

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2132826	(X3) Date Survey Completed 05/23/2018
Name of Provider or Supplier Mciver Clinic	Street Address, City, State 710 Lomax Street, Jacksonville, FL	
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
D1000	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c)</p> <p>Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory was performing testing under their Certificate of Waiver that was not within the waived category. Findings Included: During a tour of the lab area on 5/23/18 at 11:41 AM a microscope was observed sitting on the counter and an Abbott Architect chemistry analyzer was located in the room. During an interview on 5/23/18 at 11:41 AM the testing person confirmed that the laboratory performs urine microscopy with the microscope and on 5/16/18 the laboratory began using the Abbott Architect to perform Prostate-specific antigen (PSA) and Testosterone testing on patients. The lab only has a Certificate of Waiver that allows them to perform waived testing. Urine Microscopy is moderately complex testing that require the lab to have a PPMP (Provider performed microscopy) certificate and license or a Certificate of Compliance certificate and license with the subspecialty of urinalysis. PSA and Testosterone testing are moderately complex</p>

laboratory testing that require the laboratory to have a certificate of compliance certificate and license with the subspecialties of routine chemistry and endocrinology. During an interview with the Clinic Administrator on 5/23/18 at 12:05pm, it was confirmed that McIver Clinic was operating under a Certificate of Waiver by mistake. She thought the company "RAI" had merged the certificate with another laboratory that is located in the same building. The Clinic Administrator confirmed the original date of testing on the Architect was 5/16/18 and 11/2/17 for the urine microscopy. At 12:38pm she signed a letter stating the clinic will cease testing immediately.