Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0929489	11/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cancer And Hematology Centers, The	12460 Riley Street, Holland, MI	

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 a lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to enroll in an approved proficiency testing program for serum human gonadotropin (hCG) testing for 2 (November 2019 to November 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's proficiency testing records revealed a lack of documentation of testing for serum hCG testing, a test listed on the test menu given to the surveyor. 2. An interview on 11/08/2021 at 10:15 am with the TC confirmed the laboratory had not enrolled in an approved proficiency testing program for the serum hCG testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

	and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform quality control each day of patient testing for the serum human chorionic gonadotropin (hCG) testing for 2 (November 2019 to November 2021) of 2 years reviewed. Findings include: 1. A "In-House Test Menu CHC Holland" was presented to the surveyor upon arrival that included serum hCG. 2. When queried on 11/08/2021 at 10:15 am, the surveyor requested a copy of the manufacturer's product instructions, a total count of tests performed over 2 years, and documentation of the external quality control results. 3. The manufacturer's instructions for the "ICON 25 hCG" revealed the serum hCG testing to be a moderately complex test. 4. A "Order Choice Utilization Report" was pulled from 11 /05/2019 to 11/05/2021 that indicated that 58 serum hCG tests had been performed. 5. A lack of documentation to show that every day of patient testing an external positive and negative control were performed and documented and that an individual quality control plan (IQCP) had not been developed or put into place for 2 (November 2019 to November 2021) of 2 years of testing. 6. An interview on 11/08/2021 at 10:15 am, the TC confirmed serum hCG testing was being performed and that external positive and negative controls were not performed and documented each day of patient testing.