

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0664261	(X3) Date Survey Completed 08/07/2026
Name of Provider or Supplier Northeast Urologic Surgery Pc	Street Address, City, State 231 Sutton Street, Suite 1 D, 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
D0000	A CLIA recertification survey was conducted for the Northeast Urologic Surgery, PC laboratory on 08/07/2026 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director (LD) the laboratory failed to enroll in an approved proficiency testing (PT) program for all analytes. Findings include: 1. Review of the laboratory's PT Testing (NE.19.15) procedure states the laboratory "participates in a number of external proficiency testing programs" and "PT participation will mirror the scope and complexity of testing done by the laboratory." 2. Review of the 2024, 2025, and 2026 College of American Pathologists proficiency tests results revealed the laboratory did not enroll in PT for moderate complexity urinalysis on the Clinitek Advantage analyzer in FY 2025. 3. Interview with the LD on 8/7/2026 at 11:15 AM confirmed the above findings. 4. The laboratory performs 3700 urinalysis tests on the Clinitek Advantage annually.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient

workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to ensure proficiency testing (PT) samples were examined by personnel who routinely perform testing. Findings include: 1. Review of the laboratory's PT Testing (NE.19.15) procedure states "Supervisors must rotate testing personnel who engage in PT challenges such that no person is left out". 2. Review of the laboratory's CMS 209 form indicated 8 testing personnel (TP) performing urinalysis testing on the Clinitek Advantage analyzer. 3. Review of the College of American Pathologists PT records revealed 1 of 8 testing personnel (TP1) performed testing for 2024 CAP Event 3 urinalysis, 2026 CAP Event 1 urinalysis and 2026 CAP Event 2 urinalysis using the Clinitek Advantage Urinalysis analyzer. 4. The laboratory performs 3700 urinalysis tests using the Clinitek Advantage analyzer annually.