Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0864999	04/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Woods Cardiology Internal Medicine	27550 Schoenherr Rd Suite 200, Warren, MI	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #2 (TP2), the laboratory failed to follow its policy for specimen collection for 1 of 1 venous blood collection observed. Findings include: 1. The surveyor observed TP2 on 4/6/22 at 9:10 am perform a venipuncture blood collection. Prior to the collection, TP2 asked the patient to hold gauze. Once finished filling the tubes, TP2 asked the patient to hold the gauze on the site where the needle was in the puncture site with their hand prior to TP2 pulling the needle out and sheathing the needle. 2. A review of the laboratory's "Specimen Collection by Venipuncture" procedure revealed a section titled "Performing the venipuncture stating, "After the last tube is filled, remove the tube, but maintain the needle in the vein. Once the tube is removed; place gauze just above the puncture site. In one clean movement, remove the needle and apply pressure. Be sure not to apply pressure until the needle is out of the arm, as this will cause pain to the patient." 3. An interview on 4/6/22 at 1:00 pm with TP2 confirmed they did not follow the laboratory's procedure for performing venipuncture blood collection. **This is a repeated deficiency from the 9/23/21 complaint survey and the 11/10/21 revisit survey**
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 record review and interview with the Technical Consultant (TC), the laboratory failed to indicate the address of the laboratory location where testing was performed for 12 (patients 18466, HF349694575, 6405, 6963, 50120, 97230, HF326124745, HF155360188, HF305150835, 22862, HF129584972, and 5190) of 12 patient test reports reviewed. Findings include: 1. A review of test reports revealed a lack of address of the laboratory location where testing was performed for the following patients: a. Patient 18466, reported on 04/01/2022. b. Patient HF349694575, reported on 03/10/2022. c. Patient 6405, reported on 03/02/2022. d. Patient 6963, reported on 02/21/2022. e. Patient 50120, reported on 02/10/2022. f. Patient 97230, reported on 01/12/2022. g. Patient HF32612474, reported on 12/08 /2021. h. Patient HF155360188, reported on 12/15/2021. i. Patient HF305150835, reported on 11/12/2021. j. Patient 22862, reported on 11/30/2021. k. Patient HF129584972, reported on 10/20/2021. l. Patient 5190, reported on 09/22/2021. 2. An interview on 4/6/22 at 1:00 pm with the TC confirmed the laboratory did not include the address of the laboratory on test reports for the patients listed above.