Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D2134222	12/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Men's Health	14 Keewaydin Dr, Ste A, Salem, NH	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow manufacturer's instructions for waived hematology testing in 2018. Findings include: 1) Review on 12/13/18 of the "Listing of Tests Performed in the Facility" completed by the Technical Consultant revealed the laboratory performed hemoglobin testing using the Hemocue Hb 201 analyzer (Hemocue). 2) Review on 12/13/18 of the package insert for "Hemocue Hb 201 Microcuvettes" revealed the intended use of the microcuvettes is the "Quantitative determination of hemoglobin..." 3) Review on 12/13 /18 of two patient final reports from December 2018 revealed hematocrit results were reported and hemoglobin results were not reported. 4) Review on 12/13/18 of the laboratory's procedure titled "Review of Results - Manual" revealed instruction to multiply hemoglobin results by three to obtain and report the hematocrit result. 5) Interview on 12/13/18 at 10:15 with Staff A (testing personnel) revealed the laboratory did not perform hematocrit testing. Staff A confirmed the reported hematocrit results on the final reports were calculated from the hemoglobin results obtained using the Hemocue. 6) The laboratory performs an estimated 2,000 hemoglobin tests annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance

	with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to meet qualification requirements for directing a laboratory performing high complexity hematology testing and failed to provide overall management and direction for hematology testing in 2018. Findings include: 1) The laboratory director failed to meet qualification requirements to direct a laboratory performing high complexity testing. Refer to tag D6078. 2) The laboratory director failed to ensure test systems selected provided quality hematocrit results. Refer to tag D6085.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to meet qualification requirements to direct a laboratory performing high complexity hematology testing. Findings include: 1) Test system(s) not approved by the FDA, by default, constitutes high complexity testing. The laboratory failed to use a test system

	approved by the FDA for reporting hematocrit results. Refer to tag D6085. 2) The laboratory director's qualifications submitted to the State Agency on June 27, 2018 fail to meet qualification requirements to direct a laboratory performing high complexity testing.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure test methodologies selected to report hematology results have the capability of providing quality results required for patient care. Findings include: 1) Review on 12 /13/18 of the "Listing of Tests Performed in the Facility" completed by the Technical Consultant revealed the laboratory performed hemoglobin testing using the Hemocue Hb 201 analyzer (Hemocue). 2) Review on 12/13/18 of the package insert for "Hemocue Hb 201 Microcuvettes" revealed the intended use of the microcuvettes is the "Quantitative determination of hemoglobin..." 3) Review on 12/13/18 of two patient final reports from December 2018 revealed hematocrit results were reported and hemoglobin results were not reported. 4) Review on 12/13/18 of the laboratory's procedure titled "Review of Results - Manual" revealed instruction to multiply hemoglobin results by three to obtain and report the hematocrit result. 5) Interview on 12/13/18 at 10:15 with Staff A (testing personnel) revealed the laboratory did not perform hematocrit testing. Staff A confirmed the reported hematocrit results on the final reports were calculated from the hemoglobin results obtained using the Hemocue 6) Use of the Hemocue's hemoglobin test result to calculate and report a hematocrit result has not been approved by the FDA and constitutes high complexity testing. 7) The laboratory performs an estimated 2,000 hemoglobin tests annually.