Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0862659	08/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Cancer Specialists	1203 Langhorne Newton Rd, Langhorne, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with the Testing Personnel (TP)#6, the Laboratory Director (LD) failed to sign the MLE PT attestation statement documents for 2 of 3 hematology events in 2020 and 1 of 3 hematology events 2021. Findings include: 1. On the day of survey, 08/10/2021, review of MLE PT records revealed, the following MLE PT attestation statement documents were not signed by the LD: - 2020, Event #2, Hematology - 2020, Event #3, Hematology - 2021 Event #2, Hematology. 2. The TP#6 confirmed the findings above on 08/10/2021 at 10:20 a.m.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of Medical Laboratory Evaluation (MLE) proficiency test (PT)

	records and interview with the testing personnel (TP)#6, the Laboratory Director (LD) did not ensure that an approved corrective action plan was followed for 1 of 3 Hematology unsatisfactory PT results in 2020 and 1 of 3 hematology unsatisfactory results in 2021 Findings include: 1. On the day of survey 08/10/2021 at 10:20 a.m., the laboratory could not provide any documentation to show that the corrective action plans for the following test were reviewed and approved by the laboratory director: - 2021 MLE-M2 Hematology- Cell identification (0%) - 2020 MLE-M2 Hematology- Erythrocyte count (0%) and hematocrit (20%) 2. The TP#6 confirmed the findings above on 08/10/2021 at 11:15 a.m.