

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0371168	(X3) Date Survey Completed 06/05/2019
Name of Provider or Supplier Karmanos Cancer Institute Bloomfield	Street Address, City, State 43097 Woodward Avenue Ste 100, Bloomfield Hills, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure review, record review, and interview with the office manager and Testing Personnel #1 (TP1), the laboratory failed to perform quality control as required for the hematology complete blood cell count test for 1 (medical record number 781309) of 10 patient charts audited. Findings include: 1. Review of the "ABX Micros 60 Procedure" states that three levels of controls must be run and acceptable each day of patient testing. 2. Record review of the monthly quality control records revealed for patient medical record 781309 testing performed on January 2, 2019, no quality control was performed prior to testing patient specimens. 3. During the interview on June 5, 2019 at approximately 1:00 pm, the office manager and TP1 acknowledged that no quality control was performed prior to testing patient specimens on January 2, 2019.</p>