Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0861701	07/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
North Dallas Urology Assoc	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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's twice annual accuracy assessment documents for 2020, 2021 and 2022, review of laboratory's policies and procedures, review of the laboratory's CMS (Centers for Medicare and Medicaid) Form 116 and staff interview, it was determined the laboratory failed to document twice annual accuracy assessment for non-gynecological cytology testing performed by the laboratory. Findings included: 1. Review of the laboratory's twice annual accuracy assessment documents for 2020, 2021 and 2022 revealed there was no documentation of the required accuracy assessments for non-gynecological cytology testing performed by the laboratory. 2. Review of the laboratory's policies and procedures revealed there was no policy in place for performing twice annual accuracy assessment of the laboratory's

	cytology testing. 3. Review of the laboratory's CMS Form 116 revealed the laboratory performed 391 cytology tests annually. 4. In an interview on 07/22/2022 at 1005 hours in the break room, Laboratory Director (as defined on submitted Form 209), after review of the data, confirmed the findings.
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 the laboratory's 2022 American Proficiency Institute (API) proficiency testing (PT) performance evaluation documents, review of laboratory's policies and procedures and staff interview, it was determined the laboratory failed to document self-evaluation for 9 of 9 "Not Graded" analyte results as per API requirements. Findings included: 1. Review of the API's 2022 Microbiology - 1st Event proficiency testing (accuracy assessment) performance evaluation documents revealed: "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Further review of the of the API's 2022 Microbiology - 1st Event proficiency testing/accuracy assessment performance evaluation documents revealed the following specimens had performance results of "Not Graded" without documentation of self-evaluation: Specimen: UTI-01 Analyte: Bio-Rad CFX / Resistance Gene: CTX-M Group 1 Reported Result: Not Detected Expected Result: See Data Summary Performance: Not Graded There was no evidence of self-evaluation documentation Specimen: UTI-01 Analyte: Bio-Rad CFX / Resistance Gene: dfr-A Reported Result: Not Detected Expected Result: See Data Summary Performance: Not Graded There was no evidence of self-evaluation documentation Specimen: UTI-01 Analyte: Bio-Rad CFX / Resistance Gene: KPC Reported Result: Not Detected Expected Result: See Data Summary Performance: Not Graded There was no evidence of self-evaluation documentation Specimen: UTI-01 Analyte: Bio-Rad CFX / Resistance Gene: mecA Reported Result: Not Detected Expected Result: See Data Summary Performance: Not Graded There was no evidence of self-evaluation documentation Specimen: UTI-02 Analyte: Bio-Rad CFX / Resistance Gene: mecA Reported Result: Not Detected Expected Result: See Data Summary Performance: Not Graded There was no evidence of self-evaluation documentation Specimen: UTI-01 Analyte: Bio-Rad CFX / Resistance Gene: NDM Reported Result: Not Detected Expected Result: See Data Summary Performance: Not Graded There was no evidence of self-evaluation documentation Specimen: UTI-01 Analyte: Bio-Rad CFX / Resistance Gene: sul1 Reported Result: Not Detected Expected Result: See Data Summary Performance: Not Graded There was no evidence of self-evaluation documentation Specimen: UTI-02 Analyte: Bio-Rad CFX / Resistance Gene: vanA Reported Result: Not Detected Expected Result: See Data Summary Performance: Not Graded There was no evidence of self-evaluation documentation Specimen: UTI-02 Analyte: Bio-Rad CFX / Resistance Gene: vanB Reported Result: Not Detected Expected Result: See Data Summary Performance: Not Graded There was no evidence of self-evaluation documentation 3. Review of the laboratory's "Proficiency Testing Policy and Guideline" policy, signed into effect in November of 2020 revealed: "The laboratory director or designee must review the results after submission for accuracy, for trends and bias. Corrective action needs to

	be undertaken and documented as needed." 4. In an interview on 07/22/2022 at 1015 hours in the break room, Laboratory Director (as defined on submitted Form 209), after review of the data, confirmed the findings.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures for reporting of inaccurate results corrective action requirements, review of a sampling of laboratory's corrected results for the "Determination of Urinary Tract Infection Pathogens" and staff interview, it was determined the laboratory failed to document notification of corrected results to provider for 10 of 10 corrected results reviewed. Findings included: 1. Review of the laboratory's policy "Determination of Urinary Tract Infection Pathogens" for reporting of inaccurate results corrective action requirements revealed: "Corrective actions will be written for any of the following errors made in the pre-analytic, analytic, or post analytic stage of testing. Corrective actions are initiated and tracked at the laboratory site. ... Post-Analytic a.) Reporting of incorrect results..." The policy did not address notification of amended results to provider. 2. Review of a sampling of laboratory's corrected results for the "Determination of Urinary Tract Infection Pathogens" revealed the following 10 of 10 patient samples did not have documentation of notification of corrected results to provider: Patient: 06.08.1936 Specimen: CC (clean catch) urine Collected: 05/17/2022 Resulted: 05/17/2022 Analyte: vanB Vancomycin Resistance Gene Original result: Detected Amended Result: Not detected No documentation of notification of amended result to provider was available for review. Patient: 05.14.1935 Specimen: CC urine Collected: 05/17/2022 Resulted: 05/17/2022 Analyte: vanB Vancomycin Resistance Gene Original result: Detected Amended Result: Not detected No documentation of notification of amended result to provider was available for review. Patient: 06.06.1948 Specimen: CC urine Collected: 05/18/2022 Resulted: 05/18/2022 Analyte: vanB Vancomycin Resistance Gene Original result: Detected Amended Result: Not detected No documentation of notification of amended result to provider was available for review. Patient: 08.06.1939 Specimen: CC urine Collected: 05/18/2022 Resulted: 05/18/2022 Analyte: vanB Vancomycin Resistance Gene Original result: Detected Amended Result: Not detected No documentation of notification of amended result to provider was available for review. Patient: 10.25.1946 Specimen: CC urine Collected: 05/18/2022 Resulted: 05/18/2022 Analyte: vanB Vancomycin Resistance Gene Original result: Detected Amended Result: Not detected No documentation of notification of amended result to provider was available for review. Patient: 06.19.1943 Specimen: CC urine Collected: 05/18/2022 Resulted: 05/18/2022 Analyte: vanB Vancomycin Resistance Gene Original result: Detected Amended Result: Not detected No documentation of notification of amended result to provider was available for review. Patient: 08.28.1952 Specimen: CC urine Collected: 05/18/2022 Resulted: 05/19/2022 Analyte: vanB Vancomycin Resistance Gene Original result: Detected Amended Result: Not detected No documentation of notification of amended

	result to provider was available for review. Patient: 08.18.1937 Specimen: CC urine Collected: 05/18/2022 Resulted: 05/19/2022 Analyte: vanB Vancomycin Resistance Gene Original result: Detected Amended Result: Not detected No documentation of notification of amended result to provider was available for review. Patient: 10.05.1935 Specimen: CC urine Collected: 05/19/2022 Resulted: 05/19/2022 Analyte: vanB Vancomycin Resistance Gene Original result: Detected Amended Result: Not detected No documentation of notification of amended result to provider was available for review. Patient: 01.29.1949 Specimen: CC urine Collected: 05/19/2022 Resulted: 05/19/2022 Analyte: vanB Vancomycin Resistance Gene Original result: Detected Amended Result: Not detected No documentation of notification of amended result to provider was available for review. 3. In an interview on 07/22/2022 at 1015 hours in the break room, Testing Person number 1 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the laboratory's twice annual accuracy assessments, review of the 2022 American Proficiency Institute (API) proficiency testing (PT) performance evaluation documents, review of laboratory's policies and procedures and staff interview, it was determined the Laboratory Director failed to ensure PT evaluation was performed as required. Refer to D5221.