Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0973254	04/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Cancer And Hematology Centers, The	1550 Watertower Place Suite 500, East Lansing, 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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to meet the requirements for the specialty in Hematology as specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to perform calibration for hematology testing on the Beckman Coulter DxH 520 analyzer at least every 6 months. Refer to D5439. 2. The laboratory failed to manually enter the complete blood cell (CBC) count parameters into the electronic medical record (EMR). Refer to D5801.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: A. Based on observation, lack of documentation, and interview with Testing Personnel #1 (TP1), the laboratory failed to perform and document the traceable thermometer calibration checks as required by the manufacturer before the expiration for 1 (traceable thermometer) of 2 thermometers in use in the laboratory. Findings

	include: 1. During a tour of the laboratory on 4/28/2022 at 9:57 am, the surveyor observed a traceable thermometer in the Frigidaire refrigerator in use past the expiration date of 11/23/2000. 2. A lack of documentation upon review of the laboratory records revealed the thermometer was not calibrated and/or replaced by the expiration of 11/23/2000. 3. When queried on 4/28/2022 at 9:57 am, TP1 was unaware that an expiration date was present on the thermometer. 4. A interview on 4 /28/2022 at 9:57 am, TP1 confirmed the traceable thermometer was not calibrated and /or replaced by the 11/23/2000. B. . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to perform and document Beckman Coulter DxH 520 hematology analyzer monthly maintenance as required by the manufacturer for 9 of 18 months reviewed. Findings include: 1. A record review of the "DxH 520 Instrument Maintenance Checklist" log revealed a lack of documentation of the monthly maintenance for the following months: a. November and December 2020 b. February - May and October 2021 c. February and March 2022 2. An interview on 4/28/2022 at 1:30 pm, TP1 confirmed the monthly maintenance had not been performed and documented.
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 (TP1), the laboratory failed to perform calibration for hematology testing on the Beckman Coulter DxH 520 analyzer at least every 6 months for 1 (2021) of 2 years in use. Findings include: 1. A review of the laboratory's calibration documents for the Beckman Coulter DxH 520 hematology analyzer revealed a lack of documentation for the calibrations due in 2021 as follow: Due dates a. 4/2021 b. 12/2021 2. An interview on 4/28/2022 at 11:53 am, TP1 confirmed the laboratory did not perform calibrations at least every 6 months.
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 the Testing Personnel #1 (TP1), the laboratory failed to document corrective action for improper temperature of the refrigerator that stores the hematology Beckman Coulter DxH 500 Series Controls for 14 days (November 2020 to April 2022) of 18 months reviewed. Findings include: 1. A record review of the "Temperature Log Chart" revealed for 14 days of 18 months reviewed, the refrigerator temperature was above the stated range of 2 to 8 degrees centigrade and no corrective action was documented as follows: a. July 6, 2021 - temperature was 9 b. August 25, 2021 - temperature was c. August 30 and 31 - temperature was 10 d. September 2 and 14, 2021 - temperature was 9 e. October 11, 14, 21, 2021 - temperature was 9 f. November 2, 12, 16, and 29, 2021 - temperature was 9 g. November 4, 2021 - temperature was 10 2. A interview on 4/28/2022 at 11: 34 am, TP1 confirmed that no corrective action was documented for the refrigerator temperatures out of the stated range.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Practice Manager (PM), the laboratory failed to manually enter the complete blood cell (CBC) count parameters into the electronic medical record (EMR) for 3 (15177, 15638, and 15035) of 12 patient charts reviewed. Findings include: 1. Record review for 3 of 12 patient charts reviewed revealed manual results entered into the EMR were incorrect as follows: a. 15177 performed on 11/09/2020 - lymphocyte % reported as 2.23, actual result is 25.60 b. 15638 performed on 12/21/2020 - eosinophil % reported as 240, actual result is 2.40 c. 15035 performed on 8/05/2021 - basophil absolute reported as 6.31, actual is 0.02 2. An interview on 4/28/2022 at 12:59, the PM confirmed the manually entered results into the EMR were incorrect.