Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0914071	06/02/2021
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
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 record review and interview with Testing Personnel #1, the laboratory failed to establish policies and procedures to assess the competency of their three technical consultants listed on the CMS-209 form for 2 (June 2019 to June 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's competency records revealed a lack of competency documentation for the following personnel: a. Technical Consultant #1 b. Technical Consultant #2 c. Technical Consultant #3 2. An interview with Testing Personnel #1 on 6/2/21 at 9:49 am revealed the laboratory did not have policies and procedures for the assessment of consultant competency and has not performed competency assessments for the personnel listed above. ***This is a repeated deficiency from the 6/17/19 and 12/13/16 recertification surveys***
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

	system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 and #2, the laboratory failed to perform calibration on the Horiba ABX micros 60 hematology analyzer at least every 6 months for 1 (September 2019) of 4 calibration events reviewed. Findings include: 1. A review of the laboratory's calibration records for the Horiba ABX micros 60 hematology analyzer for Complete Blood Count (CBC) testing revealed a lack of documentation of a calibration performed in September 2019, after the previous calibration performed on 3/5/19. 2. A review of the laboratory's policy titled "Quality Assurance for Micros 60 Analyzer" revealed a section stating, "calibration is performed every six months and as necessary. Keep all printouts and file in folder labeled same." 3. An interview on 6/2/21 at 10:21 am with Testing Personnel #1 and #2 confirmed the laboratory did not have documentation of performing calibration for September 2019.
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, the Laboratory Director failed to ensure proficiency testing reports were reviewed for 3 (2nd event in 2019, 1st event in 2020, 1st event in 2021) of 3 events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing documentation revealed a lack of review of results performed by the laboratory director or designee and the testing personnel listed on the attestation forms for the following testing events: a. 2nd event in 2019 b. 1st event in 2020 c. 1st event in 2021 2. A review of the laboratory's "Proficiency Testing" procedure revealed a section stating, "All proficiency testing reports are reviewed by the staff to evaluate the laboratories performance and to identify any problems that require corrective action." 3. An interview on 6/2/21 at with Testing Personnel #1 confirmed the Laboratory Director had not ensured the proficiency testing reports were reviewed. ***This is a repeated deficiency from the 6/17/19 and 12/13/16 recertification surveys***

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1, the Laboratory Director failed to ensure a corrective action plan was followed for proficiency testing results found to be unacceptable for 1 (1st event in 2020) of 3 events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing documentation revealed the laboratory had an unacceptable score for the platelet count on specimen HEM-01 for the first event in 2020. 2. The surveyor requested corrective action performed after the unacceptable score for platelets on 6/2 /21 at 10:07 am and it was not made available. 3. A review of the laboratory's "Proficiency Testing" procedure revealed a section stating, "An approved corrective action plan is followed when any proficiency testing result(s) is found to be unacceptable or unsatisfactory." 4. An interview on 6/2/21 at 10:07 am with Testing Personnel #1 confirmed the Laboratory Director had not ensured corrective action was performed for unacceptable results.