Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0194044	09/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Cancer Specialists	915 Lawn Avenue, Sellersville, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory maintenance record, and interview with the Medical Assistant (MA), the laboratory failed to retain maintenance records for 2 of 2 Beckman Coulter ACT Diff-2 analyzers from 2018. Findings include: 1. On the day of survey, 09/28/2020, the laboratory could not provide maintenance records for 2 of 2 Beckman Coulter ACT Diff-2 analyzers from 02/28/2018 to 09/28/2018. 2. The MA confirmed the above finding on 09/28/2020 around 09:15 am.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory Quality Assessment (QA) policy, quality assessment records and interview with Medical Assistant (MA), the laboratory failed to retain 3 of 12 quality assessments review records from 2018. Findings include: 1. The laboratory QA policy states "quality assessment factors will be reviewed monthly and documented on the quality assessment work sheet". 2. On the day of survey, 09/28

	/2020, the laboratory could not provide the quality assessment review records for 3 of 12 months in 2018 (February, March and April). 3. On 09/28/2020 at 09:30 am, the MA confirmed the finding above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based upon review of the Quality Control (QC) policy, Beckman Coulter ACT Diff-2 QC records and interview with the Medical Assistant (MA), the laboratory failed to perform and document calibration at least once every 6 months, for 2 of 2 Beckman Coulter ACT Diff-2 Analyzers in 2018 and 2019. Findings include: 1. The laboratory QC policy states, "Calibration will be performed every 06 months using S-CAL calibrator for routine maintenance". 2. On the day of survey, 09/28/2020, review of 2 of 2 Beckman Coulter ACT Diff-2 records revealed, calibrations were not performed at least every 6 months on the following analyzers in 2018 and 2019. -Infusion room location: Performed once in 2018 (08/22/2018). -Laboratory area: Performed once in 2018 (08/23/2018). Performed once in 2019 (03/12/2019). 3. On 09/28/2020 at 10:10 am, the MA confirmed the findings above.
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 ACT Diff-2 Analyzers records and

	interview with the Medical Assistant (MA), the laboratory failed to evaluate the relationship between 2 of 2 Beckman Coulter ACT Diff-2 analyzers used for Complete Blood Count (CBC) analysis in 2018, 2019, 2020. Findings include: 1. On the day of survey 09/28/2020, review of the Beckman Coulter ACT Diff-2 records revealed, the laboratory did not perform comparison studies on 2 of 2 Beckman Coulter ACT Diff-2 CBC analyzers in 2018, 2019 and 2020. 2. On 09/28/2020 at 10: 15 am, the MA confirmed the findings above.