Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0194044	03/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Cancer Specialists	915 Lawn Avenue, Sellersville, PA	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) records, laboratory policies, and interview with Testing Personnel (TP) # 1, the laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples for 3 of 4 API Hematology/Coagulation PT events performed in 2025 and 2026. Findings: 1. On the day of survey, 3/27/2026 at 10:30 am, review of API Hematology/Coagulation PT records for complete blood count (CBC) testing revealed the laboratory tested PT samples in duplicate for the following 3 of 4 API Hematology/Coagulation PT events performed in 2025 and 2026: - API Event 1 2025 Hematology/Coagulation (5 of 5 samples) - API Event 3 2025 Hematology /Coagulation (5 of 5 samples) - API event 1 2026 Hematology/Coagulation (5 of 5 samples) 2. The laboratory's Proficiency testing policy (LAB-10) stated, "Test PT samples the same number of times as routine patient specimens are tested. The laboratory must not repeat testing or take an average of test results unless this policy also applies to patient specimens". The laboratory failed to provide a policy for repeat testing for CBC examinations performed on patient samples. 3. TP #1 (CMS-209 personnel #2, dated 02/25/2026) confirmed the above findings on 03/27/2026 at 12:00 pm.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, and interview with Testing Personnel (TP) #1, the laboratory failed to provide a complete procedural manual for hematology testing performed on 1 of 1 Sysmex XN-430 analyzer from 10/22/2024 to the date of survey. Findings include: 1. On the day of the survey, 03/27/2026 at 11:15 am, review of the laboratory's hematology procedure manual revealed the laboratory failed to include the following applicable requirements under 493.1251 (b) for the complete blood cell counts (CBC) performed on 1 of 1 Sysmex XN-430 from 10/22 /2024 to 03/27/2026: - (b)(3) Step-by-step performance of the procedure, including interpretation of results. 2. TP #1 (CMS-209 personnel #2, dated 02/25/2026) confirmed the findings on 03/27/2026 at 12:00 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with testing personnel (TP) #1, the laboratory failed to monitor and document humidity to ensure reliable test system operation and test result reporting for the Sysmex XN-430 (S/N 11372) analyzer used to perform hematology testing for 17 of 17 months from 10/22/2024 to 03/27/2026. Findings include: 1. On the date of the survey, 3/27/2026 at 11:45 am, the laboratory could not provide documentation for monitoring room humidity (manufacturer acceptable range 10-85% RH) to ensure operating conditions were met for the following instrumentation used to perform hematology testing for 17 of 17 months from 10/22/2024 to 03/27/2026: - Sysmex XN-430 (S/N 11372) 2. The lab performed

	51,579 hematology tests in 2025. (CMS-116 estimated annual volume, dated 02/25 /2026). 3. TP #1 (CMS-209 personnel #2, dated 02/25/2026) confirmed the findings above on 03/27/2026 at 12:00 pm.