Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0716775	04/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
All Womens Health Center Of Sarasota Inc	2700 S Tamiami Trail Ste 5, Sarasota, 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 All Womens Health Center of Sarasota Inc on 04/18/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a written policies and procedures that ensured positive identification of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results for 2 of 2 years (2022-2023). Findings included: 1. The Specimen Collection and Handling policy stated specimens were to be labeled but not what information was needed to ensure integrity of specimen. 2. Review of patient logs for 10/2022, 2/2023, and 7/2023 revealed only patient names used for labeling. Testing Personnel #1 confirmed on 4/18/2024 at 3:25 PM only patient names were used for identification.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document results of control materials for Bovine Albumin Quality Control used for detecting Rhesus (Rh) antibodies in 10/2022 for 4 (10/06/2022, 10/12/2022 , 10/14/2022, and 10/26/2022) out of 5 days (10/06/2022, 10/12/2022 , 10/14/2022, 10/20/22, and 10/26/2022) of testing. Findings included: 1. Review of patient testing logs for 10/2022 documented patient testing was performed 10/06/2022, 10/12/2022 , 10/14/2022, 10/20/22, and 10 /26/2022. The Bovine Albumin results failed to be documented for 10/06/2022 with 6 patients reported, 10/12/2022 with 13 patients reported , 10/14/2022 with 9 patients reported, and 10/26/2022 with 12 patients reported. 2. Testing Personnel #1 on 4/18 /2024 at 3:25 PM confirmed the Bovine Albumin Quality Control was not documented on the listed dates when patient testing was performed in 10/2022.