Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2331612	03/06/2026
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Cancer Specialists	599 W State St, Ste 301, Doylestown, 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
D0000	An initial certification survey was conducted by the Pennsylvania State Agency at Alliance Cancer Specialists on 03/06/2026. The laboratory was found out of compliance with the following condition: 493.801 Condition: Enrollment and testing of samples.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) policy, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to enroll in an HHS approved PT program for 4 of 4 months when Hematology testing was performed from 11/03/2025 to 03/06/2026. Findings include: 1. The laboratory's Proficiency Testing policy stated, "The lab must be enrolled in a CMS-approved PT program." 2. On the date of the survey, 03/06/2026 at 9:55 am, the laboratory could not provide documentation for the enrollment in an HHS approved PT program for 4 of 4 months when Hematology (Complete Blood Count) examinations were performed from 11/03/2025 to 03/06/2026. 3. Review of the laboratory's test logs revealed the laboratory performed 1005 Complete Blood Count examinations from 11/03/2025 to 03/06/2026. 4. The TC (CMS 209 personnel #4, dated 03/02/2026) confirmed the above findings on 03/06/2026 at 11:20 am.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's Competency Assessment policy, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to follow written procedures to assess the competency of 1 of 1 TC for their supervisory responsibilities when hematology testing was performed from 11/03/2025 to 03/06/2026. Findings Include: 1. The laboratory's Competency Assessment policy stated, "Each completed assessment must include: Evaluator name and signature." 2. On the date of the survey, 03/06/2026 at 9:23 am, the laboratory failed to provide a competency assessment evaluated and signed by the Laboratory Director to assess the competency of 1 of 1 TC (Personnel #4, CMS 209, dated 03/02/2026) for their supervisory responsibilities when hematology testing was performed in the laboratory from 11/03/2025 to 03/06/2026. 3. Review of the laboratory's test logs revealed the laboratory performed 1005 Complete Blood Count examinations from 11/03/2025 to 03/06/2026. 4. The TC (CMS 209 personnel #4, dated 03/02/2026) confirmed the above findings on 03/06/2026 at 11:20 am.
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: A. Based on observation in the laboratory, review of laboratory temperature records, and interview with the Technical Consultant (TC), the laboratory failed to monitor and document temperatures to ensure proper storage of reagents used for hematology testing for 41 of 124 days when testing personnel were not present in the laboratory from 11/03/2025 to 03/06/2026. Findings include: 1. On the date of the survey, 03/06 /2026 at 10:42 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - 4 bottles Sulfolyser. Manufacturer storage requirements: 1 to 30C. - 1 box CellClean Auto. Manufacturer storage requirements: 1 to 30C. - 1 pack XN-L check. Manufacturer storage requirements: 2 to 8C. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document room and refrigerator temperatures for 41 of 124 days when testing personnel were not present in the laboratory from 11/03/2025 to 03/06/2026. 3. Review of the laboratory's test logs revealed the laboratory performed 1005 Complete Blood Count examinations from 11/03/2025 to 03/06/2026. 4. The TC (CMS 209 personnel #4, dated 03/02/2026) confirmed the above findings on 03/06/2026 at 11:20

	am. B. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to monitor and document relative humidity to ensure proper operating conditions for the Sysmex XN-430 analyzer used to perform hematology testing for 124 of 124 days from 11/03/2025 to 03/06/2026. Findings include: 1. The Sysmex XN-430 Instrument manual stated, "Instrument Specifications, Operating environment: Relative humidity 20 to 85%". 2. On the date of the survey, 03/06/2026 at 10:42 am, review of the laboratory's temperature records revealed the laboratory failed to monitor and document relative humidity for 124 of 124 days that hematology testing was performed from 11/03/2025 to 03/06/2026. 3. Review of the laboratory's test logs revealed the laboratory performed 1005 Complete Blood Count examinations from 11/03/2025 to 03/06/2026. 4. The TC (CMS 209 personnel #4, dated 03/02 /2026) confirmed the above findings on 03/06/2026 at 11:20 am.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to establish criteria for acceptable performance specifications for Complete Blood Count (CBC) testing performed on 1 of 1 Sysmex XN-430 hematology analyzer before reporting patient results from 11/03/2025 to 03/06/2026. Findings Include: 1. On the day of the survey, 03/06/2026 at 9:56 am, the laboratory could not provide documentation for the verification of accuracy, precision, and that reference range/normal values are appropriate for the laboratory's patient population for the following hematology analytes performed on 1 of 1 Sysmex XN-430 hematology analyzer from 11/03/2025 to 03/06/2026: - White Blood Cell Count - Platelet Count - Red Blood Cell Count - Hemoglobin - Neutrophil % - Hematocrit - Lymphocyte % - Mean Corpuscular Volume - Monocyte % - Mean Corpuscular Hemoglobin - Eosinophil % - Mean Corpuscular Hemoglobin Concentration - Basophil % - Red Cell distribution Width - Immature Granulocyte % 2. Review of the laboratory's test logs revealed the laboratory performed 1005 Complete Blood Count examinations from 11/03/2025 to 03/06/2026. 3. The TC (CMS 209 personnel #4, dated 03/02/2026) confirmed the above findings on 03/06/2026 at 11:20 am. B. Based on lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to verify accurate and reliable results were transmitted from the hematology analyzer to the laboratory's Electronic Medical Record (EMR) before reporting patient test results for 4 of 4 months from 11/03/2025 to 03/06/2026. Findings include: 1. On the day of the survey, 03/06/2026 at 9:44 am, the laboratory failed to provide records for the verification performed to ensure test results were accurately and reliably sent from the Sysmex XN-430 Hematology analyzer to the laboratory's EMR (Onco EMR) for 4 of 4 months from 11/03/2025 to 03/06/2026. 2. Review of the laboratory's test logs revealed the laboratory performed 1005 Complete

	Blood Count examinations from 11/03/2025 to 03/06/2026. 3. The TC (CMS 209 personnel #4, dated 03/02/2026) confirmed the above findings on 03/06/2026 at 11:20 am.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to document corrective action taken when refrigerated temperatures were recorded below the laboratory's acceptable range of 35.6 to 46.4 degrees Fahrenheit (F) for 3 of 124 days when Hematology testing was performed from 11/03/2025 to 03/06/2026. Findings include: 1. On the date of the survey, 03/06/2026 at 9:46 am, review of the laboratory's refrigerator temperature logs revealed temperatures below the acceptable range of 35.6 to 46.4 F were recorded for the following days when Hematology testing was performed from 11/03/2025 to 03/06/2026: - 01/20/2026 (34 F) - 01/22/2026 (33 F) - 02/10/2026 (34 F) 2. The laboratory could not provide documentation of corrective actions taken when refrigerated temperatures were below the laboratory's established range for 3 of 124 days when Hematology testing was performed from 11/03/2025 to 03/06/2026. 3. Review of the laboratory's test logs revealed the laboratory performed 1005 Complete Blood Count examinations from 11/03/2025 to 03/06/2026. 4. The TC (CMS 209 personnel #4, dated 03/02/2026) confirmed the above findings on 03/06/2026 at 11:20 am.