| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 22D2231843 | 05/11/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Health Quality Primary Care | 217 Sutton Street, North Andover, MA | |

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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| **D0000** | An initial CLIA certification survey was conducted for the Health Quality Primary Care laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. |
| **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 procedure manual review and interview, the laboratory procedure manual failed to include all required procedures as evidenced by the following: a) A review of the laboratory's procedure manual on 5/11/23 at 9:46 AM revealed that there was no |

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| | procedure outlining imminently life-threatening test results, or panic or alert values as well as the protocol for reporting imminently life threatening results, or panic, or alert values. b) A review of sixteen patient reports on 5/11/23 at 11:12 AM for testing performed between 12/19/22 and 2/7/23 revealed one patient report containing a 700 mg/dL (milligrams per deciliter) glucose result. There was no indication on the report or in the patient's medical record that the result was reported to the appropriate personnel. c) The technical consultant interview on 5/11/23 at 9:50 AM confirmed that there was no procedure outlining imminently life-threatening test results, or panic or alert values as well as the protocol for reporting imminently life threatening results, or panic, or alert values. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory's final report contained erroneous interpretive information as evidenced by the following: a) A review of sixteen final reports on 5/11/23 for laboratory testing performed between 12/19/22 and 2/7/23 revealed that for Lipid panel testing, when the Cholesterol/HDL (High Density Lipoprotein) ratio as well as the non HDL parameters were within the normal ranges (less than 5 milligrams per deciliter for the Cholesterol/HDL and less than 130 nanograms per deciliter for Non HDL) the final report erroneously indicated that the results were abnormal (sample record numbers 2, 9, 12, 14, 15, and 16 reviewed). b) The Technical Consultant confirmed in an interview on 5/11/23 at 11:15 AM that the normal Cholesterol/HDL ratio as well as the non HDL results were being erroneously reported as abnormal. c) The laboratory performs approximately 2,900 lipid panels annually. |
| **D6011** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(2)<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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, the laboratory director failed to provide a safe environment environment in which employees are protected from chemical and biological hazards as evidenced by the following: Eyewash * During a tour of the laboratory areas it was |

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| | observed at 10:19 AM that there was no eyewash available in the Hematology testing area. Fire extinguishers * During a tour of the laboratory areas it was observed at 10: 19 AM and 11:15 AM that the fire extinguishers in the Hematology and Chemistry testing areas were not securely mounted. |