Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0873642	02/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cancer And Hematology Centers, The	145 Michigan St Ne Suite 3100, Grand Rapids, 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
D0000	The purpose of this survey was for complaint #MI00116740. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003).
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to ensure test requests were from an authorized provider for 1 (Patient #150457) of 15 patient testing records reviewed. Findings include: 1. An interview with a scheduling department employee on 2/8/21 at 9:14 am revealed staff looking to schedule patients for either a biopsy, port removal, or a port placement will look to see if they have orders placed for a Prothrombin Time (PT), Partial Thromboplastin Time (PTT), and a Complete Blood Count (CBC). If the orders are not present, the scheduling staff will place the orders for testing. The provider selected by scheduling staff as the ordering provider is not notified of these orders until they acknowledge the test results in the electronic medical record after the laboratory has concluded testing. 2. The surveyor requested a policy or procedure for the scheduling staff to order testing on 2/8/21 at 9:14 am and it was not made available. 3. A review of 15 patient test records revealed Patient #150457 had been ordered by scheduling staff and testing was completed on 3/25/20. 4. A review of the laboratory's "Laboratory Test Documentation" revealed a section titled "General" stating, "Clinical lab testing may only be done per licensed physician's or other authorized person's request." 5. An interview on 2/8/21 at 1:52 pm with the General Supervisor confirmed the patient listed above did not have a test request placed by an authorized provider and the facility did not have a policy or procedure to support the practice of scheduling staff placing laboratory testing orders.

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 the General Supervisor (GS), the laboratory failed to perform and document calibration verification for Lactic Acid testing at least every 6 months for 2 (July 2020 and January 2021) of 2 calibration verification testing events. Findings include: 1. A review of the laboratory's verification of performance specifications records revealed the laboratory started Lactic Acid testing in January 2020. 2. A review of the laboratory's calibration verification records revealed a lack of documentation for the performance of calibration verification when it was due in July 2020 and January 2021. 3. A review of the laboratory's policy titled "COBAS 6000" revealed a section stating, "The following tests need linearity done every 6 months: Lactic Acid". 4. An interview on 2 /8/21 at 1:15 pm with the GS confirmed the laboratory did not perform and document calibration verification for Lactic Acid at least every 6 months.