Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0914071	03/22/2023
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on record review and interview with the Supervisor of Operations (SO), the laboratory failed to have the white binder that housed the policies and procedures approved, signed, and dated by the Laboratory Director for 22 (June 2021 to March 2023) of 22 months of operation in use. Findings include: 1. A record review of the white binder that housed the laboratory's policies and procedures revealed the Laboratory Director never approved, signed, and dated the policies and procedures in use for 22 (June 2021 to March 2023) of 22 months in use. 2. An interview on 3/22/23 at 11:02 am, the SO confirmed the policies and procedures in the white binder were not approved, signed, and dated by the Laboratory Director.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the Supervisor of Operations (SO), the laboratory failed to perform the hematology calibration procedures at least every 6 months for 1 (second event in 2022) of 5 events reviewed. Findings include: 1. Record review of the calibration documents for the hematology Horiba Medical ABX Micros 60 hematology analyzer revealed the laboratory did not have any documentation to show the calibration procedure was performed for 1 (second event in 2022) of 5 events reviewed. 2. When queried on 3/22/2023 at 11:59 am, the SO stated the facility was having trouble with the purchasing order to receive the calibration material in a timely manner. 3. An interview on 3/22/2023 at 11:59 am, the SO confirmed the calibration verification was not performed for the 2nd event in 2022. ***Repeat Deficiency from the 12/13/2016 survey***
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 the Supervisor of Operations (SO), the Laboratory Director failed to ensure proficiency testing reports were reviewed for 5 (events 2 and 3 in 2021 and events 1 - 3 in 2022) of 5 testing events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed a lack of review for 5 of 5 events in 2021 and 2022 by the testing personnel. 2. An interview on 3/22/2023 at 10:22 am, the SO confirmed there was no documentation of the testing personnel reviewing the final proficiency testing event performances. ***Repeat Deficiency from the 12/13/2016, 6 /17/2019, and 6/02/2021 surveys***
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview with the Supervisor of Operations, the laboratory failed to ensure Technical Consultant #2, performing the duties of a Technical Consultant, had met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035.

D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: . Based on record review and interview with the Supervisor of Operations (SO), the laboratory failed to ensure personnel performing the technical consultant duty of performing testing personnel competency assessments was qualified for 11 (Testing Personnel (TP) #1 - #11) of 11 testing personnel competency assessment performed in 2021 to 2023. Findings include: 1. A review of the laboratory's personnel competency records revealed the following testing personnel had a competency assessment performed by Technical Consultant #2 as listed on the CMS-209: a. TP#1 - evaluated on 1/13/2022 and 1/27/2023. b. TP#2 - evaluated on 1/13/2022 and 1/19/2023. c. TP#3 - evaluated on 1/13/2022 and 1/27/2023. d. TP#4 - evaluated on 1/13/2022 and 1 /19/2023. e. TP#5 - evaluated on 9/6/2021, 1/13/2022, and 1/19/2023. f. TP#6 - evaluated on 1/13/2022 and 1/27/2023. g. TP#7 - evaluated on 6/06/2022, 12/06/2022, and 1/27/2023. h. TP#8 - evaluated on 1/13/2022 and 1/27/2023. i. TP#9 - evaluated on 11/12/2021, 5/06/2022, and 1/23/2023. j. TP#10 - evaluated on 4/12/2022, 10/14 /2022, and 1/27/2023. k. TP#11 - evaluated on 1/13/2022 and 1/17/2023. 2. The surveyor requested the qualifications for Technical Consultant #2 to qualify as a Technical Consultant on 3/22/23 at 10:01 am and the documentation was not made

	available. 3. A phone interview on 3/23/23 after receiving credentials for Technical Consultant #2 at 9:37 am, the SO confirmed Technical Consultant #2 was not qualified to be performing the duties of a Technical Consultant.