for incubating throat cultures. Findings Include: 1. The laboratory performs throat culture. The manufacturer of the throat culture media used for testing requires that the incubation temperature to be in the range of 35-37 degree Celsius. The incubator temperature was outside the acceptable ranges for 18 days in calendar year 2018. 2. The temperature of the incubator was not monitored from November 3, 2018 through December 31, 2018. 3. Approximately 50 specimens were tested and reported for throat culture during the above time period. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON APRIL 21, 2017.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor's review of bacteriology Quality Control (QC) documentation and an interview with the laboratory director/testing person, the laboratory failed to perform QC as required from April 2017 through survey date. The laboratory failed to: 1. Perform and document the sterility for the SSA Media; 2. Document the physical characteristics of the SSA Media for any deterioration; 3. Approximately 400 specimens were tested and reported for throat culture during the above time period. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON APRIL 21, 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 findings and interview with the laboratory director/testing person, 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 4/21/2017; 1. Maintained the laboratory's QC program for bacteriology. Refer to D6020; and, 2. Maintained the laboratory's established QA program for all phases of laboratory testing. Refer to D6021. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON APRIL 21, 2017.
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 a review of QC records, and confirmed in an interview with the laboratory director/testing person at the time of this survey, the laboratory director failed to ensure that the QC program for bacteriology testing was maintained to assure the quality of laboratory services. Refer to: D5413, D5477 THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON APRIL 21, 2017.
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 lack of the Quality Assessment (QA) records, and an interview with the laboratory director/testing person, the laboratory director failed to ensure that the general laboratory systems QA reviews were performed three times a year, as required by their QA policy, in calendar years 2017, 2018 and up to survey date. Refer to D5291 THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON APRIL 21, 2017.