

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2154552	<b>(X3) Date Survey Completed</b>  06/13/2019
<b>Name of Provider or Supplier</b>  Crown Heights Medical Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the laboratory's director, the laboratory failed to have a complete procedure manual. Finding Include: The laboratory director confirmed in an interview on June 13, 2019, at approximately 12:45 PM, that the laboratory failed to have a complete procedure for the lot to lot verification of new control material.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory procedure manual and an interview with the laboratory director, the director did not approve, sign and date the laboratory's procedures. Finding Include: It was confirmed by the laboratory director on June 13, 2019, at approximately 1:00 PM, that the laboratory director failed to approve, sign and date the Individualized Quality Control Plan (IQCP) validation procedure for throat culture testing.

**D5411**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on a review of patient test reports, package inserts for the Bacitracin disk, Becton Dickinson/Healthlinks Strep Selective Agar plates and an interview with the laboratory director, the laboratory failed to follow the manufacturer's instructions for plating patient specimens on the SSA plates and reporting throat culture test results. Finding Includes: It was confirmed with the laboratory director on June 13, 2019, at approximately 1:15 PM pm, that: 1) patient test results for throat cultures are reported as "Positive". 2) The manufacturer's package inserts for the Bacitracin disk and SSA media states that patient test results for throat culture testing are to be reported as "presumptive positive". 3) The laboratory testing personnel places four patient test specimens on one 100 mm SSA plates. 4) The manufacturer's package inserts for the SSA plates states that "To culture, a specimen from a swab, inoculate the medium by rolling the swab over a third of the agar surface and streak the remainder of the plate to obtain isolated colonies".

**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 review of the incubator temperature records and an interview with the laboratory director, the laboratory failed to follow the manufacturer's instructions for monitoring and maintaining incubator temperatures for incubating throat cultures.

Findings Include: 1. The director confirmed on June 13, 2019, at approximately 1:15 PM that the laboratory did not follow the manufacturer's temperature range instructions for the incubation of throat cultures. 2. Throat cultures are to be incubated at a temperature range of 33 - 37C. The documented incubator temperatures from December 18, 2018, through June 13, 2019, ranged between 22 - 32C and 38 - 42C for 91 of the 190 days of patient testing. 3. Approximately 858 patient samples were tested and results reported during this time period.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on a lack of validation records and an interview with the laboratory director, the laboratory failed to establish and verify the performance specifications for plating more than one specimen on a SSA plate with Bacitracin disk to show accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range of test results for the test system, reference intervals (normal values), any other performance characteristic required for test performance. How does the laboratory prevent cross-contamination? How does the laboratory show that the zone size will be the same for all additional specimens plated on the media that is 100 mm in diameter Findings Include: 1. On June 13, 2019, at approximately 1: 15 PM it was confirmed with the laboratory director that four patient specimens were placed on the SSA plates with bacitracin disk. 2. The PI stated "To culture, a specimen from a swab, inoculate the medium by rolling the swab over a third of the agar surface and streak the remainder of the plate to obtain isolated colonies". 3. The laboratory failed to validate placing four patient specimens on one-100 mm SSA plate with bacitracin disk prior to the lab performing patient testing. 4. Approximately 858 patient specimens were tested and reported for throat cultures from December 2018 through June 13, 2019. 5. Please also note, a qualified high complexity director is required when off-label use is instituted.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii)

Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:  
Based on a review of calibration records and an interview with the laboratory director, the laboratory failed to calibrate the hematology analyzer every six months. Findings Include: It was confirmed by the laboratory director on June 13, 2019, at approximately 1:30 PM that; 1. The Manufacturer requires calibration to be performed every six months; 2. Calibration was performed on September 10, 2018; 3. Calibration was due March 10, 2019; 4. The Abacus 3ct was out of calibration from March 10, 2019, through June 13, 2019 (3 months). Approximately 150 patient specimens were tested and reported for hematology testing when calibration was not performed.

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on a review of hematology control records and an interview with the laboratory director, it was not possible to determine if appropriate remedial action had been taken when results of control material failed to meet the laboratory's established criteria for acceptability. Findings: Include: It was confirmed with the director on June 13, 2019, at approximately 1:30 PM that the control ranges for the new lot was not entered into the Abacus hematology analyzer, therefore, the Levy Jennings graph with the ranges for the three levels of controls could not be printed on the control sheet. It was not possible to determine if prior control values were within acceptable limits and if not, whether appropriate remedial action had been taken for unacceptable controls tested from April 16, 2019, through June 13, 2019. Approximately 59 patients were tested and results released during that time.

**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.

	<p>This CONDITION is not met as evidenced by: Based on a review of laboratory records and interview with the laboratory director, the laboratory director failed to provide overall management and direction for the laboratory and ensure that: 1. The QC procedures are maintained for bacteriology testing; Refer D6020 2. The QA policies are maintained; Refer to D6021 3. Training records for laboratory personnel were available for review; Refer to D6029</p>
<b>D6020</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of QC and calibration records, and an interview with the laboratory director, the laboratory director failed to ensure that the QC program for hematology was maintained to assure quality laboratory services. Refer to: D5437 &amp; D5469</p>
<b>D6021</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory procedures, patient test reports, observation, and an interview with the laboratory director, the laboratory director failed to maintain an effective QA program for bacteriology and hematology testing. Refer to D5403, D5407, D5411, D5413, and D5423</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p>

	<p>This STANDARD is not met as evidenced by:  Based on a review of personnel records and an interview with the laboratory director, the laboratory failed to have documentation of training for the throat culture testing. Findings Include: On June 13, 2019, at approximately 12:30 AM, it was confirmed with the laboratory director that the director failed to ensure that appropriate training was done for five of five testing personnel who perform moderate complexity testing for throat cultures testing.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b>  CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by:  Based on a lack of education records and an interview with the laboratory director, the laboratory director failed to ensure that the five of five testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing. Refer to D6065</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b>  CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by:  Based on a review of personnel records and confirmed in an interview with the laboratory managers on June 11, 2019, at approximately 11:00 AM, the laboratory director failed to ensure that the three of three new testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing.</p>