

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2154552	(X3) Date Survey Completed 07/24/2020
Name of Provider or Supplier Crown Heights Medical Pc	Street Address, City, State 1 Main Street, Monsey, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) desk review of Center for Medicaid and Medicare Service (CMS) PT data reports, the laboratory failed to enroll in an approved PT program for the sub- specialty Bacteriology/Throat Culture and the specialty Hematology/Complete Blood Count (CBC) for the calendar year 2020.</p>
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p>

	<p>This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT data reports and the 2019 American Proficiency Institute (API) PT program reports, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the specialty Hematology and the test analytes Red Blood Cell Count (RBC), White Blood Cell Count (WBC), Hematocrit (Hct), Hemoglobin (Hgb), Cell Identification (Cell I.D.) /WBC Differential (WBC Diff.) and Platelets. 2019 third event = 0% [non-participation] This is considered unsatisfactory PT performance.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on PT desk review of CMS PT data reports, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory was enrolled in an HHS approved PT program. Refer to D6015.</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT data reports, the laboratory director failed to enroll the laboratory in a HHS PT program for the sub-specialty Bacteriology/Throat Culture and the specialty Hematology/CBC in the calendar year 2020. Refer to D2000.</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on PT desk review of the PT CMS data reports and the 2019 API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program for the specialty Hematology and the test analytes RBC, WBC, Hct, Hgb, Cell I.D./WBC Diff. and Platelets. The following score was assigned: 2019 third event = 0% [non-participation] This is considered unsatisfactory PT performance.