Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0914071	06/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Karmanos Cancer Institute - Lapeer	1295 Barry Drive Suite B, Lapeer, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 and #2 (TP1 and TP2), the Laboratory Director (LD) and TP failed to attest to the routine integration of the hematology proficiency testing samples into the patient workload for 6 (2nd and 3rd events 2017, 1st-3rd events 2018 and the 1st event of 2019) of 6 events reviewed. Findings include: 1. Record review of the American Proficiency Institute (API) hematology proficiency testing documents revealed the attestation statement sheet was not signed by the LD and TP for 6 of 6 events in 2017 - 2019. 2. During the interview on June 17, 2019 at 10:45 am, TP1 and TP2 acknowledged the attestation statement sheets were not signed.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during

	the PT event. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 and #2 (TP1 and TP2), the laboratory failed to 1) retain the original proficiency testing (PT) program report forms for 2 (3rd event 2017 and 2018) of 6 events reviewed and 2) the instrument printouts for 1 (3rd event 2017) of 6 events reviewed for the hematology PT. Findings include: 1. Record review of the American Proficiency Institute (API) final PT documents revealed the laboratory did not retain the original proficiency testing program report forms and the instrument printouts as follows: a. original PT program report forms - 3rd event 2017 and 2018 b. original instrument printouts - 3rd event 2017 2. During the interview on June 17, 2019 at 10:45 am, TP1 and TP2 acknowledge the original PT program report forms and the hematology instrument printouts was not available to the surveyor.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on procedure review, record review, and interview with Testing Personnel #1 and #2 (TP1 and TP2), the laboratory failed to ensure competency policies were followed for 14 (#1 - #14) of 14 TP performing the moderately complex hematology complete blood cell count testing. Findings include: 1. Review of the "Personnel Competency Policy/Procedure" in the CLIA manual revealed competency is to be completed, initially, at 6 months, and annually thereafter. 2. Record review of the TP competency assessments revealed the following: a. No initial competency - TP5 b. No 6 month competency - TP4 and TP11 c. no annually competency in 2017 - TP7 and TP12 c. no annual competency in 2018 - TP1 - TP3, TP5 - TP9, and TP11 - TP14 d. no annual competency in 2019 - TP2 - TP4, TP6, TP8 - TP9, and TP12 - TP14 3. During the interview on June 17, 2019 at 9:28 am, TP1 and TP2 acknowledged the competency assessments had not been performed or documented as stated in the policy. ***Repeat Deficiency from the 12/03/16 survey***
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 and #2 (TP1 and TP2), the laboratory failed to document corrective action for improper storage of the Minotrol Horiba Medical ABX Micros 60 hematology analyzer quality control material for 2 (January and February) of 6 months reviewed in 2019. Findings include: 1. Record review of the "Refrigerator Temp Log 2019 Temp Range 2-8 C"

	revealed 18 days of operation the temperature was below the stated range and no corrective action was documented as follows: a. January - 9 - 11, 14 - 17, 22, 24, and 28 - 30 b. February - 1 and 4 - 8 2. During the interview on June 17, 2019 at 10:12 am, TP1 and TP2 acknowledged no corrective action was documented for the temperatures outside the stated range.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 and #2 (TP1 and TP2), the laboratory director failed to ensure the final American Proficiency Institute (API) proficiency testing (PT) reports were reviewed by the appropriate staff for 6 (2nd - 3rd events 2017, 1st - 3rd events 2018 and 1st event 2019) of 6 events reviewed. Findings include: 1. Record review of the final API reports revealed the appropriate staff did not review the final PT program report forms to evaluate their performance and to identify any problems that require corrective action as follows: a. 2nd and 3rd events 2017 - no review by the appropriate TP b. 1st-3rd events 2018 and 1st event 2019 -no review by Laboratory Director and TP 2. During the interview on June 17, 2019 at 10:45 am, TP1 and TP2 acknowledged the appropriate staff did not document review the final PT program test reports. ***Repeat Deficiency from the 12 /03/16 survey***