Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1004076	11/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Florida Cancer Specialists & Research Institute,	3530 Kraft Rd, Ste 300, Naples, 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 validation survey was conducted at Florida Cancer Specialists & Research Institute, LLC from November 4, 2025 to November 6, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5805	TEST REPORT CFR(s): 493.1291(c) (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 review of Patient reports and staff interview, the laboratory failed to include the name of the laboratory that performed the Hematology testing on 5 out of 5 (Patients #1, #2, #3, #4 and #5) reports reviewed. Findings included: 1- Review of random patient final reports pulled 03/01/2024 (#1), 09/23/2024 (#2), 04/28/2025 (#3), 08/11/2025 (#4), and 10/10/2025 (#5) revealed that all five reports did not have the laboratory name that performed the testing. 2- During interview on 11/04/2025 at approximately 11:50 AM, the Clinic Lab Operations manager confirmed that the Laboratory name on the final reports was not correct.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)

	(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to sign off on annual competency assessment for the Technical Consultant position in the specialty of Hematology in 2024 and 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 10/03/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant. The laboratory had one Technical Consultant (TC) for Hematology specialty, and four testing persons (TP#1, TP#2, TP#3 and TP#4). 2-Review of personnel record's competency evaluations for the TC on 07/18/2024 and 08/14/2025 revealed that it was signed by a non-testing person. The Laboratory Director had no signature listed on the competency assessments in 2024 and 2025. 3- During interview on 11/04/2025 at approximately 1: 42 PM, the Clinic Lab Operations Manager stated to have signed off on the TC competency assessment in 2024 and 2025 without a delegation.