

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0955355	(X3) Date Survey Completed 05/15/2019
Name of Provider or Supplier Fort Wayne Endocrinology	Street Address, City, State 5010 W Jefferson Blvd, Fort Wayne, IN	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, document review, and interview, the laboratory failed to follow specimen processing procedures for microscopic urinalysis testing from 11-4-2018 to date of survey. Findings included: 1. On 5-15-2019 at 4:04 PM, one "Quest" centrifuge was observed in the specimen processing area. There was a sticker on the back of the centrifuge, dated 4-21-2017, which indicated the centrifuge was operating at 3300 revolutions per minute (RPM). 2. Review of procedure titled: "Urine Microscopic Procedure," approved by the laboratory director on 11-4-2018, read "Secure with Kova Cap and centrifuge urine specimen for 5 minutes at 1500 RPM's."</p>

3. Review of "Enclosure 1 Test Methodology and Annual Test Volume Log," signed by the laboratory director on 3-6-2019, indicated the laboratory performed 20 microscopic urinalysis tests per year. 4. Review of patient test reports indicated the following patients had microscopic urinalysis testing performed: Patient #1 (4-15-2019 at 10:44 AM); and Patient #2 (4-17-2019 at 2:32 PM) 5. In interview on 5-15-2019 at 4:03 PM, SP1, laboratory supervisor, and SP2, testing person, indicated the "Quest" centrifuge was the only centrifuge used to process microscopic urinalysis samples, and acknowledged the centrifuge was operating at 3300 RPM instead of the 1500 RPM required by approved procedure.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on observation, document review, and interview, the laboratory failed to perform function checks for one of two centrifuges (the "Quest" centrifuge), as defined by the laboratory. Findings included: 1. On 5-15-2019 at 4:04 PM, one "Quest" centrifuge was observed in the specimen processing area. The sticker on the back of the centrifuge indicated the last function check was performed on 4-21-2017 and the centrifuge was operating at 3300 revolutions per minute (RPM). 2. Review of procedure titled: "Centrifuge Maintenance," approved by the laboratory director on 8-10-2018 read: "It is recommended this (sic) centrifuge be calibrated at least every 6 months..." 3. In interview on 5-15-2019 at 4:03 PM, SP1, laboratory supervisor, and SP2, testing person, indicated the "Quest" centrifuge was used to process microscopic urinalysis samples, and acknowledged the last RPM check performed on the centrifuge was on 4-21-2017. 4. Review of patient test reports indicated the following patients had microscopic urinalysis testing performed, using the "Quest" centrifuge: Patient #1 (4-15-2019 at 10:44 AM); and Patient #2 (4-17-2019 at 2:32 PM). 5. Review of "Enclosure 1 Test Methodology and Annual Test Volume Log," signed by the laboratory director on 3-6-2019, indicated the laboratory performed 20 microscopic urinalysis tests per year, using the "Quest" centrifuge.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory director failed to ensure one of three testing personnel (SP2) demonstrated they could reliably perform testing operations prior to testing patient specimens for three of five analyzers (Immolute, Dimension EXL, and Medonics). Findings include: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 5-14-2019, indicated SP2 was a testing person. 2. Review of policy/procedure titled: "Annual and Semi-Annual Competencies," approved by the laboratory director on 10-16-2018, read: "All personnel prior to testing patient samples must have... demonstrated that they can perform all testing operations reliably to provide and report accurate results." 3. Review of personnel records did not indicate SP2, hire date 2-1-2017, demonstrated the ability to reliably and accurately perform testing operations on the Dimension EXL analyzer, Medonics analyzer, or Immolute analyzer prior to testing patient specimens. 4. Review of patient test report indicated SP2 performed testing on the following patients: Patient # Date of Testing Analyzer
 _____ 1 4-16-2019 EXL Medonics 2 4-17-2019
 Medonics 3 4-10-2019 Medonics EXL Immolute 6 5-15-2019 Medonics 7 3-28-2019
 Medonics 11 3-25-2019 Medonics EXL - Dimension EXL analyzer 5. In interview on 5-15-2019, SP1, laboratory supervisor, indicated SP2 did not demonstrate the ability to reliably and accurately perform testing operations prior to testing patient samples.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
 Based on document review and interview, the laboratory director failed to ensure competency policies and procedures were followed for two of three testing personnel reviewed (SP2 and SP3). Findings included: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 5-14-2019, indicated SP2 and SP3 were testing personnel. 2. Review of policy/procedure titled: "Annual and Semi-Annual Competencies," approved by the laboratory director on 10-16-2018, read: "Documented assessment will occur at least semi-annually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually..." 3. Review of personnel records indicated the following: a. SP2, hire date 2-1-2017, completed training for the "Dimension EXL" analyzer on 6-5-2017. There was no documentation of semi-annual competencies during the first year SP2 tested patient specimens. b. The most recent annual competency documentation for SP3, hire date 9-9-1999, was signed by the laboratory director on 9-6-2016. 4. Review of patient test reports indicated SP2 performed testing on the Dimension EXL analyzer for Patient #1 (4-16-2019) and Patient #3 (4-10-2019). 5. Review of patient test reports indicate SP3 performed testing on the following patients: Patient # Date of Testing Analyzer
 _____ 1 4-16-2019 Immolute 2 4-17-2019
 EXL Immolute 3 4-10-2019 Immolute 4 5-15-2019 Medonics EXL IDS Immolute 5 3-12-2019 Medonics EXL IDS Immolute 6 5-15-2019 Medonics EXL IDS Immolute 7 3-28-2019 EXL Immolute IDS 8 3-5-2019 EXL Immolute 9 3-25-2019 Immolute 10 3-6-

2019 EXL 11 3-25-2019 EXL Immulite IDS EXL - Dimension EXL analyzer; IDS - Immunodiagnostic Systems i-SYS analyzer 6. In interview on 5-15-2019 at 2:52 PM, SP1 indicated there were no competency assessments for the Dimension EXL analyzer for SP2 and acknowledged the most recent competency assessment for SP3 was dated 9-6-2016.