

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0861701	(X3) Date Survey Completed 08/13/2024
Name of Provider or Supplier North Dallas Urology Assoc	Street Address, City, State 5300 W Plano Pkwy Suite 200, Plano, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiency was cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, environmental logs, patient sample volumes in 2024 and confirmed in interview, the laboratory failed to follow specimen storage instructions prior to analysis for 10 of 15 patient specimens reviewed in 2024. Findings included: 1. Review of laboratory policy, "Determination of Urinary Tract Pathogens " (Approved by the Laboratory Director on 12/22/2023) revealed the following: "3.3 Storage and Transport Conditions: If the specimen will be processed (nuclear extraction) for analysis within 5 days after collection, keep it at room temperature (20-25 C) ..." 2. Review of laboratory environmental logs in 2024, revealed the following: a. 01/16/2024 Temperature Recorded: 18.6 C b. 01/21/2024 Temperature Recorded: 19.0 C c. 02/18/2024 Temperature Recorded: 19.0 C 3. Review of patient sample volumes on the above day's when specimen storage temperatures exceeded acceptable limits, revealed the following: a. 01/16/2024 Patient 1: See Patient Alias List Received: 01/12/2024 Analyzed on: 01/17/2024 Patient 2: See Patient Alias List Received: 01/17/2024 Analyzed on: 01/17/2024 Patient 3: See Patient Alias List Received: 01/17/2024 Analyzed on: 01/17/2024 b. 01/21/2024 Patient 4: See Patient Alias List Received: 01/19/2024 Analyzed on: 01/22</p>

/2024 Patient 5: See Patient Alias List Received: 01/22/2024 Analyzed on: 01/22/2024 Patient 6: See Patient Alias List Received: 01/22/2024 Analyzed on: 01/22/2024 c. 02/18/2024 Patient 7: See Patient Alias List Received: 02/18/2024 Analyzed on: 02/18/2024 Patient 8: See Patient Alias List Received: 02/18/2024 Analyzed on: 02/18/2024 Patient 9: See Patient Alias List Received: 02/18/2024 Analyzed on: 02/18/2024 Patient 10: See Patient Alias List Received: 02/18/2024 Analyzed on: 02/18/2024 The surveyor requested documentation of sample rejection for the above days temperatures exceeded acceptable specimen storage limits prior to analysis, and no documentation was provided. 4. In an interview on 08/13/2024 at 01:16 PM in the laboratory break room, the General Supervisor (GS-1) confirmed the laboratory failed to follow specimen storage instructions prior to analysis for 10 of 15 patient specimens reviewed in 2024. Word Key C- Celsius