Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0996505	02/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Adventhealth Lab Oncology Denver	2555 S Downing St, Ste 240, Denver, CO	

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
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 environmental records and interview with lab staff the laboratory failed to retain records for room temp and humidity for at least two years. Findings include: A) Review of environmental records in the laboratory revealed logs were not kept for at least two years for the following: a. No room temperature documentation for 7 of 12 months in 2016. b. No humidity documentation 7 of 12 months in 2016 B) Interview with the lab staff conducted on 02/13/2018 @ 10:00 AM confirmed temperature and humidity logs were not retained on the dates specified above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of temperature logs, and interview with the laboratory staff, the

	laboratory failed to monitor the temperature for the Cypress Hematology Laboratory Refrigerator (sensor ID: C9970724/2, Description PO23308) for 2 of 12 months in 2017. Findings include: 1. Review of temperature logs in the TempTrack system revealed temperatures were not monitored due to the TempTrack system being off line from 07/24/2017 through 09/28/2017. 2. In an interview conducted on 02/13/2018 at approximately 10:00 AM, laboratory staff confirmed the TempTrack system was offline from 07/24/2017 through 09/28/2017 and the temperature for the Cypress Hematology Laboratory Refrigerator was not monitored during that timeframe.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of temperature logs, hematology quality control package insert, and interview with the laboratory staff, the laboratory failed to document corrective actions for temperatures that were out of range on the hematology reagent refrigerator on for 7 of 7 months reviewed. Findings include: 1. Review of temperature logs in the TempTrack system revealed temperatures were out of range on the following days for the Cypress Hematology Laboratory Refrigerator (sensor ID: C9970724/2, Description PO23308, acceptable range 2-8 degrees Celsius): a. July 2016, 1 of 31 days: 29th b. August 2016, 5 of 31 days: 23rd. 25th, 29th, 30th, and 31st c. September 2016, 8 of 30 days:7th, 14th, 15th, 19th, 21st, 22nd, 26th, and 27th d. November 2016, 7 of 30 days: 3rd. 8th, 17th, 22nd, 28th, and 29th e. February 2017, 5 of 28 days: 8th, 14th, 16th, 21st, and 22nd f. June 2017, 9 of 30 days: 5th, 8th, 11th, 13th, 14th, 19th, 22nd, 26th, and 27th g. July 2017, 7 of 18 days: 9th, 10th, 14th, 15th, 16th, 17th, and 18th. 2. The E Check (XS) hematology quality control package insert stated the acceptable range for storage was from 2-8 degrees Celsius. 3. No corrective actions were documented for the dates mentioned above where the TempTrack system revealed temperatures were out of range for the Cypress Hematology Laboratory Refrigerator. 4. In an interview conducted on 02/13/2018 at approximately 10:00 AM, laboratory staff confirmed no corrective actions were documented for the dates mentioned above where the TempTrack system revealed temperatures were out of range for the Cypress Hematology Laboratory Refrigerator.