Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0915056	09/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Highlands Oncology Group Lab I	3232 North North Hills Blvd, Fayetteville, AR	

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
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: Through review of the manufacturer's instrument manual, laboratory temperature and humidity records, and interview it was determined that the laboratory failed to maintain appropriate operating humidity levels on twenty of twenty-two days of operation in January 2020. Findings follow: A) Review of the manufacturer's instrument manual for the Beckman AU 680 chemistry analyzer revealed an operating humidity level requirement of 40% to 80%. B) Review of the laboratory's room temperature and humidity records revealed that acceptable humidity level was defined as 20% to 80%. C) Review of laboratory room temperature and humidity level records for January 2020 revelealed that room humidity level was recorded as less than 40% on twenty of twenty-two days of operation in January 2020. D) In an interview on 9/22 /20 at approximately 03:00 PM, the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the laboratory's defined acceptable humidity range did not conform to the manufacturer's requirements for the Beckman AU 680 chemistry analyzer and that recorded room humidity was less than manufacturer's defined requirement on twenty of twenty-two days in January 2020.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Through observation, review of package insert, and interview it was determined that the laboratory failed to document the date opened and the expiration date of three of three vials of XN Check Hematology controls in current use. A) The package insert of the XN Check Hematology controls states that the product expiration date changes to seven days after the vial is opened and the product is placed into use. B) During a tour of the laboratory on 9/23/20 at approximately 11:15 AM three vials of XN Check Hematology controls (lot 02331101, 02331102, 02331103) were observed in the laboratory refrigerator without labels of the date opened or the amended expiration date. C) In an interview on 9/23/20 at approximately 11:15 AM the testing personnel, identified as number three on the CMS 209 form, verified that the vials were the controls currently in use and that they were not labeled with the date opened and/or the amended expiration date.
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: Through observation, and interview it was determined that phlebotomy supplies that had exceeded their date of expiration were present and available for use on one of one phlebotomy tray. Findings follow: A) During a tour of the laboratory on 9/23/20 at approximately 11:00 AM two BD Lytic/10 Anaerobic Culture vials, lot# 9253475 with expiration date 2020-06-30, one BD Aerobic Culture vial, lot# 9302537 expiration date 2020-08-31, and one BD EDTA trace element blood collection tube lot# 9095803 expiration date 2020-4-30 were observed on a phlebotomy tray and no other containers of those types were present on the tray. B) In an interview on 9/23/20 at approximately 11:00 AM, the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the items identified above had expired and were available for use.
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: Through review of maintenance records, lack of documentation, review of

	maintenance procedures prescribed by the manufacturer for the Beckman AU 680 chemistry analyzer and interview it was determined that the laboratory failed to document the maintenance program as required by the instrument manufacturer on twenty-four of twenty-four months reviewed. Findings follow: A) Upon review of the instrument manual it was determined that the Beckman AU 680 chemistry analyzer manufacturer defines a daily, monthly, and six-month maintenance regimen required for the analyzer to maintain optimum performance. B) Review of maintenance records for the Beckman AU 680 chemistry analyzer revealed that all daily maintenance records for 2019 and 2020 had a hand-written notation stating "see analyzer". C) Upon request, the laboratory was unable to provide documentation of the performance of daily maintenance procedures for the Beckman AU 680 chemistry analyzer. D) During an interview on September 23,2015 at approximately 11:15 AM the laboratory staff member identified as number two on the CMS 209 form verified that the documentation of daily maintenance performance on the Beckman AU 680 chemistry analyzer was not available.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Through review of personnel records, lack of documentation and interview it was determined that the laboratory failed to evaluate competency on an annual basis of one of three testing personnel listed on the CMS 209 form. Findings follow: A) Review of the records of competency evaluation for the testing person, identified as number three on the CMS 209 form, revealed competency evaluations for 2015, 2016 and 2017 and no competency evaluations for 2018 and 2019. B) Upon request, the laboratory was unable to provide competency evaluations for 2018 and 2019 for the testing person, identified as number three on the CMS 209 form. C) In an interview on 9/22/20 at approximately 01:40 PM, the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the laboratory testing personnel, identified as number three on the CMS 209 form, had been continuously employed in the laboratory since 2015 and competency evaluations for 2018 and 2019 were not documented.