Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0915057	09/25/2020
Name of Provider or Supplier	**Street Address, City, State**	
Highlands Oncology Group Lab Ii	808 South 52nd Street, Rogers, 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, tour of the laboratory, lack of documentation and interview it was determined that the laboratory failed to maintain appropriate operating humidity levels on 87 of 152 days of operation in January 2020 through May 2020 and failed to monitor temperature in three of five rooms in which supply items with a storage temperature requirement were stored. Findings follow: I: The laboratory failed to maintain appropriate operating humidity levels required for the operation of the Beckman AU 680 chemistry analyzer. 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%. The lower limit of the laboratory's range is below the manufacturer's requirement for the Beckman AU 680. C) Review of laboratory room temperature and humidity level records for January 2020 through May 2020 revelealed that room humidity level was recorded as less than 40% on 87 of 152 days recorded. D) In an interview on 9/25/20 at approximately 10:30 AM, the laboratory staff member, identified as number five 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 87 of 152 days in January 2020 through May 2020. II: The laboratory failed to monitor temperature in three of five rooms in which supply items with a storage temperature requirement were stored. A) On a tour of the laboratory on 9/24/20 at approximately 08:45 AM, it was observed that the laboratory had five separate rooms (main laboratory, main laboratory separate storage room, phlebotomy area, two separate phlebotomy area storage rooms) in which supply items with a storage temperature requirement were stored. B) Review of the laboratory temperature records for 2020 revealed temperatures recorded for the main laboratory and the phlebotomy area but no temperature records for the main laboratory storage room, or the two separate phlebotomy area storage rooms. C) On a tour of the laboratory on 9/25/20 at approximately 11:00 AM, two cases of BacT/Alert blood culture bottles lot# 00405592 with a temperature requirement of 15 degrees C. to 30 degrees C. were observed in phlebotomy storage room number 1; 80 Vacuette 5cc EDTA blood collection tubes lot# B200833C. 60 Vacuette Heparin blood collection tubes lot# B20073KA and 80 BD 15cc serum separator blood collection tubes lot# 01764 all with a storage temperature requirement of 4 degrees C. to 25 degrees were observed in phlebotomy storage room number 2 and 4 bottles of Coulter ISE mid standard solution lot# M008099 with a storage temperature requiirement of 2 degrees C. to 29 degrees C. were observed in the main laboratory storage room. D) Upon request, the laboratory was unable to provide room temperature records for the main laboratory storage room or the two phlebotomy area storage rooms identified above. E) In an interview on 9/25/20 at approximately 11:30, the laboratory staff member identified as number five on the CMS 209 form confirmed that temperature measurements were not recorded in the three rooms identified above.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the laboratory's quality control policy and procedure, daily quality control printouts for the Beckman AU 680 Clinical Chemistry System utilizing Biorad Lyphocheck lot number 26440 quality control material, a review of patient test reports, and interviews with laboratory staff, it was determined that patient results were reported when results of control materials failed to meet the laboratory's criteria for acceptability. Survey findings follow: A) The laboratory's quality control policy and procedure states that quality control is unacceptable when both levels of control are plus/minus 2SDI from target values B) A review of the Beckman AU 680 daily quality control printouts for 9/24/19 revealed the ALT result on the Level 1 and Level 2 Chemistry Control (26440) was outside of the acceptable criteria. The acceptable range listed for ALT for Level 1 is 26 plus/minus 2 and Level 2 is 80 plus/minus 4. Results documented for 9/24/29 are 23 for Level 1 (-2SDI) and 75 for Level 2 (-2 SDI). C) Through a review of patient chemistry reports it was determined 136 patients had ALT results reported on 9/24/20, when the chemistry control was unacceptable. D) A review of the Beckman AU 680 daily quality control printouts for 1/17/20 revealed the PO4 result on the Level 1 and Level 2 Chemistry Control (26440) was outside of the acceptable criteria. The acceptable range listed for PO4 for Level 1 is 3.5 plus/minus 0.4 and Level 2 is 7.4 plus/minus 0.7. Results documented for 1/17/20

	are 4.0 for Level 1 (+2SDI) and 8.1 for Level 2 (+2SDI). E) Through a review of patient chemistry reports it was determined 127 patients had PO4 results reported on 1 /17/20, when the chemistry control was unacceptable. F) A review of the Beckman AU 680 daily quality control printouts for 1/27/20 revealed the PO4 result on the Level 1 and Level 2 Chemistry Control (26440) was outside of the acceptable criteria. The acceptable range listed for PO4 for Level 1 is 3.5 plus/minus 0.4 and Level 2 is 7.4 plus/minus 0.7. Results documented for 1/27/20 are 4.0 for Level 1 (+2SDI) and 8.1 for Level 2 (+2SDI). G) Through a review of patient chemistry reports it was determined 151 patients had PO4 results reported on 1/27/20, when the chemistry control was unacceptable. H) In an interview on 9/25/20 at approximately 11:30 AM the laboratory employee number 5 (as listed on the form CMS-209) confirmed that quality control results were not acceptable for the tests and dates listed above. She further confirmed that patients were reported on those dates.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Through review of Unity peer group comparison monthly evaluation reports for Biorad Lyphocheck Lot # 26440, proficiency testing reports, laboratory quality assurance reports and interview it was determined that the laboratory's quality assurance program failed to assess the effectiveness of corrective action taken to resolve problems experienced in clinical chemistry procedures. Findings follow: A) Review of Unity peer group comparison monthly evaluation reports for Biorad Lyphocheck Lot # 26440 for September 2019, revealed that "Warning: acceptable values are above -2 and below 2" flags were present for ALT, AST, Chol, IgM, PO4, and Uric Acid and the corrective action comments were " Reviewed all and consistent with last month". B) Review of Unity peer group comparison monthly evaluation reports for Biorad Lyphocheck Lot # 26440 for Novemebr 2019, revealed that "Warning: acceptable values are above -2 and below 2" flags were present for ALT, AST, Chol, IgG, PO4,GGT and Uric Acid and the corrective action comments were " will monitor". C) Review of Unity peer group comparison monthly evaluation reports for Biorad Lyphocheck Lot # 26440 for January 2020, revealed that "Warning: acceptable values are above -2 and below 2" flags were present for ALT, AST, Chol, Creat, PO4, and Uric Acid and the corrective action comments were " will monitor". D) Review of API Chemistry Core proficiency testing results for 1st event 2019 revealed a score of 80 % for chloride and PO4 with a corrective action comment "will monitor". E) Review of API Chemistry Core proficiency testing results for 2nd event 2019 revealed a score of 80 % for Chloide with no notes of corrective action. F) Review of API Chemistry Core proficiency testing results for 3rd event 2019 revealed PO4 values with a positive bias of over 2 SDI from peers with no corrective action comments ". G) Review of API Chemistry Core proficiency testing results for 1st event 2020 revealed a score of 80 % for PO4 with a corrective action comment "wrong calibrator value". H) Review of the laboratory's monthly quality assurance reports for 2019 and 2020 revealed that under the heading "Analytical Quality Assurance" that all eighteen reports reviewed had the statement "nothing to report". I)

	In an interview on 9/25/20 at approximately 11:30 AM, the laboratory staff member identified as number 5 on the CMS 209 form confirmed that there were analytical issues in several clinical chemistry assays for the period of September 2019 through January 2020 and that no corrective action was initiated.