| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 33D1002531 | 08/08/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Women's Health Care Pc | 87-16 Avon Street, Jamaica Est, 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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory procedure manual and an interview with the technical consultant and the laboratory testing person, the laboratory failed to have a complete procedure manual. Finding Include: The technical consultant confirmed in an interview on August 8, 2019, at approximately 1:15 PM, that the laboratory failed to have the following procedures available for review: 1) The lot to lot verification for the new lots of control material. 2) Periodically verification of the electronic calculations from the Laboratory Information System (LIS) for eGFR test results. |
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| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the storage refrigerator temperature records, and an interview with the technical consultant and the laboratory testing person, the laboratory's storage freezer temperature failed to have a reading of -20 degrees Celsius or lower as required by the manufacturer. Findings Include: 1) The manufacturer's package insert states that controls and calibrator for Free T 4, Prolactin, and B-hCG are to be stored in the freezer at -20 degrees Celsius. 2) A review of the documented freezer temperature records for 2018 through the date of this survey showed that the temperature was -18 degrees Celsius and above. 3) The testing person stated, "I did not know that the freezer temperature for those analytes required a specific freezer temperature for storage". 4) The technical consultant and the laboratory testing person confirmed on August 8, 2019, at approximately 2:45 pm that the package insert stated the freezer temperature Free T4, Prolactin, and B-hCG is to be stored at -20 degrees Celsius. 5) Approximately 69 patient specimens were tested and results released during that time. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a surveyor's review of QC records and an interview with the technical consultant and the laboratory testing person, the laboratory failed to perform and document lot to lot verification for the assayed quality controls prior to testing patient specimens. Findings Include: On August 8, 2019, at approximately 1:15 am, the technical consultant confirmed that the laboratory had not verified assayed QC material tested on the Horiba ABX Micros 60, ABX Pentra 400 and BD Access 2 prior to patient testing for the year 2018 through the date of this survey. |

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| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of quality assurance (QA) procedure and an interview with the technical consultant and the laboratory testing person, the laboratory failed to have a mechanism in place to verify the accuracy of their LIS system transfer of data. Finding include: It was confirmed with the technical consultant at approximately 1:45 pm that the laboratory failed to have a mechanism in place to periodically verify the accuracy of the calculated data, results sent to the interfaced system and patient data for Glomerular Filtration Rate (GFR). |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory procedures, QC records and an interview with the technical consultant and laboratorty testing person, the laboratory director failed to ensure that the QC program was maintained for testing. Refer to: D5469 |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of QA procedures, and an interview with the laboratory director and testing person, the director failed to ensure that the laboratory's QA program was maintained for all areas of laboratory testing. Refer to: D5403, D5413 and D5801 |

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| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of personnel records and an interview with the technical consultant and testing person, the laboratory director failed to ensure that documentation of education was available at the time of the survey for the new testing person. Refer to D6065 |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(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<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of personnel records and confirmed in an interview with the the technical consultant on August 8, 2019, at approximately 4:00 pm, the laboratory director failed to ensure that the new testing person performing moderate and high complexity testing met the minimum educational requirements of an Associates degree and/or a foreign education diploma evaluated prior to performing patient testing. |