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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0863263 | (X3) Date Survey Completed 07/12/2018 |
| Name of Provider or Supplier North Dfw Urology, Llp | Street Address, City, State 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 |
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| D0000 | <p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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 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 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.</p> |
| D1001 | <p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions of the Siemens Multistix PRO 10LS Reagent Strips, surveyor observation of reagent strips currently in use by the laboratory, patient test records, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for: A) running quality control, and B) not performing testing utilizing expired strips. The findings were: A) Quality Control 1. A review of the manufacturer's instructions for the Siemens PRO 10LS Reagent Strips (Rev. 10/10 USA) under the section titled "Quality Control" revealed: "Test negative and positive controls when you first open a new bottle." 2. The laboratory was asked to provide documentation of testing quality control material each time a</p> |

new bottle of strips was opened. No documentation was provided. 3. An interview with a testing person on 07/12/2018 at 1000 hours in the laboratory revealed the laboratory did not perform quality control testing on the reagent strips. She added the laboratory would open a new bottle roughly every Tuesday and Thursday because they tested so many people. This confirmed the findings. B) Expired Strips 1. A review of the manufacturer's instructions for the Siemens PRO 10LS Reagent Strips (Rev. 10/10 USA) under the section titled "Procedure" revealed: "Check the expiration date on the Reagent Strip bottle. If the date has passed, discard and get a new bottle.... Use of Reagent Strips beyond the expiration date may yield inaccurate results." 2. Surveyor observation of reagent strips currently in use by the laboratory on 07/12/2018 at 0955 hours in the laboratory revealed: 1 bottle of Multistix PRO 10LS strips Lot: 701050 expiration: 2018-06-30 opened date: 07/11/2018 94 of 100 strips still remaining 3. A review of the laboratory's patient test records revealed the following patients were tested utilizing the expired strips: 012725 - test discarded, not reported 194880 198300 198230 198960 - test repeated on new strip 19790 - test repeated on new strip 4. An interview with the assistant manager on 07/12/2018 at 1002 hours in the laboratory - after her review of the records- confirmed the 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 the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for urine microscopic testing, prostate biopsies, and urine cytology in 2017. The findings were: 1. A review of the laboratory records revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for urine microscopic testing, prostate biopsies, and urine cytology in 2017. 2. The laboratory was asked to provide documentation of the missing accuracy assessments. No documentation was provided. 3. An interview with the assistant manager on 07/12/2018 at 1115 hours in the office revealed the laboratory was unable to locate any records of the assessments being performed. She wasn't sure if they had or had not been performed. This confirmed the findings.

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 the laboratory current procedure manual, and staff interview, it was revealed the laboratory failed to have documentation of procedures for urine microscopic testing. The findings were: 1. A review of the laboratory's current procedure manual revealed the manual failed to contain procedures for how to perform urine microscopic testing. 2. The laboratory was asked to provide

documentation of a procedure, signed by the current laboratory manager, for urine microscopic testing. No documentation was provided. 3. An interview with the assistant manager on 07/12/2018 at 1130 hours in the office - after her review of the procedure manual - confirmed the findings.

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 the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing annual competency assessments on testing personnel #3 in 2017. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed testing personnel #3 (as listed on Form CMS 209) failed to have documentation of a competency assessment being performed in 2017. 3. The laboratory was asked to provide documentation of a competency assessment being performed. No documentation was provided. 4. An interview with the assistant manager on 07/12/2018 at 1115 hours in the office revealed she was unsure if a competency assessment had been performed. She was unable to locate one. This confirmed the findings.

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 the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure quality assessment reviews were performed. The findings were: 1. A review of the laboratory's records revealed quality assessment reviews were last performed in March 2016. 2. The laboratory was asked to provide documentation of quality assessment reviews being performed from April 2016 to current. No documentation was provided. 3. An interview with the assistant office manager on 07/12/2018 at 1115 hours in the office - after her review of the records- confirmed the findings.