Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0862659	03/13/2019
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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with Testing Personnel (TP) #4 and #5, the laboratory failed to establish a Quality Assurance Policy from 2017 to the date of survey. Findings include: 1. On the day of survey, 03/13/2019, review of the laboratory's manuals revealed that the laboratory could not provide a written policy to assess the quality of its laboratory systems from 08/22/2017 to 03/19/2019. 2. TP #4 and #5 confirmed the findings above on 03/13/2019 around 10:50 am.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with Testing Personnel (TP) #4 and #5, the laboratory failed to ensure that 3 of 5 boxes of BD Vacutainer Safety-Lok Blood collection set needles were not used beyond their expiration date. Finding Include: 1. On the day of survey, 03/13/2019, while on tour of the laboratory, surveyor #2

	observed, 3 of 5 boxes of BD Vacutainer Safety-Lok Blood Collection Sets, 21 Gauge needles, used to collect patient blood for the Complete blood count (CB) test, had expired: a. Lot Number: 53111 Expiration Date: 07/2018. B. Lot Number: 50511, Expiration Date: 07/2018. ac. Lot Number: 50811, Expiration Date: 09/2018. 2. TO#5 stated the needles were not in use, but could not provide documentation stating the claim. 3. TO #4 and #5 confirmed the above findings on 03/13/2019 around 9:30 am.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the complete blood count (CBC) quality control (QC) records, review of Controls not within Limits procedure, and interview with Testing personnel (TP) #4 and #5, the laboratory failed to follow and document all corrective actions taken when the Beckman coulter AcT Diff 2 QC was out of range on 9 out of 61 days from November 2018 to December of 2018. Findings include: 1. The laboratory's QC procedure, Procedure To Follow When Controls Not Within Limits, stated in section 5 that, "Document evidence of any corrective action taken". 2. The laboratory ran 3 levels of QC for the CBC test, each day of patient testing. 3. On the day of survey, 03 /13/2019, review of quality control records from November 2018 to December 2018 revealed: a. 11/21/2018: High Level, RBC, Hemoglobin (HGB) and Hematocrit (HCT) b. 11/29/2018: High Level, HGB c. 12/20/2018: High Level, HGB d. 12/24 /2018: Normal Level, HGB e. 12/24/2018: High Level, HGB f. 12/26/2018: Normal Level, HGB g. 12/26/2018: High Level, HGB h. 12/27/2018: Normal Level, HGB i. 12 /28/2018: High Level, HGB 4. The laboratory could not provide documentation of corrective actions taken on days QC was out of range. 4. TP #4 and #5 confirmed the finding above on 03/13/2019 around 10:30 am