Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2258408	03/31/2025
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Men's Health	11 Apex Drive, Suite 203, Marlborough, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and confirmed through an interview with the technical consultant (TC) and testing personnel #1 (TP1), the laboratory did not have an ongoing mechanism to evaluate the TC based on their CLIA responsibilities. Findings Include: 1. Record review on 3/31/2025 of the laboratory's 2023, 2024 and 2025 to date personnel competency records revealed the laboratory did not have documented competency evaluation for the TC based on their CLIA responsibilities. 2. Record review on 3/31/2025 of the laboratory's, 'Staff Orientation, Training and Competency' procedure revealed: a. The procedure contained a form entitled, 'Competency Evaluation: Technical Consultant/Technical Supervisor.' b. The procedure did not contain any information about the above form. c. The procedure did not contain any information about TC competency based on their CLIA responsibilities. 3. During staff interview on 3/31/2025 at 9:55 AM with TP1, TP1 confirmed the laboratory does not have documented competency assessment of the TC both past and present based on their CLIA responsibilities. 4. Staff Interview by telephone on 3/31/2025 at 10:00 AM with the TC confirmed the above findings. The TC stated, "I am new to this position and I haven't been on site yet. The Old TC left on 3/25/2025." 5. The laboratory performs 4,000 tests annually in the specialty of Chemistry.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on quality control (QC) record review and interview with Testing Personnel #1 (TP1) and Testing Personnel #2 (TP2) the laboratory failed to perform and document two control materials as specified in the laboratory's Individualized Quality Control Plan (IQCP). Findings Include: 1. Record review on 3/31/2025 of the laboratory's IQCP revealed 2 levels of QC material are run weekly for Prostate Specific Antigen (PSA) and Testosterone. 2. Record review on 3/31/2025 of the laboratory's QC records revealed QC was not run on the following dates: a. 8/12/2024, 10/3/2024, 11 /26/2024 (PSA) b. 9/9/2024, 9/19/2024, (Testosterone) c. 10/3/2024, 10/31/2024, 11/6 /2024 (PSA and Testosterone) 3. During staff Interview on 3/31/2025 at 9:55 AM with TP1, a. TP1 confirmed the above findings. b. TP1 stated, "We had a very hard time getting in touch with the TC when we needed them. We would frequently receive an away message. Our old TC is no longer working with our laboratory. We have a new TC that recently took over." 4. During staff interview on 3/31/2025 at 12:35 PM with TP2, a. TP2 stated, "I was the only person running controls and when I am not working, the staff does not always remember to run controls or how to troubleshoot." b. The Technical Consultant told us that corrective action was to run QC daily until we consistently did it for 2 weeks, then we could go back to weekly QC. c. TP2 confirmed QC was not run on the days indicated above and patient results were reported for: 8/12/2024 - 8/19/2024 (24 patients) PSA 10/3/2024 - (3 patients) PSA 11 /26/2024 - (1 patient) PSA 9/9/2024 - 9/19/2024, (35 patients) Testosterone 10/3/2024 - (3 patients) PSA and Testosterone 10/31/2024 - (3 patients) PSA and Testosterone 5. The laboratory performs 4,000 tests annually in the Specialty of Chemistry.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers 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 review of the laboratory's quality control (QC) records and interview with Testing Personnel #1 and #2 (TP1) and (TP2), the laboratory failed to ensure the results of control materials were within the acceptable ranges prior to reporting patient test results in the specialty of Chemistry. Findings include: 1. Record review on 3/31 /2025 of the laboratory's Chemistry QC Records revealed: a. On 10/31/2024 QC controls were out of acceptable range and failed for Testosterone and Prostate Specific Antigen. b. Corrective action was not performed and patient results were reported on 3 patients. 2. Staff interview with the TP1 and TP2 on 3/31/2024 at 1:00 PM: a. TP1 confirmed the above QC material was out of the acceptable range on the date noted above and corrective action was not taken. b. TP2 confirmed final patient results were

	reported on 3 patients that were run on 10/31/2024. c. TP2 stated that TP2 was the only person running controls and when TP2 is not working, the staff does not always remember to run controls or how to troubleshoot. 3. The laboratory performs 4,000 tests annually in the specialty of Chemistry.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Refer to D5445 and D5481.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Refer to D5481.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on personnel competency record review and interview with Testing Personnel #1 (TP1), the Technical Consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: Findings Include: 1. Record review on 3/31/2025 of the laboratory's CMS form 209 for the current survey revealed 4 new testing personnel (NTP) hired since the last CLIA survey and 1 new TP who was still in training during the last survey. 2. Record review on 3/31/2025 of the laboratory's TP competency records revealed, 5 of 5 NTP referred to in #1 above were only evaluated once during the first year of patient testing. 3. Record review on 3/31/2025 of the laboratory's, 'Staff Orientation, Training & Competency' policy revealed, "After the initial competency assessment at the completion of orientation and training, competency assessment will occur at 6 months, 12 months, and annually thereafter for testing personnel." 4. Staff interview on 3/31/2025 at 9:55 AM with TP1 confirmed the above findings. TP1 stated: a. "We had a very hard time getting in touch with the TC when we needed them." b. "We would frequently receive an away message." c. "Our old TC is no

	longer working with our laboratory. We have a new TC that recently took over." 5. During staff interview on 3/31/2025 at 10:00 AM with the TC, the TC stated, "I am new to this position and I haven't been on site yet. The Old TC left on 3/25/2025." 6. The laboratory performs 4,000 tests annually in the specialty of Chemistry.