Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0199415	11/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Cancer Specialists, Pc	Marcy Baron, Philadelphia, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation the laboratory microscope and interview with Testing Personnel (TP) #1, the laboratory failed to perform maintenance for 1 of 1 Olympus CH -2 microscope in 2020. Findings include: 1. On the day of survey, 11/19/2020, observation of the laboratory microscope revealed, the service sticker on 1 of 1 Olympus CH -2 microscope was due for annual maintenance on 10/20/2020. 2. TP#1 confirmed the finding above on 11/19/2020 around 10:15 am.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter Ac T Diff 2 records and interview with testing personnel (TP) #1, the laboratory failed to evaluate the relationship between 2 of 2 Beckman Coulter Ac T Diff 2 hematology analyzers in 2018, 2019 and 2020. Findings include: 1. On the day of survey, 11/19/2020, the laboratory could not

	provide comparison studies performed on 2 of 2 Beckman Coulter Ac T Diff 2 hematology analyzers in 2018, 2019 and 2020. 2. TP #1 confirmed the finding above on 11/19/2020 around 09:45 am.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory daily temperature log records and interview with testing personnel (TP) #1, the laboratory failed to document all corrective actions taken when refrigerator and laboratory room temperatures exceeded acceptable ranges in 2019 and 2020. Findings include: 1. The laboratory daily temperature log states, optimal refrigerator temperature (2-8 degrees Celsius), freezer and laboratory room temperatures (68-77 degrees Fahrenheit). "All discrepancies must be reported to supervisor." 2. On the day of survey, 11/19/2020, review of the laboratory daily temperature log records revealed, the following number of days each month temperatures exceeded acceptable ranges in 2019 and 2020. 2019: - Laboratory Temperature: 08 of 19 days temperatures were below acceptable range in August. - Laboratory Temperature: 07 of 20 days temperatures were below acceptable range in September. - Laboratory Temperature: 12 of 22 days temperatures were below acceptable range in October. - Laboratory Temperature: 07 of 18 days temperatures were below acceptable range in November. - Laboratory Temperature: 05 of 21 days temperatures were below acceptable range in December. 2020: - Laboratory Temperature: 07 of 22 days temperatures were below acceptable range in January. - Laboratory Temperature: 09 of 20 days temperatures were below acceptable range in February. - Laboratory Temperature: 07 of 22 days temperatures were below acceptable range in March. - Laboratory Temperature: 10 of 23 days temperatures were below acceptable range in April. - Laboratory Temperature: 01 of 21 days temperatures were below acceptable range in May. - Laboratory Temperature: 01 of 22 days temperatures were below acceptable range in June. - Refrigerator Temperature: 01 of 22 days temperatures were above acceptable range in June. - Refrigerator Temperature: 01 of 23 days temperatures were below acceptable range in July. - Laboratory Temperature: 01 of 21 days temperatures were below acceptable range in August. - Refrigerator Temperature: 02 of 21 days temperatures were below acceptable range in August. - Laboratory Temperature: 03 of 21 days temperatures were below acceptable range in September. - Laboratory Temperature: 06 of 21 days temperatures were below acceptable range in October. - Refrigerator Temperature: 06 of 21 days temperatures were below acceptable range in October. 3. TP #1 could not provide correction actions documented for temperatures out of range in 2019 and 2020. 4. TP #1 confirmed the finding above on 11/19/2020 around 09:20 am.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on review of personnel files, testing personnel competency assessment records and interview with testing personnel (TP) #1, the technical supervisor (Laboratory Director) failed to evaluate the competency for 2 of 8 TP performing differential smears in 2018, 2019 and 2020. Findings include: 1. On the date of survey, 11/19 /2020, review of personnel files and TP competency assessment records revealed, 2 of 8 TP (TP#1 and TP#2) performing differential smears in 2018, 2019 and 2020 were not assessed for competency. 2. TP #1 confirmed the finding above on 11/19/2020 around 9:00 am.