Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0988200	11/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Cancer Specialists	700 Horizon Circle Suite 106, Chalfont, 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 review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the medical technician and site manager, the laboratory director failed to attest to 2 of 5 attestation statements in 2020 and 2021. Findings Include: 1. On the day of survey, 11/09/2021, review of the API PT records revealed, the laboratory director did not sign the attestation statements for the following event in 2020 and 2021. - 2020 API - Hematology - Event #3. - 2021 API - Hematology - Event #2. 2. The medical technician and site manager, confirmed the findings above on 11/09/2021 around 09:50 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 competency assessment policy and interview with the medical technician and site manager, the laboratory failed to have a complete competency assessment policy that states to evaluate all new testing personnel (TP) for competency at least semiannually during the first year the individual tests patient

	specimens in 2020. Findings include: 1. On the day of survey, 11/09/2021, the laboratory could not provide a competency assessment policy that states to evaluate new testing TP (3 of 4) for competency at least semiannually during the first year the individual tests patient specimens in 2020. 2. The laboratory could not provide semi annual competency assessment records performed during the first in 2020 for TP #3, 5 and 6. 3. The medical technician and site manager confirmed the findings above on 11 /9/2021 around 9:10 am.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of records and interview with the medical technician and site manager, the laboratory failed to establish a maintenance policy to assess the maintenance/function for 2 of 2 laboratory thermometers from November 2019 to the day of survey. Findings Include: 1. On the day of survey, 11/09/2021, the surveyor observed the following thermometers in use to monitor temperatures in the laboratory: - DURCA thermometer - refrigerator temperature. - Unlabelled thermometer - room temperature. 2. The laboratory could not provide a thermometer maintenance policy or maintenance records for the thermometers in use. 3. The technician and site manager confirmed the findings above on 11/09/2021 around 10: 00 am.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the medical technician and site manager, the laboratory director failed ensure proficiency testing reports received, identify any problems that require corrective actions in 2020 and 2021. Findings include: 1. On the day of survey, 11/09/2021, review of the API PT records revealed, the laboratory did not document complete corrective actions for the following PT events in 2020 and 2021: -

	2020 API Event #2 - Hematology - Cell identification - Score 80%. - 2021 API Event #2 - Hematology - Platelets - Score 60%. 2. The medical technician and site manager confirmed the findings above on 11/09/2021 around 09: 55 am. .
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with the medical technician and site manager, the laboratory director (LD) failed to specify, in writing, the responsibilities and duties for 2 of 3 clinical consultant (CC) engaged in the performance of post analytic phases of testing in 2019 to the day of survey. Findings include: 1. On the date of survey, 11/09/2021, the laboratory stated, one medical doctor is on site each day of patient testing to review and sign off on patient complete blood counts final reports. 2. Review of testing personnel records revealed, 2 of 3 MDs who perform responsibilities as CC were not listed on the CLIA 209 Laboratory Personnel Report form. 3. The laboratory could not provide the following documentation for 2 of the 3 MDs: - Documentation of written responsibilities. - Competency assessment records for their responsibilities as a CC. 4. The medical technician and site manager confirmed the findings above on 11/09/2021 around 10: 30 am.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency assessment records, peer review records and interview with the medical technician and site manager, the technical consultant failed to assess 5 of 6 TP through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for hematology testing in 2020. Findings Include: 1. On the day of survey, 11/09/2021, a review of TP competency assessment records and peer review records revealed, 5 of 6 testing personnel were not assessed for test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in 2020 for hematology testing. 2. The medical technician and site manager confirmed the finding above on 11/09/2021 around 9:52 am.