Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0290593	04/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Tampa Womens Health Center Inc	2010 E Fletcher Ave, Tampa, 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
D0000	An announced CLIA recertification survey was conducted at Tampa Womens Health Center Inc on 4/22/2024 to 4/29/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level 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, interview, and record review it was determined the laboratory failed to follow written policies and procedures for specimen labeling for 4 of 4 patients samples (#1,2,3,4). Findings included: During a tour of the laboratory on 4/22 /2024 at 9:20 AM, one sample tube containing blood did not have any label to indicate patient identification, three additional sample tubes containing blood were labeled with patient names only. Interview with Testing Person (TP) D on 4/22/2024 at 9:20 AM revealed patient sample tubes required patient names only. TP D did not know where the unlabeled sample tube came from or the patient it belonged to. Interview with TP A on 4/22/2024 at 9:40 AM, confirmed the lack of any labeling on one sample tube, and the other three samples labeled with patient names only. Review of the procedure "BLOOD DRAW Duties and Responsibilities" showed testing tubes were to be labeled with patient names, date of birth, time of draw, and date of draw.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(11) 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)(11) 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 record review and interview, the Laboratory Director (LD) failed to ensure prior to testing patients' specimens appropriate training was received for 2 of 5 Testing Personnel (TP-D, TP-E). Findings included: 1. Review of the LD job description dated 3/10/19 revealed the LD responsibilities for moderate (M) complexity testing showed prior to testing client specimens, all personnel receive the appropriate training for the type and complexity of the services offered. Personnel must have demonstrated they can perform all testing operations reliably to provide and report accurate results. 2. Review of the Form CMS-209, Laboratory Personnel Report, the laboratory had 5 TP performing M complexity testing. 3. Review of personnel records revealed, TP-D was hired 7/6/2023 and TP-E was hired 4/1/2023. No documentation of training prior to patient testing was provided for TP-D and TP-E. 4. Lack of training documentation for TP-D and TP-E was confirmed on 4/22/2024 at 2:10 PM by TP-B.