Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0884173	01/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Northwoods Urology Of Texas, Pllc	135 Vision Park Blvd, Shenandoah, TX	

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	An announced survey of the laboratory was conducted on 01/25/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records, policies/procedures and staff interview, the laboratory failed to document evaluation of "Not Graded" results for 4 of 4 PT events reviewed for 2022 and 2023. Findings included: 1. Review of laboratory's PT records revealed the laboratory used American Proficiency Institute (API) as its PT provider. Review of API's instructions revealed: "Laboratories are responsible for documenting and performing corrective action for failures and must perform self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Further review of the PT records from 2022 and 2023 revealed the following analytes' "Not Graded" results did not have documentation of self-evaluation for 4 of 4 API Microbiology PT events reviewed: API Microbiology Event 3 - 2022 Analytes/samples with "Not Graded" results: - Resistance Gene: CTX-M Samples: UTI-05 - Resistance Gene: dfrA Samples: UTI-05 - Resistance Gene:KPC Samples: UTI-05 - Resistance Gene: mecA Samples: UTI-05 UTI-06 - Resistance Gene: NDM Samples: UTI-05 - Resistance Gene: qnr Samples: UTI-05 - Resistance Gene: sul Samples: UTI-05 - Resistance Gene: vanA Samples: UTI-05 UTI-06 - Resistance Gene: vanB Samples: UTI-05 UTI-06 API Microbiology Event 1 - 2023 Analytes/samples with "Not Graded" results: - Candida tropicalis Sample: UTI-01 - Resistance Gene: CTX-M Samples: UTI-01 UTI-02 UTI-03 UTI-04 - Resistance Gene: dfrA Samples: UTI-01 UTI-03 UTI-04 - Resistance Gene: KPC Samples: UTI-01 UTI-03 UTI-04 - Resistance Gene: mecA Samples: UTI-01 UTI-02

	UTI-03 UTI-05 - Resistance Gene: NDM Samples: UTI-01 UTI-03 UTI-04 - Resistance Gene: qnr Samples: UTI-01 UTI-03 UTI-04 - Resistance Gene: sul Samples: UTI-01 UTI-03 UTI-04 - Resistance Gene: vanA Samples: UTI-01 UTI-02 UTI-03 UTI-04 UTI-05 - Resistance Gene: vanB Samples: UTI-01 UTI-02 UTI-03 UTI-04 UTI-05 API Microbiology Event 2 - 2023 Analytes/samples with "Not Graded" results: - Resistance Gene: CTX-M Samples: UTI-07 UTI-09 - Resistance Gene: dfrA Samples: UTI-07 UTI-09 - Resistance Gene: KPC Samples: UTI-07 UTI-09 - Resistance Gene: mecA Samples: UTI-06 UTI-07 UTI-08 UTI-09 UTI-10 - Resistance Gene: NDM Samples: UTI-07 UTI-09 - Resistance Gene: qnr Samples: UTI-07 UTI-09 - Resistance Gene: sul Samples: UTI-07 UTI-09 - Resistance Gene: vanA Samples: UTI-06 UTI-08 UTI-09 UTI-10 - Resistance Gene: vanB Samples: UTI-06 UTI-08 UTI-09 UTI-10 API Microbiology Event 3 - 2023 Analytes/samples with "Not Graded" results: - Resistance Gene: CTX-M Samples: UTI-12 UTI-13 UTI-14 - Resistance Gene: dfrA Samples: UTI-12 UTI-13 UTI-14 UTI-15 - Resistance Gene: KPC Samples: UTI-12 UTI-13 UTI-14 - Resistance Gene: mecA Samples: UTI-11 UTI-12 UTI-13 UTI-14 UTI-15 - Resistance Gene: NDM Samples: UTI-12 UTI-13 UTI-14 - Resistance Gene: qnr Samples: UTI-12 UTI-13 - Resistance Gene: sul Samples: UTI-12 UTI-13 UTI-14 UTI-15 - Resistance Gene: vanA Samples: UTI-11 UTI-12 UTI-14 - Resistance Gene: vanB Samples: UTI-11 UTI-12 UTI-13 UTI-14 3. Review of laboratory's policies/procedures revealed there were no protocols in place addressing self-evaluation of "Not Graded" PT results. 4. An interview with the General Supervisor number 2 (as indicated on the CMS 209 form) on 01/25/2024 at 1020 hours in the conference room, confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, quality control (QC) records, provided test volumes and staff interview, the laboratory failed to document evaluation of quality control over time to ensure accuracy and precision of test performance for 18 of 18 months reviewed from July 2022 to December 2023. Findings included: 1. Review of laboratory's policies/procedures revealed the laboratory did not have in place protocols to address evaluation of quality control over time to ensure accuracy and precision of test performance, and detection of shifts and /or trends. 2. Review of laboratory's QC records from July 2022 to December 2023 revealed the laboratory did not document monitoring of QC over time to detect shifts /trends and ensure accuracy/precision of test performance. 3. Review of laboratory's provided test volumes revealed the laboratory performed approximately 43,200 tests

	annually. 4. An interview with the General Supervisor number 2 (as indicated on the CMS 209 form) on 01/25/2024 at 1125 hours in the conference room, confirmed the above findings.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's test establishment studies, policies/procedures, quality control (QC) records, patient test records and staff interview, the laboratory failed to document performance of NOVA Scientific Molecular UTI (urinary tract infection) real time PCR (polymerase chain reaction) positive and negative external controls each day of patient testing for 44 of 56 days testing was performed from 11/01/2023 to 01/24/2024. Findings included: 1. Review of laboratory's test establishment studies revealed the laboratory placed the NOVA Scientific Molecular UTI panel in use on 11 /01/2023. The studies did not document evaluation of an Individualized Quality Control Plan (IQCP) to allow the daily QC requirements to be changed to a lesser frequency. 2. Review of laboratory's "Quality Control Procedure General Laboratory Policy" (last reviewed 01/17/2024) revealed: "Every run will include a non-template control and positive control, per the CLIA guidelines for molecular diagnostics testing. If the method includes step, an extraction control will be utilized in every control and patient well." 3. Review of laboratory's Molecular UTI QC records from 11/01/2023 to 01/24/2024 revealed the laboratory documented positive and negative control testing weekly as follows: QC documented on: 11/06/2023 11/13/2023 11/20 /2023 11/27/2023 12/04/2023 12/11/2023 12/18/2023 12/27/2023 01/02/2024 01/08 /2024 01/15/2024 01/22/2024 There was no documentation of positive and negative control testing for the reminding 44 days patient testing was performed during the 11 /01/2023 to 01/24/2024 interval. 4. Review of laboratory's patient test records revealed 360 patient test samples were tested during the 11/01/2023 to 01/24/2024 interval. 5. An interview with the General Supervisor number 2 (as indicated on the CMS 209 form) on 01/25/2024 at 1120 hours in the conference room, confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory's test establishment studies, policies/procedures, quality

	control (QC) records, patient test records and staff interview, the laboratory's Quality Assurance failed to identify and correct issues with quality control for one of one test platforms used in the laboratory from 11/01/2023 to 01/24/2024, the NOVA Scientific Molecular UTI panel. Refer to D5441 and D5455.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory's test establishment studies, policies/procedures, quality control (QC) records, patient test records and staff interview, the Laboratory Director failed to ensure QC was maintained for one of one test platforms used in the laboratory from 11/01/2023 to 01/24/2024, the NOVA Scientific Molecular UTI panel. Refer to D5441 and D5455.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory's test establishment studies, policies/procedures, quality control (QC) records, patient test records and staff interview, the Laboratory Director failed to ensure laboratory's Quality Assurance identified and corrected issues with QC for one of one test platforms used in the laboratory from 11/01/2023 to 01/24 /2024, the NOVA Scientific Molecular UTI panel. Refer to D5791.