Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0915057	08/10/2022
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
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Through interview it was determined that the laboratory failed to report results of Covid-19 testing to the Arkansas Department of Health within twenty-four hours of test performance. Findings follow: A) In an interview on 8/10/2022 at 1:20 pm a staff member (#2 on personnel identification list) confirmed that Covid-19 positive results were not reported to the health department. B) When asked how many Covid-19 had been performed, a staff member (#2 on personnel identification list) said records indicated 113 Covid-19 tests had been performed in 2022 with 25 of those tests indicating positive results.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Through a review of proficiency test documentation for 2021 and 2022 it was determined the laboratory failed to document a review or corrective actions for proficiency test failures in two of twelve events in 2021 and 2022. Survey findings include: A. During a review of proficiency test documentation for 2021 and 2022, the

	following events included failures with no documented corrective actions: Immunology 3rd event 2021 (IgA 60%); and Chemistry Core 1st Event 2022 (CA125 50%, and Calcium 60%). B. In an interview, at 9:35 a.m. on 8/10/2022, laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of corrective actions documented for the proficiency test failures.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through lack of documentation, a review of maintenance documentation for the Beckman Coulter AU 680 for November and December 2021 and March and July 2022, a review of laboratory policies and procedures, quality control policy and procedure, a lack of written policies and procedures for determining quality control ranges or addressing shifts in data, a review of the BioRad Control manufacturer's requirements, and a review of the Beckman Coulter AU 680 and TOSOH AIA - 2000 quality control (QC) documentation, and interviews with laboratory staff it was determined the laboratory failed to meet analytic systems requirements as evidenced by: D5429 - the laboratory failed to document all maintenance in three of four months reviewed D5441 - the laboratory failed to have control procedures that monitor the accuracy and precision of the complete analytic process D5433 - the Laboratory failed to perform and document centrifuge maintenance as specified by the Laboratory D5469 - the laboratory failed to use statistical parameters to calculate criteria for acceptability of QC for sixteen of sixteen tests reviewed for the AU 680 and seven of seven tests reviewed for the TOSOH AIA in which BioRad Controls were the quality control material D5481 - the laboratory did not follow its policy of taking corrective action before releasing patient test results when quality control results were outside of acceptable range D5791 - the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor and correct problems identified in the analytic systems
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 a review of maintenance documentation for the Beckman Coulter AU 680 for November and December 2021 and March and July 2022, and interviews with laboratory staff, it was determined the laboratory failed to document all maintenance in three of four months reviewed. Survey findings include: A. The AU680 Maintenance Schedule List included the following required daily maintenance:

	Inspect the syringes for leaks; Inspect the Wash Solution Roller Pump for leaks; Inspect the Wash Solution and Replenish as needed; Inspect the Stability of the Upper Cover; Inspect, Clean, and Prime the Sample Probes, Reagent Probes, and Mix Bars; Replace the Deionized Water or Diluent in the Pre-dilution Bottle; Inspect/Prepare the Sample Probe Wash Solutions; Inspect the Printer and Paper; Clean the ISE; and Calibrate the ISE. The schedule included the following weekly maintenance: Clean sample probes and mix bars; Perform W2; Perform Photocal; Clean the Pre-dilution bottle; Check Selectivity of the NA/K electrodes; and Enhanced cleaning of ISE Electrode line. B. A review of November 2021 maintenance documentation for the Beckman Coulter AU 680 revealed daily maintenance was not documented on 11/8 /2021, 11/10/2021, or 11/11/2021 although quality control was performed on those dates. C. The surveyor requested Beckman Coulter AU 680 maintenance documentation for December 2021. None was provided in the records provided to the surveyor. At 2:29 p.m. on 8/10/2022 laboratory employee #2 (as documented on the form CMS-209) stated that the December 2021 maintenance checklist could not be found. D. Through a review of the Beckman Coulter AU 680 maintenance checklist for March 2022, it was determined daily maintenance was not documented on 3/28 /2022, 3/29/2022, 3/30/2022, or 3/31/2022, although quality control was documented. E. In an interview at 2:29 p.m. on 8/10/2022, laboratory employee #2 confirmed the maintenance had not been documented on the dates listed above.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of documentation, as well as interviews with staff, it was determined the Laboratory failed to perform and document centrifuge maintenance to ensure accurate centrifugation force as required per BD Vacutainer package insert: A. The BD Vacutainer package insert (3/2018) states to spin BD SST tubes between 1000 and 1300 RCF (relative centrifugal force) for 10 minutes. B. The surveyor requested centrifuge maintenance records and centrifuge speed checks for 2021 and 2022 none was provided. C. In an interview on 08/10/2022 2:30pm, Laboratory employee #2 (as listed on CMS form 209) confirmed the Laboratory failed to document centrifuge maintenance and speed checks.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

	conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of laboratory policies and procedures, a review of quality control documentation, and interviews with laboratory staff, it was determined the laboratory failed to have control procedures that monitor the accuracy and precision of the complete analytic process. Survey findings include: A. During a review of the laboratory policies and procedures, it was determined the policies and procedures didn't include a written policy for establishing quality control acceptable ranges, didn't include a policy for evaluating acceptability of daily quality control, and did not include a policy for evaluating quality control over time for shifts and trends. B. During a review of quality control for December 2021, March 2022, and July 2022, the surveyor observed quality control ranges that were too wide to be effective, as cited at 5469, and had no documentation of origin, as cited at D5469, and the surveyor observed shifts in quality control results that were not addressed by the laboratory as listed below. C. Through a review of Beckman Counter AU 680 quality control for December 2021 the surveyor observed Phosphorous Level II control (lot # 26470) shifted below the mean for the entire month (17 consecutive points below the mean). A review of the TOSOH AIA - 2000 quality control for December 2021 revealed Ferritin Level I control (lot # 40380) was shifted above the mean all month (23 consecutive points). D. During a review of Beckman Counter AU 680 quality control for March 2022 the suveyor noted that Transferrin level II control (lot # 26470) was below the mean all month (23 consecutive points). E. In an interview, at 1:01 p.m. on 8 /10/2022, laboratory employee #2 (as listed on the form CMS-209) confirmed the laboratory did not have written policies for evaluating quality control for immediate errors or for errors over time such as shifts and trends. He further confirmed the laboratory had no written policies and procedures for establishing acceptable quality control ranges.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a lack of written policies and procedures for quality control, a review of the BioRad Control manufacturer's requirements, and a review of the Beckman Coulter

	AU 680 and TOSOH AIA - 2000 quality control (QC) documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to use statistical parameters to calculate criteria for acceptability of QC for sixteen of sixteen tests reviewed for the AU 680 and seven of seven tests reviewed for the TOSOH AIA in which BioRad Controls were the quality control material. Survey findings include: A. During a review of the laboratory policies and procedures, it was determined the policies and procedures didn't include a written policy for establishing quality control acceptable ranges. B. BioRad quality control instructions for use (as stated on their quality control website QCnet My e-Inserts) state, "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." C. Through a review of Beckman Coulter AU 680 quality control documentation for December 2021 the surveyor observed quality control ranges used as 2 standard deviation (SD) acceptable ranges that were much wider than the calculated 2 SD ranges listed in the Unity Monthly Evaluation provided by BIO-RAD (the quality control material manufacturer). Examples of ranges that were much wider than the calculated ranges are as follows for quality control lot # 26470 which expires 2/28 /2023: Albumin Level II 2 SD in use by the laboratory was 2.9 and the 12 month calculated 2 SD based on 420 points from BIO-RAD was 0.16; BUN (Blood Urea Nitrogen) Level II 2 SD in use by the laboratory was 20.7 and the cumulative calculated 2 SD based on 464 points from BIO-RAD was 3.34; Amylase Level I 2 SD in use by the laboratory was 24.5 and the 12 month calculated 2 SD based on 420 points from BIO-RAD was 2.46; and Alkaline Phosphates Level II 2 SD in use by the laboratory was 144 and the 12 month calculated 2 SD based on 420 points from BIO-RAD was 37.7. D. Through a review of Beckman Coulter AU 680 quality control documentation for March 2022 the surveyor observed quality control ranges used as 2 SD acceptable ranges that were much wider than the calculated 2 SD ranges listed in the Unity Monthly Evaluation provided by BIO-RAD. Examples of ranges that were much wider than the calculated ranges are as follows for quality control lot # 26470 which expires 2/28/2023: Albumin Level II 2 SD in use by the laboratory was 2.9 and the cumulative 2 SD based on 521 points from BIO-RAD was 0.16; BUN Level II 2 SD in use by the laboratory was 20.7 and the cumulative calculated 2 SD based on 565 points from BIO-RAD was 3.2; Amylase Level I 2 SD in use by the laboratory was 24.5 and the cumulative calculated 2 SD based on 2500 points from BIO-RAD was 2.48; and Alkaline Phosphatase Level II 2 SD in use by the laboratory was 144 and the cumulative calculated 2 SD based on 542 points from BIO-RAD was 37.7. E. Through a review of Beckman Coulter AU 680 quality control documentation for July 2022 the surveyor observed quality control ranges used as 2 SD acceptable ranges that were much wider than the calculated 2 SD ranges listed in the Unity Monthly Evaluation provided by BIO-RAD. Examples of ranges that were much wider than the calculated ranges are as follows for quality control lot # 26470 which expires 2/28 /2023: Albumin Level II 2 SD in use by the laboratory was 2.9 and the cumulative 2 SD based on 556 points from BIO-RAD was 0.16; BUN Level II 2 SD in use by the laboratory was 20.7 and the cumulative calculated 2 SD based on 565 points from BIO-RAD was 3.2; Amylase Level I 2 SD in use by the laboratory was 24.5 and the cumulative calculated 2 SD based on 2535 points from BIO-RAD was 2.5; and Alkaline Phosphatase Level II 2 SD in use by the laboratory was 144 and the cumulative calculated 2 SD based on 577 points from BIO-RAD was 37.5. F. In an interview, at 1:01 on 8/10/2022, laboratory employee #2 (as listed on the form CMS-209) confirmed there were no written policies for establishing quality control ranges and confirmed the quality control ranges in use were too wide for identifying failures of the test system and that there was no documentation of the origin of the ranges in use.

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 review of quality control policy and procedure, quality control results, lack of documentation, and interview it was determined that on one out of three months reviewed the laboratory did not follow its policy of taking corrective action before releasing patient test results when quality control results were outside of acceptable range. Findings follow: A. Through review of the laboratory's policy for quality control it was determined that successive quality control results exceeding 2 standard deviations from the mean must be investigated and corrective action taken and documented before patient results can be released. B. Through review of the quality control results for November 2021 it was determined that on November 15 at 0723 and 0739 hours level 3 quality control results for ~PLT-F assays exceeded greater than 2 standard deviations from the mean (574 mean, 41.6 SD) with values of 488 and 482 in succession. C. Through review of provided documentation, there were no corrective action logs for 2021. D. During an interview on 8/10/22 at 1:51pm the laboratory personnel identified as number 2 CMS 209 report verified that the quality control results for ~PLT-F on the above listed date were out of acceptable range, that no documentation of corrective action could be found, and that patient ~PLT-F results were reported in violation of laboratory policy and procedure.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Through lack of policies and procedures, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor and correct problems identified in the analytic systems. Survey findings include: A. During a review of policies and procedures, the surveyor requested a copy of the laboratory's quality assurance policies. None was provided. B. A review of the BIO-RAD Unity reports for November 2021, March 2022, and July 2022 revealed quality control ranges were not set appropriately (as cited at D5469). The BIO-RAD Unity reports had no documentation that the laboratory had identified the inappropriate quality control ranges or documentation that the laboratory had taken steps to correct them. C. Through a review of Beckman Counter AU 680 and the TOSOH AIA - 2000 quality control for December 2021 and March 2022, the surveyor observed shifts in quality control data for Phosphorous Level II control (lot # 26470), Ferritin Level I control (lot # 40380), and Transferrin level II control (lot # 26470), that were not identified by quality assurance reviews and had no documentation of corrective actions. D. A review of maintenance documentation for the Beckman Coulter AU 680 for

	November and December 2021 and March and July 2022, and interviews with laboratory staff, revealed the laboratory failed to document all maintenance in three of four months reviewed. There was no documentation that these failures were identified or corrected through quality assurance reviews. E. In an interview, at 2:30 on 8/10 /2022, laboratory employee #2 (as listed on the form CMS-209) stated the laboratory had no written quality assurance policies and further stated the only quality assurance records available were the BIO-RAD Unity reports received from the quality control material manufacturer. He confirmed there was no documentation of identifying errors in the analytic systems or corrective actions for those errors.