Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0863263	10/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
North Dfw Urology, Llp	1601 Lancaster Dr # 180, Grapevine, 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 entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives 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 to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1240 Pre-Analytic Systems 493.1403 Laboratory Director, (moderate complexity). 493.1409 Technical Consultant 493.1441 Laboratory Director, (high complexity) 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 Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records and staff interview the laboratory failed to test urine microscopy and qualitative PT samples in the same manner as patient specimens for 2 of 2 testing events in 2020 (E-1, E-2). Findings: 1. Review of the laboratory's policy "Personnel Responsibilities For A High Complexity Laboratory" revealed: "Proficiency Testing (PT) Duties ... Ensure that PT samples are tested in the same manner as patient samples." 2. Review of API Attestation Statement revealed the following: "LAB DIRECTOR or designee- I certify that as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens." "PERSON(S) PERFORMING THE TEST- We certify that as closely as possible, these proficiency testing samples were tested in the same manner as possible." Further review of the attestation statement revealed the following testing persons (TP) performed testing and the corresponding PT sample: 2020 E-1 TP-3, TP-5 and TP-6 all qualitative semen analysis and urine microscopy 2019 E-2 TP-3, TP-5 and TP-6 signed the attestation form, but they did not specify which TP tested the sample sets for qualitative semen analysis and urine microscopy. The laboratory failed to test qualitative semen analysis and urine microscopy PT samples in the same manner as it tests patient specimens. 3. During an interview on 10/29/2019 at 11:00 am, the practice manager stated that TP-3, TP-5 and TP-6 participated in proficiency testing. She stated that the same PT samples were tested by TP-3, TP-5 and TP-6, but only one result was reported. This confirmed the laboratory failed to test qualitative semen analysis and urine microscopy PT samples in the same manner as it tested patient specimens.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on direct observation, American Proficiency Institute (API) Proficiency Testing (PT) records and in interview with staff, the laboratory failed to attest to the routine integration of proficiency samples into the patient workload for 2 of 2 hematology /coagulation (microscopy) events in 2020 (E1, E2). Findings: 1. Review of API test records revealed: "Attestation Statement SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results, and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 2. Review of PT records from 2020, revealed the laboratory director failed to sign the attestation forms for the following events: 2020 Hematology/Coagulation (microscopy) E1 and E2, the laboratory director failed to sign the attestation form. The attestation was only signed by the individuals performing the test. 3. During an interview on 10/29/2019 at 12:30 pm, the laboratory director confirmed the laboratory failed to attest to the routine integration of proficiency samples into the patient workload.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to review and evaluate the results obtained on proficiency testing for hematology /coagulation (microscopy) for 2 of 2 events in 2020 (E1, E2). Findings: 1. Review of laboratory policy "Personnel Responsibilities For A High Complexity Laboratory" revealed: "Proficiency Testing (PT) Duties ... Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT samples are found to be unsatisfactory." 2. Review of API PT records 2020 revealed the laboratory did not ensure the laboratory director/technical consultant documented their review /evaluation of hematology/coagulation (microscopy) PT results, as follows: 2020 Event 1 was not signed. Event 2 there was no copy of the final results available. The laboratory director/technical consultant failed to sign the review. 3. During an interview on 10/29/2020 at 2:30 pm, the laboratory director confirmed the above findings. II. Based on review of laboratory policy, laboratory split samples proficiency testing (PT) records and confirmed in interview, the laboratory failed to review and evaluate the results obtained on proficiency testing for urine microscopy and qualitative semen analysis for 4 of 4 events in 2019 (E1, E2, E3, E4). 1. Review of laboratory policy "Personnel Responsibilities For A High Complexity Laboratory" revealed: "Proficiency Testing (PT) Duties ... Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT samples are found to be unsatisfactory." 2. Review of the laboratory split sample records in 2019 revealed the laboratory did not ensure the laboratory director/technical consultant documented their review/evaluation of urine microscopy and qualitative semen analysis PT results, as follows: 2019 Event 1 (02/20/2019) final results were not signed. There was a written note that stated: "Lab Director was not available to review the results of the split samples study, however, based on the acceptance criteria, all tests passed. Event 2 (10/24/2019) final results were not signed. Event 3 (11/06/2019) final results were not signed. Event 4 (11/27/2019) final results were not signed. The laboratory director/technical consultant failed to sign the review. 3. During an interview on 10/29/2020 at 2:30 pm, the laboratory director confirmed the above findings.
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 Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated urine sediment examination, qualitative semen analysis, slide examinatins for prostate biopsies and urine cytology at least twice annually for 2 of 2 testing events in 2018. Findings included: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed urine sediment examination, qualitative semen analysis, slide examinations for prostate

	biopsies and urine cytology. 2. Review of the laboratory's proficiency testing records for 2018 revealed the laboratory failed to verify the accuracy of urine sediment examination, qualitative semen analysis, slide examinations for prostate biopsies and urine cytology at least twice annually for 2 of 2 testing events in 2018. 3. During an interview on 10/28/2020 at 11:00 hours, the practice manager was asked for documentation of twice annual accuracy for urine sediment examination, qualitative semen analysis, slide examinations for prostate biopsies and urine cytology for 2018. The practice manager stated that she could not find the twice annual accuracy assessments for 2018. This confirmed the above findings. This was a repeat deficiency for a recertification survey conducted on 07/12/2018
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, laboratory QuantStudio 12K Real Time PCR system establishment studies, and patient test records, the laboratory failed to meet pre-analytic system requirements as evidenced by: 1. The laboratory failed to ensure urine specimen for molecular urinary tract infection pathogens were NOT analyzed beyond the laboratory's established stability. Refer to D5311.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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. This STANDARD is not met as evidenced by: Based on review of laboratory records, laboratory QuantStudio 12K Real Time PCR system establishment studies, patient test records, and staff interview, the laboratory failed to ensure urine specimens for molecular urinary tract infection pathogens testing were NOT analyzed beyond the laboratory's established stability for 7 of 23 urine specimens (collected 09/21/2020 - 10/22/2020) and for 48 of 48 frozen urine specimens with extracted DNA from 10/06/2020 through 10/09/2020. Findings included: 1. Review of laboratory records revealed the laboratory performed PCR testing on urine specimens using the KingFisher Duo Prime instrument for automated extraction of DNA and RNA, the QuantStudio 12K Real Time PCR system with a Thermo Fisher TaqMan customized assay to the following pathogens in urine: Acinebacter baumanni; Candida albicans; Candida glabrata; Citrobacter koseri; Enterobacter aerogenes; Enterobacter cloacae; Enterococcus faecalis; Escherichia

coli; Gardnerella vaginalis; Haemophilus influenzae; Klebsiella oxytoca; Klebsiella pneumoniae; Morganella morganii; Mycobacterium tuberculosis; Proteus mirabilis; Pseudomonas aeruginosa; Serratia marcescens; Staphylococcus aureus; Staphylococcus epidermidis; Staphylococcus haemolyticus; Staphylococcus saprophyticus; Streptococcus agalactiae; Streptococcus pyogenes; Chlamydia trachomatis; HHV-6; HPV-16; HPV-18; HSV-1; HSV-2; Mycoplasma hominis; Mycoplasma urealyticum; Neisseria gonorrhoeae; Treponema pallidium; Trichomonas vaginalis. The Thermo Fisher TagMan customized assay also detected antibiotic resistance to the following: Actinomycin, Cephalosporin, Monobactam Cephalosporin Sulfonamide, Trimethoprim Lincosamide, Macrolide, Streptogramin MRSA Cephalosporin, Monobactam Carbapenem, Cephalosporin, Monobactam Fluoroquinolone Carbapenem, Cephalosporin Tetracycline Vancomycin 2. Review of the laboratory record titled "North DFW Urology's UTI Panel Validation Summary" (signed by the laboratory director 09/21/2020) in the section titled "Specimen Requirements" stated the following: "I. Specimen Requirements: Urine specimens collected in sterile containers, urinalysis yellow top tubes, and boric acid culture and sensitivity containers are acceptable. The following specimen acceptance or rejection criteria were established through our stability studies: Sterile Container; Storage 2-8C; Acceptable up to 144 hours Sterile Container; Storage 24-30C; Acceptable up to 48 hours Boric Acid C&S; Storage 2-8C; Acceptable up to 120 hours Boric Acid C&S; Storage 24-30C; Acceptable up to 72 hours Urinalysis [Yellow top tube]; Storage 2-8C; Acceptable up to 144 hours Urinalysis [Yellow top tube]; Storage 24-30C; Acceptable up to 120 hours Extracted nucleic acid from urine samples was found to be stable in the following conditions and timepoints: Condition: Room temperature 24-30C; Stability: Up to 72 hr Condition: Refrigerator 2-8C; At least 168 hr Condition: Freezer -30 to -10 C; Stability: At least 168 hr" NOTE: 120 hours is 5 days. 144 hours is 6 days. 168 hours is 7 Days. 3. Review of the laboratory's establishment studies raw data revealed the following statement: Sterile Container; Storage 2-8C; Acceptable up to 120 hours This stability differed from the "North DFW Urology's UTI Panel Validation Summary" of 144 hours Sterile Container; Storage 24C; Acceptable up to 72 hours This stability differed from the "North DFW Urology's UTI Panel Validation Summary" of 48 hours Boric Acid C&S; Storage 2-8C; Acceptable up to 120 hours Boric Acid C&S; Storage 24C; Acceptable up to 96 hours This stability differed from the "North DFW Urology's UTI Panel Validation Summary" of 72 hours Urinalysis [Yellow top tube]; Storage 2-8C; Acceptable up to 96 hours This stability differed from the "North DFW Urology's UTI Panel Validation Summary" of 144 hours Urinalysis [Yellow top tube]; Storage 24C; Acceptable up to 72 hours This stability differed from the "North DFW Urology's UTI Panel Validation Summary" of 120 hours The laboratory's establishment studies raw data listed data for "DNA Stability Post-Extraction" for samples at room temperature, 2-8C, and Freezer (-20C) that included baseline, 24-hour, 48-hour, 72-hour, 96- hour, 120-hour, 114-hour, and 168-hour measurements. No statement of acceptability was documented for post-extraction DNA stability on this record. NOTE: 96 hours is 4 days. 120 hours is 5 days. 144 hours is 6 days. 168 hours is 7 Days. 4. During a tour of the laboratory area on 10/30 /2020 at 10:50 AM, a rack containing patient urine specimens was observed in the refrigerator. The urine specimens were in yellow top collection tubes and were collected from 10/20/2020 through 10/22/2020. A random review patient test records (09/21/2020 - 10/22/2020) revealed the following 7 of 23 patient urine specimens that were analyzed beyond this laboratory's established stability of 96 hours (4 days) for refrigerated urine specimens stored in yellow top collection tubes. a. Patient 314; Date Collected 10/22/2020; Date Received 10/27/2020 Urine specimen 5 days old at time of receipt and tested 1 day beyond established stability. b. Patient 324; Date Collected 10/22/2020; Date Received 10/27/2020 Urine specimen 5 days old at time of receipt

and tested 1 day beyond established stability. c. Patient 325; Date Collected 10/21 /2020; Date Received 10/27/2020 Urine specimen 6 days old at time of receipt and tested 2 days beyond established stability. d. Patient 332; Date Collected 10/22/2020; Date Received 10/27/2020 Urine specimen 5 days old at time of receipt and tested 1 day beyond established stability. e. Patient 327; Date Collected 10/22/2020; Date Received 10/28/2020 Urine specimen 7 days old at time of receipt and tested 3 days beyond established stability. f. Patient 328; Date Collected 10/22/2020; Date Received 10/27/2020 Urine specimen 5 days old at time of receipt and tested 1 day beyond established stability g. Patient 330; Date Collected 10/22/2020; Date Received 10/27 /2020 Urine specimen 5 days old at time of receipt and tested 1 day beyond established stability 4. Review of the laboratory record titled, "Daily QC Review" from 09/23/2020 through 10/28/2020 revealed no quality control (QC) was documented for 10/03/2020 through 10/19/2020. Review of the laboratory record titled, "TaqMan Array cards" revealed no QC testing using the Taqman Customized Array cards from 10/03/2020 through 10/19/2020. Review of the laboratory record titled, "Extraction of nucleic acid in King Fisher Duo prime" revealed the extraction process was performed on 10/06/2020, 10/07/2020, 10/08/2020, 10/09/2020, 10/14 /2020, and 10/16/2020. 5. In an interview on 10/30/2020 at 11:13 AM, testing person #2 was asked why no quality control was performed from 10/03/2020 through 10/19 /2020. She stated that the laboratory had used all of the TaqMan array cards and were waiting on the arrival of more TaqMan array cards from the manufacturer. She further stated that she had performed the extraction process on all pending specimens and had frozen those specimens until the array cards were received. 6. Review of the laboratory record titled, "Extraction of nucleic acid in King Fisher Duo prime" and review of the record titled, "TaqMan Array cards" revealed the date the extraction process was performed and date the TaqMan assay was performed for the following patient urine specimens: a. Extraction Process performed 10/06/2020 for the following patients: Patient 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 203, 204 TaqMan Assay performed 10/20/2020 for the following patients: Patient 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 203, 204 Frozen urine specimens were tested 8 days beyond the acceptable 7-day extraction stability. b. Extraction Process performed 10/06/2020 for the following patients: Patient 205, 206, 207, 208, 209 TaqMan Assay performed 10/21/2020 for the following patients: Patient 205, 206, 207, 208, 209 Frozen urine specimens were tested 9 days beyond the acceptable 7-day extraction stability. c. Extraction Process performed 10/07/2020 for the following patient: Patient 202 TaqMan Assay performed 10/21/2020 for the following patient: Patient 202 Frozen urine specimens were tested 8 days beyond the acceptable 7-day extraction stability. d. Extraction Process performed 10/07/2020 for the following patients: Patient 218, 219, 220, 221, 222, 223 TaqMan Assay performed 10 /22/2020 for the following patients: Patient 218, 219, 220, 221, 222, 223 Frozen urine specimens were tested 9 days beyond the acceptable 7-day extraction stability. e. Extraction Process performed 10/08/2020 for the following patients: Patient 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234 TaqMan Assay performed 10/22/2020 for the following patients: Patient 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234 Frozen urine specimens were tested 8 days beyond the acceptable 7-day extraction stability. f. Extraction Process performed 10/09/2020 for the following patients: Patient 235, 236, 237, 238, 239 TaqMan Assay performed 10/22/2020 for the following patients: Patient 235, 236, 237, 238, 239 Frozen urine specimens were tested 7 days beyond the acceptable 7-day extraction stability. g. Extraction Process performed 10/09/2020 for the following patients: Patient 240, 241, 242, 243, 244, 245 TaqMan Assay performed 10/23/2020 for the following patients: Patient 240, 241, 242, 243, 244, 245 Frozen urine specimens were tested 8 days beyond the acceptable 7-day extraction stability. The laboratory failed to ensure urine specimen for

	molecular urinary tract infection pathogen testing were NOT analyzed beyond the laboratory's established stability. 7. In an interview on 10/30/2020 at 12:22 PM, after review of the findings, the Laboratory Director confirmed the findings. WORD KEY: PCR = Polymerase Chain Reaction DNA= Deoxyribonucleic acid RNA = Ribonucleic Acid MRSA = Methicillin Resistant Staphylococcus aureus HHV=Human Herpes Virus HPV=Human papillomavirus HSV=Herpes Simplex Virus
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and confirmed in interview, it was revealed the laboratory failed to have documentation of procedures for qualitative semen analysis. Findings: 1. Review of the laboratory's procedure manual revealed the manual failed to contain procedures for how to perform qualitative semen analysis. 2. The laboratory was asked to provide documentation of procedure for qualitative semen analysis. No documentation was provided. 3. During an interview on 10/29 /2020 at 2:30 pm, the laboratory director confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on direct observation, review of laboratory QuantStudio 12K Real Time PCR system establishment studies, laboratory environmental records from 09/01/2020 through 10/30/2020, and confirmed in staff interview, the laboratory failed to ensure refrigerator temperature ranges were within urine specimen storage specifications. Findings included: 1. During a tour of the Pre-PCR room on 10/30/2020 at 10:50 AM, urine specimens were observed stored in a refrigerator. In an interview during the tour, testing person #2 was asked about the urine specimens. She stated that after a urine specimen was collected in the clinic area of the facility, the specimen is stored in the refrigerator until tested. 2. Review of the laboratory's QuantStudio 12K Real Time PCR system establishment studies provided stability temperature requirements for urine specimens collected in a sterile urine container, a Boric Acid (gray top) tube, and a yellow top urine tube (Urinalysis). The studies stated the following for urine specimen stability requirements: Sterile container; Storage 2 -8 C Boric Acid C&S; 2 -8 C Urinalysis; 2 -8 C 3. Review of the laboratory environmental records, titled "Pre-PCR Room Maintenance Checklist", from 09/01/2020 through 10/30/ 2020 revealed

	the laboratory's "Refrigerator Temperature Range: 1 - 12 C". The laboratory failed to ensure room temperature ranges were within urine specimen storage specifications determined by the laboratory's establishment studies. 4. In an interview on 10/30/2020 at 12:22 PM, after review of the findings, the Laboratory Director confirmed the findings. II. Based on direct observation, review of KingFisher Duo Prime instrument operator's manual, laboratory environmental records from 09/01/2020 through 10/30 /2020, and confirmed in staff interview, the laboratory failed to ensure relative humidity levels were within the specifications for the KingFisher Duo Prime instrument for automated extraction of DNA and RNA for 42 of 42 days. Findings included: 1. During a tour of the Pre-PCR room on 10/30/2020 at 10:50 AM, a KingFisher Duo Prime instrument was observed. 2. The KingFisher Duo Prime instrument operator's manual (Rev. 1.0) stated the following in the section titled "Technical Specifications": "Humidity; Requirement: Maximum relative humidity 80% for temperatures up to 31C ... ." 3. Review of the laboratory environmental records, titled "Pre-PCR Room Maintenance Checklist", from 09/01/2020 through 10 /30/ 2020 revealed "Humidity Range: 20 - 80%". Further review of this laboratory environment record revealed no humidity levels were documented on the following days: 09/01/2020 - 09/03/2020 09/08/2020 - 09/11/2020 09/14/2020 - 09/18/2020 09 /21/2020 - 09/25/2020 09/28/2020 - 09/30/2020 10/01/2020 - 10/02/2020 10/05/2020 - 10/09/2020 10/12/2020 - 10/16/2020 10/19/2020 - 10/23/2020 10/26/2020 - 10/30 /2020 4. In an interview on 10/30/2020 at 12:22 PM, after review of the findings, the Laboratory Director confirmed the findings. WORD KEY PCR = Polymerase chain reaction C = Celsius C&S = culture and sensitivity DNA=Deoxyribonucleic Acid RNA=Ribonucleic Acid
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and staff interview, it was revealed the laboratory failed to ensure that quality control materials for the QuantStudio 12K Real Time PCR system were labeled with identification of contents, concentration, storage requirements, storage stability, preparation date and expiration date. Findings included: 1. During a tour of the Pre-PCR room on 10/30/2020 at 10:50 AM, 4 plastic tubes were observed stored in the refrigerator. Two tubes were labeled "Pos" and two tubes were labeled "Neg". During the tour, Testing person #2 stated that these tubes were the positive and negative quality control (QC) material used for the QuantStudio 12K Real Time PCR test system. She further stated that the Technical Supervisor prepares the QC material offsite and brings the tubes to the laboratory when needed. The laboratory failed to ensure that quality control materials were labeled with identification of contents, storage requirements, storage stability, preparation date and expiration date. 2. Review of the laboratory record titled "North DFW Urology's UTI Panel Validation Summary" (signed by the laboratory director 09 /21/2020) in the section titled "Quality Control Material" stated the following: "Positive and negative controls will be run on each day of testing. Thermo Scientific's multi-target plasmid containing ATCC organisms listed in Table 2 will be used as

	Positive Control for this assay. Positive control will contain all of the assay targets. Multi-organism controls can also be prepared from fresh bacterial culture and used as controls ....Negative extraction control and negative template control will be prepared by generating a 1:2 dilution of an off-target organism's DNA (S. pneumoniae)." Review of laboratory records from 09/23/2020 through 10/28/2020 revealed this QC material was used on the following dates: 09/23/2020; 09/24/2020; 09/25/2020; 09/28 /2020; 09/29/2020; 09/30/2020; 10/01/2020; 10/02/2020; 10/20/2020; 10/21/2020; 10 /22/2020; 10/23/2020; 10/27/2020; 10/28/2020. 3. In an interview on 10/30/2020 at 11: 00 AM, Testing person #2 was asked to provide documentation of identification of the contents, concentration, storage requirements, storage stability, preparation date, and expiration date for the QC material. No documentation was provided. This confirmed the above findings. WORD KEY: S=Streptococcus ATCC=American Type Culture Collection
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: I. Based on direct observation, laboratory QuantStudio 12K Real Time PCR system establishment studies, laboratory records, and confirmed in interview, the laboratory failed to document complete establishment studies for the positive and negative control material used for PCR testing on urine specimens using the KingFisher Duo Prime instrument for automated extraction of DNA and RNA, the QuantStudio 12K Real Time PCR system with a Thermo Fisher TaqMan customized assay. Findings included: 1. During a tour of the Pre-PCR room on 10/30/2020 at 10:50 AM, 4 plastic tubes were observed stored in the refrigerator. Two tubes were labeled "Pos" and two tubes were labeled "Neg". During the tour, Testing person #2 stated that these tubes were the positive and negative quality control (QC) material used for the QuantStudio 12K Real Time PCR test system. She further stated that the Technical Supervisor prepares the QC material offsite and brings the tubes to the laboratory when needed. 2. Review of the laboratory's QuantStudio 12K Real Time PCR system establishment studies stated the following" "J. Quality Control Material: Positive and negative controls will be run on each day of testing. Thermo Scientific's multi-target plasmid containing ATCC organisms listed in Table 2 will be used as Positive control for this assay. Positive control will contain all of the assay targets. Multi-organism controls can also be prepared from fresh bacterial culture and used as controls ...Negative extraction control and negative template control will be prepared by generating a 1:2 dilution of an off-target organism's DNA (S. pneumoniae)." Further review of the establishment studies revealed no documentation of stability studies for the quality control material that included identification of the quality control material (Thermo Scientific material or fresh bacterial culture material), preparation instructions,

	concentration, storage requirements and storage stability. 3. In an interview on 10/30 /2020 at 11:00 AM, Testing person #2 was asked to provide documentation of establishment studies that included identification of the quality control material (Thermo Scientific material or fresh bacterial culture material), preparation instructions, concentration, storage requirements, and storage stability for the QC material. No documentation was provided. This confirmed the above findings. II. Based on laboratory records and QuantStudio 12K Real Time PCR system establishment studies, the laboratory failed to ensure urine specimen stability specified in validation summary correlated with urine specimen stability determined by the laboratory's establishment study data. 1. Review of the laboratory record titled "North DFW Urology's UTI Panel Validation Summary" (signed by the laboratory director 09/21/2020) in the section titled "Specimen Requirements" stated the following: "I. Specimen Requirements: Urine specimens collected in sterile containers, urinalysis yellow top tubes, and boric acid culture and sensitivity containers are acceptable. The following specimen acceptance or rejection criteria were established through our stability studies: Sterile Container; Storage 2-8C; Acceptable up to 144 hours Sterile Container; Storage 24-30C; Acceptable up to 48 hours Boric Acid C&S; Storage 2-8C; Acceptable up to 120 hours Boric Acid C&S; Storage 24-30C; Acceptable up to 72 hours Urinalysis [Yellow top tube]; Storage 2-8C; Acceptable up to 144 hours Urinalysis [Yellow top tube]; Storage 24-30C; Acceptable up to 120 hours Extracted nucleic acid from urine samples was found to be stable in the following conditions and timepoints: Condition: Room temperature 24-30C; Stability: Up to 72 hr Condition: Refrigerator 2-8C; At least 168 hr Condition: Freezer -30 to -10 C; Stability: At least 168 hr" 2. Review of the laboratory's establishment studies raw data revealed the following statement: Sterile Container; Storage 2-8C; Acceptable up to 120 hours This stability differed from the "North DFW Urology's UTI Panel Validation Summary" of 144 hours Sterile Container; Storage 24C; Acceptable up to 72 hours This stability differed from the "North DFW Urology's UTI Panel Validation Summary" of 48 hours Boric Acid C&S; Storage 2-8C; Acceptable up to 120 hours Boric Acid C&S; Storage 24C; Acceptable up to 96 hours This stability differed from the "North DFW Urology's UTI Panel Validation Summary" of 72 hours Urinalysis [Yellow top tube]; Storage 2-8C; Acceptable up to 96 hours This stability differed from the "North DFW Urology's UTI Panel Validation Summary" of 144 hours Urinalysis [Yellow top tube]; Storage 24C; Acceptable up to 72 hours This stability differed from the "North DFW Urology's UTI Panel Validation Summary" of 120 hours The laboratory's establishment studies raw data listed data for "DNA Stability Post-Extraction" for samples at room temperature, 2-8C, and Freezer (-20C) that included baseline, 24-hour, 48-hour, 72-hour, 96- hour, 120-hour, 114-hour, and 168- hour measurements. No statement of acceptability was documented for post-extraction DNA stability on this record.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy, Quality Control (QC) logs, and

confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 6 of 6 days in 2020 (08 /2020 through 9/2020). Findings: 1. Review of the laboratory's policy "Quality Monitors" revealed: "QUALITY MONITORS ... Analytic Indicators ... Objective: to ensure testing personnel competency, accurate and high quality histology and cytology preparations Laboratory Indicators ... 5. Histology and cytology slide staining quality Frequency: on days when slide reading is performed" The policy did not define intended reactivity of the H&E stain to ensure predictable characteristics. 2. Review of the "DAILY HISTOLOGY QC" log revealed the following: The log had columns for "Date", "TUS No.", "Measurement & number of tissue", "Ink", "Histology", "Comment" and "Corrective action" and each day QC was documented in the "Histology" column with a "checkmark" in the column. The log did not specify what the "checkmark" meant. The following dates in 2020 were observed to be documented with "checkmark": 2020 August: 3, 13, 20 September: 3, 17, 23 The log did not specify what the "checkmark" meant. The laboratory failed to document the staining characteristics for the H&E stain. 3. The laboratory failed to document intended reactivity of the H&E stain on the following dates patients were tested in 2020: 08/06/2020 Patient ID: 20-122 08/13/2020 Patient ID: 20-1229 08/20/2020 Patient ID: 20-1325 09/03/2020 Patient ID: 20-001412 09/17/2020 Patient ID: 20-1489 09/23/2020 Patient ID: 20-001523 4. During an interview on 10/29/2020 at 12: 36 pm, the laboratory director confirmed the above findings. II. Based on review of the laboratory's policy, Quality Control (QC) logs, and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Papanicolaou QC for 8 of 8 days in 2020 (08/2020 through 9/2020). Findings: 1. Review of the laboratory's policy "Quality Monitors" revealed: "QUALITY MONITORS ... Analytic Indicators ... Objective: to ensure testing personnel competency, accurate and high quality histology and cytology preparations Laboratory Indicators ... 5. Histology and cytology slide staining quality Frequency: on days when slide reading is performed" The policy did not define intended reactivity of the Papanicolau stain to ensure predictable characteristics. 2. Review of the "PAPANICOLAOU STAIN DAILY QC" log revealed the following: The log had columns for "NUCLEAR STAINING" and "CYTOPLASM STAINING". The bottom of the log had legend with the following symbols and meanings: "U = Unsatisfactory", "S = Satisfactory", "N = None", "P = Present" The following dates in 2020 were observed to be documented with "checkmark" under the nuclear staining and cytoplasm staining colums: 2020 August: 6, 13, 20, 27 September: 3, 10, 17, 23 The log did not specify what the "checkmark" meant. The laboratory failed to document the staining characteristics for the Papanicolaou stain. 3. The laboratory failed to document intended reactivity of the Papanicolaou stain on the following dates patients were tested in 2020: 08/06/2020 Patient ID: 20-2283 08/13/2020 Patient ID: 20-2940 08/20/2020 Patient ID: 20-3095 08/27/2020 Patient ID: 20-003219 09/03/2020 Patient ID: 20-003328 09/10/2020 Patient ID: 20-003482 09/17/2020 Patient ID: 20-003559 09/23/2020 Patient ID: 20-003751 4. During an interview on 10/29/2020 at 12:36 pm, the laboratory director confirmed the above findings. III. Based on review of the laboratory's policy, Quality Control (QC) logs, and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for positive and negative reactivity to ensure the predictable staining characteristics for the prostate stain QC for 2 of 2 days in 2020 (09 /2020 through 10/2020). Findings: 1. Review of the laboratory's policy "Quality Monitors" revealed: "QUALITY MONITORS ... Analytic Indicators ... Objective: to ensure testing personnel competency, accurate and high quality histology and cytology preparations Laboratory Indicators ... 5. Histology and cytology slide

	staining quality Frequency: on days when slide reading is performed" The policy did not define positive and negative reactivity of the prostate stain to ensure predictable characteristics. 2. Review of patient requisition forms for prostate stains revealed a box on the right-hand side that stated "Positive/negative controls reviewed and of acceptable quality". The following dates in 2020 were observed to be documented with "checkmark" in the box: 09/24/2020 10/15/2020 The laboratory failed to document the staining characteristics for the prostate stain. 3. The laboratory failed to document positive and negative reactivity of the prostate stain on the following dates patients were tested in 2020: 09/24/2020 Patient ID: 20-001523 10/25/2020 Patient ID: 20-001603 4. During an interview on 10/29/2020 at 12:36 pm, the laboratory director confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records, and confirmed by staff interview, and confirmed in staff interview, the laboratory director failed to provide overall management and direction as evidenced by: 1. The Laboratory Director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance. Refer to D6007.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records, and confirmed by staff interview, the Laboratory Director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance as evidenced by: 1. The laboratory failed to verify the accuracy of non-regulated urine sediment examination, qualitative semen analysis at least twice annually for 2 of 2 testing events in 2018. Refer to D5217. This was a repeat deficiency for a recertification survey conducted on 07/12/2018
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS-209 form, laboratory policy, personnel files, and confirmed in staff interview, the technical consultant failed to provide technical oversight, as evidenced by: 1. The technical consultant (TC) failed perform annual personnel competency assessment for 3 of 6 Testing Persons (TP-3, TP-5, TP-6) responsible for moderate complexity testing in 2018. Refer to D6054.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of Centers for Medicaid and Medicare Services (CMS) 209 form, personnel records and confirmed in interview, the technical consultant (who is also the laboratory director) failed to evaluate and document the annual performances 3 of 6 Testing Persons (TP-3, TP-5, TP-6) responsible for moderate complexity testing. Findings: 1. Review of the CMS 209 form revealed the laboratory identified 3 testing persons who perform moderate complexity testing. 2. Review of personnel records for TP-3 revealed there was no annual competency assessment performed in 2018. Review of personnel records for TP-5 revealed there were no annual competency assessments performed in 2018. Review of personnel records for TP-6 revealed there were no annual competency assessments performed in 2018. 3. The laboratory was asked to provide documentation of a competency assessment being performed. No documentation was provided. 4. During an interview on 10/29/2020 at 11:10 am, the practice manager stated she did not know where the competency assessments for 2018 were located. This confirmed the above findings. This was a repeat deficiency from a recertification survey conducted on 07/12/2018.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records, laboratory QuantStudio 12K Real Time PCR system establishment studies, patient test records, and confirmed by staff interview, the Laboratory Director failed to provide overall management and direction as evidenced by: 1. The Laboratory Director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance. Refer to D6079.

D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records, laboratory QuantStudio 12K Real Time PCR system establishment studies, patient test records, and confirmed by staff interview, the Laboratory Director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance as evidenced by: 1. The laboratory failed to ensure urine specimens for molecular urinary tract infection pathogens testing were NOT analyzed beyond the laboratory's established stability for 7 of 23 urine specimens (collected 09/21/2020 - 10/22/2020) and for 48 of 48 frozen urine specimens with extracted DNA from 10/06/2020 through 10/09/2020. Refer to D5311. 2. The laboratory failed to verify the accuracy of non-regulated slide examinations for prostate biopsies and urine cytology at least twice annually for 2 of 2 testing events in 2018. Refer to D5217. This was a repeat deficiency for a recertification survey conducted on 07/12/2018