

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2105934	(X3) Date Survey Completed 02/25/2020
Name of Provider or Supplier Wfhn Medical Plaza North Elm	Street Address, City, State 3903 North Elm Street, Suite 101, Greensboro, NC	
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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 API (American Proficiency Institute) proficiency testing records and interview with TP (testing personnel) 2/25/20, the laboratory failed to retain all proficiency testing records for at least two years. Review of 2018 and 2019 API proficiency testing records revealed: 1. The laboratory did not have copies of signed attestation statements available for the 2018 Hematology 3rd event, the 2019 Hematology 1st, 2nd, and 3rd events, and the 2019 Microbiology 1st, 2nd, and 3rd events. 2. The laboratory did not have a copy of the comparative evaluation for the 2018 Microbiology 2nd event. 3. The laboratory did not have copies of the report forms used to record results, the signed attestation statement, or the graded results for the 2018 Microbiology 3rd event. During interview at approximately 10:45 a.m., TP #1 stated she was unaware they needed to keep attestation statements.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of personnel records 2/25/20, the laboratory failed to follow established policies and procedures for evaluating the competency of testing personnel. Findings: The laboratory's "Clinical</p>

Laboratory Point-of-Care Testing Competency Assessment for Non-Waived Testing" policy states "... 3) Policy: Personnel that perform tests of moderate and/or high complexity (non-waived) in a CLIA-certified laboratory or point-of-care testing area must have documented competency. A. New Testing Staff Members will have competency assessment: 1. Initially 2. 6-Months 3. Annually B. After the first year, each staff member is required to have documented annual competency on each method used by the staff member. C. The following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing for each test that the individual is approved by the laboratory director to perform: 1. Direct observations of routine patient test performance ... 2. Monitoring the recording and reporting of test results. ... 3. Review of intermediate test results or worksheets, quality control records, ... 4. Direct observations of performance of instrument maintenance and function checks. ... 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. ... 6. Assessment of problem solving skills. ... E. Competency Observation: Must be completed by a qualified individual, meeting CLIA Technical Consultant requirements. ..." Review of personnel records revealed: 1. Competency evaluations for TP #1 conducted in May and November 2019 did not include a competency evaluation for post vasectomy semen analysis. Competency evaluations for TP #2 conducted in July 2019 and January 2020 did not include a competency evaluation for post vasectomy semen analysis. Both TP #1 and TP #2 had documentation of an on-line "TRAINING TEST" for post vasectomy semen analysis from June 2019. The test consisted of three images which required the participant to determine presence or absence of sperm. It was unclear whether the test was used for training or to determine competency. 2. Competency evaluations for TP #1 and TP #2 did not include all six procedures included in the minimal regulatory requirements for assessment of competency. The "COMPETENCY ASSESSMENT FORM" used to document urine microscopic competency states "... COMPETENCY ELEMENTS INCLUDE TWO (2) OF THE FOLLOWING COMPONENTS: 1. Assessment of problem solving skills. ... 2. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. ... 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. ..." 3. The May 2019 urine microscopic competency assessment for TP #1 was signed by TP #2. There were no records available to indicate that the laboratory director had delegated the responsibility for the performance of competency evaluations to TP #2. TP #1's November 2019 urine microscopic competency evaluation was not signed, so it was unclear who performed the evaluation.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures and interview with TP (testing personnel) 2/25/20, the laboratory's procedure manual was not complete and current for the testing performed. Review of the laboratory's procedure manual revealed it did not include written policies and procedures describing how orders are received, how specimens are submitted to the laboratory, and how specimens are labeled. The procedure manual contained a "Patient Identification" policy which described the use of identification bracelets for patient identification and was not applicable to this laboratory. During interview at approximately 11:00 a.m., TP #1 stated that patient specimens are labeled with computer-generated labels.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of a random patient test report (MRN 1862706) and interview with TP (testing personnel) 2/25/20, the laboratory's test reports failed to include all required information. Review of a random patient post vasectomy semen analysis test report (MRN 1862706) printed from the electronic medical records system revealed the test report did not include the name and address of the laboratory where the test was performed. During interview at approximately 1:30 p.m., TP #1 confirmed that the test report did not include the laboratory's name and address.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, review of 2018 and 2019 API (American Proficiency Institute) proficiency testing records, review of email records, and interview with TP (testing personnel) 2/25/20, the laboratory director failed to ensure corrective action was taken and documented for all unacceptable proficiency testing results. The laboratory's "Corrective Action for Proficiency Testing" policy states "All final PT results must be maintained for a minimum of two years. The results are reviewed within 30 days of receipt by the laboratory director or designee ... Corrective action must be completed for PT scored with: Any value less than 100% Any failed event or analyte Any result documented as unscored or lack of consensus ... Corrective action is performed as per the specific event/analyte or result noted. ... Document all corrective action performed and signed by the laboratory director." Review of 2018 and 2019 API proficiency testing records revealed the laboratory received a score of 50% on the 2019 Microbiology 3rd event. The attestation statement for the 2019 Microbiology 3rd event was not available for review during the survey, but TP #1 stated at approximately 10:50 a.m. that TP #3 performs all of the KOH (potassium hydroxide) proficiency testing because TP #3 is the only person who reads patient KOH slides. Review of email records revealed TP #3 was notified by email 12/12/19, 1/22/20, 2/7/20, and 2/12/20 that corrective action was needed for the API 2019 Microbiology 3rd event. The laboratory director was included on the email 2/12/20, but there was no corrective action available for review at the time of the survey.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with TP (testing personnel) 2/25/20, the laboratory failed to document training for 1 of 2 testing personnel (TP #2) for all testing performed. Review of personnel records for TP #2 revealed there were no records available to indicate TP #2 was trained to perform urine microscopies prior to testing and reporting patient test results. During interview at approximately 10:45 a. m., TP #1 stated that TP #2 was trained by the TP at a sister facility in January 2019. She stated she was unsure whether the training was documented.