Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2121304	03/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northwest Regional Cancer Care Center	171 Carraway Drive, Winfield, AL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on an interview with Testing Personnel (TP) #1, a review of the proficiency testing enrollment record for 2019 and a lack of documentation for 2018 proficiency testing participation/enrollment, the surveyor determined the laboratory failed to enroll in proficiency testing for Hematology (Complete Blood Count) testing in 2018. The laboratory previously held a CLIA Certificate of Accreditation, under the management of the hospital; but terminated the certificate in August 2018. The CLIA certificate was reactivated in October of 2018. According to TP #1 on 3/19/2019, the laboratory, under new ownership began patient testing on January 15, 2018. However, the last proficiency testing participation recalled by TP #1 was in late 2017, when the laboratory was managed by the hospital. The laboratory did not enroll in proficiency testing until 2019; although patient testing was performed in 2018. The findings include: 1. Upon tour of the laboratory, at 11:30 AM, the surveyor explained the records and documents needed for the surveyor's review. At this time, the surveyor stated proficiency testing records were needed. TP #1 explained the laboratory, under its new ownership, had only participated in the first testing event of 2019 (results are pending); and the previous participation occurred when the laboratory had been owned by the hospital, in late 2017. TP #1 stated the "new" laboratory began patient

	testing [Complete Blood Counts (CBCs)] on January 15, 2018. TP #1 further stated the laboratory had not participated in proficiency testing in 2018. 2. A review of the proficiency testing records revealed the laboratory's enrollment in API (American Proficiency Institute) program for 2019. There was no documentation of enrollment nor participation in proficiency testing for 2018; although the laboratory performed CBC testing in 2018, beginning on January 15.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of laboratory records, a lack of documentation, and interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to: 1. Ensure the laboratory was enrolled in proficiency testing for Hematology, Complete Blood Count testing, in 2018. 2. Ensure a Quality Assessment program was established to ensure the quality of laboratory services provided. 3. Employ a Technical Consultant to provide technical oversight to the laboratory. 4 Ensure laboratory testing personnel presented with appropriate educational credentials, were trained, prior to testing patients' specimens; and perform assessments to ensure testing personnel maintained their competency. 5. Provide the laboratory staff with complete and sufficient policies and procedures to ensure quality laboratory systems and services. The findings include: 1. Refer to D6015. 2. Refer to D6021. 3. Refer to D6028, D6033 and D6034 4. Refer to D6021 and D6066 5. Refer to D6031.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on an interview with Testing Personnel (TP) #1, a review of the proficiency testing enrollment record for 2019 and a lack of documentation for 2018 proficiency testing participation/enrollment, the surveyor determined the laboratory director failed to ensure the laboratory enrolled in proficiency testing for Hematology (Complete Blood Count) testing in 2018. The laboratory previously held a CLIA Certificate of Accreditation, under the management of the hospital; but terminated the certificate in August 2018. The CLIA certificate was reactivated in October of 2018. According to TP #1 on 3/19/2019, the laboratory, under new ownership began patient testing on January 15, 2018. However, the last proficiency testing participation recalled was in late 2017, when the laboratory was managed by the hospital. The laboratory did not enroll in proficiency testing until 2019; although patient testing continued throughout 2018. The findings include: 1. Upon tour of the laboratory, at 11:30 AM, the surveyor

	explained the records and documents needed for the surveyor's review. At this time, the surveyor stated proficiency testing records were needed. TP #1 explained the laboratory, under its new ownership, had only participated in the first testing event of 2019 (results are pending); and the previous participation occurred when the laboratory had been owned by the hospital, in late 2017. TP #1 stated the "new" laboratory began patient testing [Complete Blood Counts (CBCs)] on January 15, 2018. TP #1 further stated the laboratory had not participated in proficiency testing in 2018. 2. A review of the proficiency testing records revealed the laboratory's enrollment in API (American Proficiency Institute) program for 2019. There was no documentation of enrollment nor participation in proficiency testing for 2018; although the laboratory performed CBC testing in 2018, beginning on January 15.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual (LABORATORY OVERVIEW policy), a lack of documentation of quality assurance monitoring, and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure a quality assessment program was established and maintained to assure the quality of laboratory services (pre-analytic, analytic, and post-analytic systems) provided. The findings include: 1. A review of the laboratory's policy and procedure manual revealed the LABORATORY OVERVIEW policy. However the overview did not address a quality assessment program or monitoring. 2. In an interview on 3/19/2019 at 12:30 PM, the surveyor inquired of TP #1 if the laboratory performed any quality assurance verifications, specifically, any patient chart reviews (patient results were manually entered into the computer). TP #1 stated the laboratory staff did not perform any quality checks; however the nurses did. TP #1 did not provide any further information of what was actually verified by the nurses, and could not provide documentation. The surveyor discussed with TP #1 what aspects of laboratory systems needed to be monitored (pre-analytic, analytic and post-analytic processes).
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

	This STANDARD is not met as evidenced by: Based on a review of personnel records, a review of the CMS form #209 (Laboratory Personnel Report) for CLIA , a lack of documentation of a Technical Consultant, and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to employ a Technical Consultant, qualified (493.1411) to provide technical oversight in accordance with 493.1413, Technical Consultant Responsibilities. The findings include: 1. Refer to D6033 and D6034.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of personnel records and a lack of documentation of personnel records, a review of the "LABORATORY OVERVIEW," and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure personnel hired to perform moderate complexity laboratory testing, presented with the appropriate educational credentials, prior to testing patient specimens and reporting the results. The Laboratory Director further failed to ensure the testing personnel received training, prior to testing patient specimens, and demonstrated continued competency. This affected three of three testing personnel, listed on the Laboratory Personnel Report. The findings include: 1. A review of the Laboratory Personnel Report, submitted by the laboratory on 3/19/19, listed three testing personnel. 2. The personnel records (manual) of the three testing personnel failed to include the appropriate educational credentials, as required by 42 CFR, Part 493. At a minimum, testing personnel, who perform moderate complexity testing, must provide proof of high school education, by either a diploma, general education diploma (GED) or high school transcript. Three of three personnel records failed to include any of these items of evidence. 3. None of the three testing personnel records included training documentation for CBC (Complete Blood Count, Hematology) testing, performed on the Beckman Coulter Act Diff 2. (Refer also to D6066). 4. The competency of the three testing personnel had not been demonstrated, as evidenced by a lack of documentation of competency assessments; although the testing personnel had been identified as testing personnel for greater than one year. 5. A review of the laboratory's "LABORATORY OVERVIEW" revealed the following: "...Employees that perform lab testing are to have competency evaluated on those procedures the employee is to perform in the beginning of assignment of patient testing and then at least annually. ...A job description is to be read and signed initially, evaluation in six months and then annually thereafter..." 6. The above noted findings were confirmed by TP #1, on March 19, 2019 at 11:45 AM.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure the laboratory staff were provided with policies and procedures, complete and sufficient, to ensure quality laboratory systems for pre-analytic, post-analytic and analytic processes. The laboratory provided a manual which included a "LABORATORY OVERVIEW," however this overview did not include all aspects of laboratory systems. The Beckman Coulter Act diff 2 Operators' Manual was presented for the analytic processes, which was not signed (noting approval) by the director. The findings include: 1. The laboratory's policy and procedure manual included a "LABORATORY OVERVIEW" with the following references: "Collection procedure is to be followed establishing patient identification, tests to be performed, tubes to be used, any special collection requirements or needs, any problems or issues to be noted for the patient... Personnel records will be kept in HR (Human Resources) department of the hospital and will include past training and experience, formal certification, copy of academic degree or transcript, references... All patient information is to be kept confidential and all HIPAA regulations are to be maintained. ...Employees that perform lab testing are to have competency evaluated on those procedures the employee is to perform in the beginning of assignment of patient testing and then at least annually. ...A job description is to be read and signed initially, evaluation in six months and then annually thereafter. ..." This "LABORATORY OVERVIEW" policy was signed by the Laboratory Director and dated 1/12/2017, and by the three testing personnel, dated 1/15/2019. 2. A review of the laboratory's policy and procedure manual did not include policies and procedures on how the following would be accomplished: * Specimen collection, labeling, and handling * Specimen referral * Reporting and recording of panic values (a list of panic values were posted near the Hematology analyzer) * Communications and how complaint investigations were handled * Quality Assurance This list is not all inclusive of the laboratory systems. 3. The Beckman Coulter Act diff 2 Operators' Manual was presented by TP #1 for the analytic processes; however this manual was not signed (noting approval) by the Laboratory Director. 4. On 3/19/2019 at 12:19 PM, the surveyor discussed the above noted items with TP #1, who confirmed the lack of documentation for the above mentioned policies and procedures.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Laboratory Personnel Report (CMS form #209), completed

	by the laboratory staff, a review of personnel records, a lack of documentation, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to employ a technical consultant to provide technical oversight in accordance with 493.1413 (Technical Consultant Responsibilities) of the CLIA (Clinical Laboratory Improvement Amendments) requirements. The findings include: 1. After the initial tour of the laboratory and upon review of the CLIA forms, at 11:45 AM, the surveyor inquired of TP #1, if the laboratory had a technical consultant, as none was listed on the CMS form #209. At this time, TP #1 was not aware of the CLIA requirement to employ a technical consultant (only testing personnel were listed on the form). The surveyor discussed with TP #1 the qualifications of a technical consultant for moderate-complexity laboratories. 2. At this time, TP #1 called staff, at another location and who were affiliated with the laboratory, to inquire of who might be serving in the technical consultant capacity. The name of a former technical consultant was given; however this person was contacted (at 12:09 PM) and stated she had not been associated with the laboratory in over six years. The laboratory failed to provide a technical consultant for the laboratory. 3. The manual containing the testing personnel's documentation failed to include documentation of a technical consultant.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report (CMS form #209), completed by the laboratory staff, a review of personnel records, a lack of documentation, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to employ a technical consultant to provide technical oversight in accordance with 493.1413 (Technical Consultant Responsibilities) of the CLIA (Clinical Laboratory Improvement Amendments) requirements. The findings include: 1. Refer to D6033, 493.1409 Technical Consultant.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records and a lack of documentation of training, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the testing personnel, who performed moderate complextity testing, recieved training, prior to testing patient specimens. This affected three of three testing personnel, listed on the "Laboratory Personnel Report." The findings include: 1. After the tour of the laboratory on March 19, 2019 at 11:30 AM, TP #1 provided the Laboratory Personnel Report with three testing personnel listed,

	who performed moderate complextity testing. 2. A review of the personnel records revealed three of three testing personnel, who had no training documentation for CBC (Complete Blood Count, Hematology) testing, performed on the Beckman Coulter Act Diff 2. (Also refer to D6029). 3. The above noted findings were confirmed by TP #1 on March 19 at 11:45 AM.