Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2014577	03/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Matthews Internal Medicine	434 N Trade Street, Suite 104, Matthews, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, observation, and interview with TP (testing personnel) 3/26/19, the laboratory failed to follow manufacturer's instructions for storage of the BD Affirm VPIII test kits. The BD Affirm VPIII product insert states "... Storage of Reagents The BD Affirm VPIII test kit is stable until the expiration date indicated on the kit box when stored at 2 to 8 degrees C. Alternatively, store at room temperature (up to 30 degrees C) no more than 3 months. ..." During a tour of the laboratory at approximately 3:30 p.m., the surveyor observed 1 BD Affirm VPIII kit (lot #8318523, expiration date 10/17/19) stored in a cabinet in the laboratory. The kit did not include the date the kit was placed at room temperature or a 3 month expiration date. During interview at approximately 3:30 p.m., TP #1 stated that they store the Affirm kits at room temperature until they are used up. The laboratory performed 69 patient Affirm VPIII tests from 3/28/17 (the date of the last survey) to 3/26/19.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TP (testing personnel) 3/26 /19, the laboratory director failed to ensure the job duties and responsibilities for the TP (testing personnel) were updated to reflect the laboratory's current test menu. Review of personnel records revealed the job description for 3 of 3 TP included tests the laboratory does not perform. The "LABORATORY JOB DESCRIPTION" states "... 2. Perform CBC, Strep, UA pregnancy, Urinalysis, Lipid Panel, ALT/AST, Glucose, BNP, Hemoglobin A1C, Protime, and Affirm Testing, Allergy. ..." During interview at approximately 3:20 p.m., TP #1 confirmed the laboratory does not perform CBC, lipid panel, ALT/AST, BNP, or Allergy testing.