Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 07D2289541	**(X3) Date Survey Completed** 05/09/2024
Name of Provider or Supplier Northeast Men's Health	**Street Address, City, State** 231 Farmington Ave, Ste 105, Farmington, CT	
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**
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure quality control (QC) was within acceptable range prior to reporting patient results in the subspecialty of endocrinology. Findings include: 1. Record review on 5/9/2024 of the manufacturer's 'FastPack System Control Range Card, Control kit lot No.2305031-3 and Control kit lot No.2305031-4 revealed the following: a. Acceptable QC range for Testosterone Control Level 1 (L1) was listed as 170-270 ng/dL b. Acceptable QC range for Prostate Specific Antigen (tPSA) Control L1 was listed as 0.69-1.6 mg/mL 2. Record review on 5/9/2024 of 'Northeast Men's Health Quality Control Chart' revealed the following: a. QC for Testosterone FastPack Control L1 lot number 2305031-3 expiration date 11/3/2024 was recorded as 136 ng/dL on 4/8/2024. b. Prostate Specific Antigen (tPSA) FastPack Control L1 lot number 2305031-4 expiration date 11/3/2024 was recorded as 0.47 mg/mL on 4/22/2024. Note: The laboratory only runs two levels of QC for Testosterone and tPSA. 3. Record review on 5/9/2024 of the 'PSA/Testo Results' log revealed 7 patients were tested and reported for Testosterone on 4/8/2024 and 6 patients were tested and reported for tPSA on 4/22/2024. 4. Staff interview on 5/9/2024 at 12:30 PM with the Technical Consultant and Testing Personnel 1 and 2 confirmed the above findings.