Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2123790	(X3) Date Survey Completed 02/12/2019
Name of Provider or Supplier Crown Heights Medical Pc	**Street Address, City, State** 4426 18th Avenue, Brooklyn, 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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor's review of American Proficiency Institute (API) Proficiency Testing (PT) records, lack of documentation and confirmed in an interview with the chief operations officer , the laboratory failed to retain API records to include: signed attestation forms, test result forms, and signed PT summary reports for the 2017 3rd event and all three events for 2018. FINDINGS: 1. The chief operations officer confirmed on February 12, 2019 at approximately 12:30 PM, the laboratory failed to retain API records to include: signed attestation forms for 2017 3rd event and all three events in 2018, test result forms for 2017 3rd event and all three events in 2018, and signed PT summary reports for the 2017 3rd event and all three events in 2018. 2. Surveyor was not able to determine if the PT samples were tested by all testing personnel who perform bacteriology/throat culture testing for the 3rd event in 2017 and all three events in 2018.
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 surveyor's review of the laboratory's Quality Assessment (QA) policies and

	procedures, lack of documentation and confirmed in an interview with the chief operations officer, at the time of this survey, the laboratory failed to follow their established QA policy and perform a QA review for the 2018 calendar year. FINDINGS: The chief operations officer confirmed on February 12, 2019 at approximately 1:00 PM, the laboratory failed to follow their laboratory's QA policy to include an annual review of the following systems: monitoring, assessing, and, when indicated, correct problems identified in the general laboratory system. actions must be taken to correct the situation for specimen identification and integrity; personnel competency; Quality control for bacteriology and proficiency testing performance.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the surveyor's review of API PT records and reports and confirmed in an interview with the chief operations officer, the laboratory director failed to review (sign and date) the scored proficiency testing reports received from API to evaluate the laboratory's performance for the 3rd event of 2017 and all three events of 2018. Refer to D3037.
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 laboratory's QA policy, lack of documentation and interview with the chief operations officer, the laboratory director failed to follow and maintain their QA policy to monitor, assess and when indicated correct problems identified in the general laboratory system for bacteriology in calendar year 2018. Refer to D3037 and D5291.