Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2129156	08/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
The Center For Cancer And Blood Disorders	800 W Magnolia Avenue, Fort Worth, TX	

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
D0000	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: Based on review of laboratory policy, proficiency testing (PT) records and confirmed in interview, the laboratory failed to review and evaluate the results obtained on proficiency testing for hematology (flow cytometry) results for 1 of 1 events in 2019 (Event 1), 1 of 2 events in 2020 (Event 2) and 1 of 1 events in 2021 (Event 1). Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a policy for proficiency testing procedures. 2. Review of NeoGenomics PT records for 2019, 2020 and 2021 revealed the laboratory did not ensure the laboratory director documented their review/evaluation of hematology (flow cytometry) PT results, as

	follows: 2019-Event 1 PT final report was not signed 2020- Event 2 PT final report was not signed 2021- Event 1 PT final report was not signed 3. During an interview on 08/24/2021 at 10:18 am, Testing Person-1 (TP-1) stated that he had reviewed and signed the final reports, but the laboratory director failed to review/sign the final reports. This confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on direct observation, laboratory establishment studies on the Beckman Coulter Gallios flow cytometer, and confirmed in interview, the laboratory failed to document complete establishment studies for all antibody panels tested on peripheral blood and bone marrow specimens for malignant immunophenotyping testing using the Beckman Coulter Gallios flow cytometer. Findings: 1. During a tour of the laboratory on 08/24/2021 at 9:15am, a Beckman Coulter flow cytometer (Serial Number AZ35612) was observed. This instrument was used to perform laboratory developed testing for malignant immunophenotyping on peripheral blood and bone marrow specimens. 2. Review of the laboratory Beckman Coulter Gallios flow cytometer antibody panels establishment studies revealed peripheral blood and bone marrow specimens were tested for the following antigen markers: CD38 CD56 CD3 CD5 CD7 CD2 CD19 CD4 CD8 CD45 Kappa Lambda CD23 CD10 CD11c CD34 CD20 CD16 CD13 CD64 CD117 CD33 CD14 HLA-DR 3. Further review of the Beckman Coulter Gallios flow cytomtery establishment studies revealed the following: "SUMMARY and CONCLUSION This validation shows the comparison of both qualitative and quantitative malignant immunophenotyping data and results obtained using Gallios S /N AZ35612 at the "XX" FC Laboratory with the data obtained using previously validated Navios instruments at the "XX" flow laboratories ... The reproducibility /precision results show a coefficient of variation of less than 20% for all populations, and are acceptable. The specificity and sensitivity are all 100%." The laboratory failed to include documentation of establishment studies for specimen stability (peripheral blood and bone marrow), interfering substances and stability for antibody panels. 4. During an interview on 08/24/2021 at 1:20 pm, Testing Person-1 (TP-1) was asked to provide the establishment studies for specimen stability, antibody panel stability and interfering substances. TP-1 stated that the antibody panels were stable for 14 days and patient specimens were stable for 3 days. TP-1 was asked where he obtained the stability and he stated that the stability was obtained by the reference laboratory that provided the interpretations of the flow cytometry patient final reports. TP-1 further stated that no establishment studies were performed for interfering substances. This

	confirmed the above findings. The laboratory failed to document complete establishment studies for specimen stability, interfering substances and antibody panel stability on the Beckman Coulter Gallios flow cytometer.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of Center for Medicare and Medicaid Services (CMS) 209 form, personnel records, and confirmed in interview, the laboratory director failed to specify, in writing, responsibilities and duties of each technical supervisor (TS) for 5 of 5 TS (TS-1, TS-2, TS-3, TS-4, TS-5), each general supervisor (GS) for 1 of 1 GS (GS-1), and each testing person (TP) for 1 of 1 TP (TP-1). Findings: 1. Review of the CMS 209 form revealed the laboratory identified 5 technical supervisors (TS-1, TS-2, TS-3, TS-4, TS-5), 1 general supervisor (GS-1)and 1 testing person (TP-1). Note: GS-1 was also TP-1. 2. Review of personnel records revealed the following: TS-1, TS-2, TS-3, TS-4, TS-5 and GS-1/TP-1 did not have delegation of duties/responsibilities assigned in writing by the laboratory director. The laboratory director failed to specify, in writing, responsibilities and duties for the above-mentioned supervisors and testing persons. 3. During the exit interview on 08/24/2021 at 2:30 pm, GS-1/TS-1 confirmed the above findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory's policy, personnel records, and confirmed in interview, the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 1 of 1 testing persons (TP-1) performing high complexity testing. Findings: 1. Review of the CMS 209 form revealed 1 testing persons (TP1) performing high complexity testing. TP-1: hire date 02/04/2019 2. Review of the laboratory's policy manual revealed there was no policy for personnel performing high complexity testing. 3. Review of personnel records for TP-1 performing high complexity testing revealed no evaluation and documentation of competency assessments for TP-1 at least semiannually. Refer to D6127. The Laboratory director failed to ensure that competency assessments had

	been performed and documented for testing persons to include: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. f) Assessment of problem solving skills. 4. During the exit interview on 08/24/2021 at 2:30 pm, the Testing Person-1 confirmed the above findings. Word key: CMS: Centers for Medicare and Medicaid Services
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory records, CMS 209, personnel records and confirmed in interview, the laboratory failed to ensure 3 of 5 Technical Supervisors (TS-2, TS-3, TS-5) met the education requirements to provide technical supervision for high complexity toxicology testing. Findings: 1. Review of the laboratory's test menu included laboratory developed tests in the specialty of hematology. 2. Review of the CMS 209 form revealed the laboratory listed TS-2, TS-3 and TS-5 as individuals providing technical oversight of high complexity hematology testing. 3. Review of personnel records for TS-2, TS-3 and TS-5 revealed there was no documentation of education available for review. 4. During an interview on 08/24/2021 at 1:20 pm, Testing Person-1 confirmed the above findings. Word key: CMS: Centers for Medicare and Medicaid Services
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, CMS form 209, personnel records, and interview with staff, the Technical Supervisor failed to evaluate competency assessment for 1 of 1 testing persons (TP-1) responsible for high complexity testing, at least semiannually during the first year of testing. Findings: 1. Review of the laboratory's policy manual revealed the laboratory failed to have a policy for personnel competency assessments. 2. Review of the CMS 209 form revealed TP-1 performed high complexity testing. 3. Review of personnel records for TP-1 performing high complexity testing included documented training on 06/04/2019 and 08/29/2019 for flow cytometry. Records did not include documented semiannual

	competency assessments for TP-1. The technical supervisor failed to evaluate and document competency assessments for TP-1 at least semiannually. 4. During an interview on 08/24/2021 at 9:55 am, TP-1 confirmed the above findings. Word key: CMS: Centers for Medicare and Medicaid Services