Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0674305	07/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Cancer Spec - Hem Onc	1078 W Baltimore Pk, Suite 1, Media, 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	A recertification survey conducted by the Pennsylvania State Agency on 07/29/2025 found the Alliance Cancer Specialists Hematology Oncology laboratory to be out of compliance with the following condition: 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
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: Based on review of the laboratory's verification of performance specifications records, lack of documentation, and interview with Testing Personnel (TP)#1 (CMS 209 personnel #2), the laboratory failed to verify the required performance specifications for testing performed on 1 of 1 Sysmex XN-L430 hematology analyzer prior to reporting patient test results from 04/01/2024 to the date of the survey. Findings Include: 1. On the day of the survey, 07/29/2025 at 9:47 am, review of the laboratory's verification of performance specification records for the 1 of 1 Sysmex XN-L430 hematology analyzer (s/n 12002) performed on 04/01/2024, revealed the laboratory failed to perform a reference range/normal value study appropriate for the laboratory's patient population for the following analytes prior to reporting patient test results for Complete blood counts (CBC) from 04/01/2024 to 07/29/2025. - White Blood Count (WBC) - Red Blood Count (RBC) - Hemoglobin (HGB) - Hematocrit (HCT) - Mean Corpuscular Volume (MCV) - Mean Corpuscular Hemoglobin (MCH) - Mean

	Corpuscular Hemoglobin Concentration (MCHC) - Mean Platelet Volume (MPV) - Red Blood Cell Distribution Weight (RDW) - Platelet (PLT) - Neutrophils (NEUT) - Lymphocytes (LYMPH) - Monocytes (MONO) - Eosinophils (EO) - Basophils (BASO) 2. The laboratory failed to provide a policy that included the laboratory's criteria to ensure a reference range/normal value study was appropriate for the laboratory's patient population. 3. The laboratory performed 11,906 CBC tests from 04 /01/2024 to 07/29/2025. 4. TP#1 confirmed the findings above on 07/29/2025 at 10:42 am.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of competency assessment records, personnel credentials and interview with testing personnel, the laboratory failed to have a technical consultant who met the qualification requirements of 493.1411 and provided technical oversight in accordance with 493.1413 to assure performance of hematology testing and accuracy of test result reporting for 5 of 5 testing personnel in 2024 and 2025. Refer to D6035
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical

	laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on review of competency assessment (CA) records, personnel credentials, and interview with testing personnel (TP) #1, the laboratory failed to ensure that 1 of 2 Technical Consultants (TC) #2 met the requirements to perform technical consultation for moderate complexity testing in hematology in 2024 and 2025. Findings include: 1. On the day of the survey, 07/29/2025 at 9:26 am, review of CA records revealed that TC #2 (CMS 209 personnel #7, dated 07/21/2025) failed to evaluate the competency of the following 5 of 5 TP that performed Complete Blood Counts (CBC) in 2024 and 2025: - 2024: TP #3 and TP #4 (CMS 209 personnel #4 and #5, dated 07/21/2025) - 2025: TP #3, TP #4 and TP #5 (CMS 209 personnel #4, #5 and #6, dated 07/21/2025) 2. Further review of CA records revealed that TP #1 (CMS 209 personnel #2, dated 07/21/2025) performed the competency assessments for CBC testing performed by TP #3 and TP #4 in 2024 and by TP #3, TP #4 and TP #5 in 2025. 3. Interview with TP #1 on 07/29/2025 at 9:50 am and review of personnel credentials revealed TP #1 did not meet the minimum requirements of 493.1411 to perform technical consultation for moderate complexity testing in hematology. 4. TP #1 confirmed the findings above on 07/29/2025 at 10:42 am.