Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0973254	01/11/2024
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
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: A. Based on record review and interview with the Office Manager and Testing Personnel #2 and #7, the laboratory failed to ensure written competency policies established contained all the requirements from subpart M for 8 (Testing Personnel #1 - #8) of 8 Testing Personnel reviewed in 2022 and 2023. Findings include: 1. Record review of the testing personnel competency evaluation records on 1/11/2024 at 9:25 am, revealed for 8 of 8 testing personnel a lack of documentation for the assessment of problem-solving skills. 2. When queried, the Office Manager and Testing Personnel #2 and #7 were not aware of that skill to be evaluated. 3. An interview on 1/11/2024 at 12:45 pm, the Office Manager and Testing Personnel #2 and #7 confirmed the above findings. B. Based on record review and interview with the Office Manager and Testing Personnel #2 and #7, the laboratory failed to establish and implement policies and procedures to assess the competency of personnel serving the roles of Clinical Consultant, Technical Consultant, and Testing Personnel job responsibilities for 23 (April 2022 to January 2024) of 23 months reviewed. Findings include: 1. A review of the laboratory's personnel records revealed a lack of documentation for the competency assessments for the CC, TC, and TP job responsibilities. 2. A review of the laboratory's policy and procedure for assessing competency revealed a lack of job responsibilities for the CC, TC, and TP. 3. An interview on 1/118/24 at 12:45 pm, the Office Manager and Testing Personnel #2 and #7 confirmed the laboratory had not established or implemented a policy or procedure for assessing competency for job responsibilities for the roles listed above.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to include the patient's scanned final complete blood cell count (CBC) report into the electronic medical records (EMR) for 1 (#5) of 9 patient charts audited. Findings include: 1. Record review revealed for 1 of 9 patient charts audited, the final CBC report for patient #5 tested on 5/25/2023 was not scanned into the patient's EMR file. 2. An interview on 1/11/2024 at 12:45 pm, the Office Manager confirmed the final CBC report for patient #5 was not scanned into the EMR system.
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 Office Manager and Testing Personnel #2 and #7, the Laboratory Director failed to ensure proficiency testing reports were reviewed for 5 (2nd and 3rd events 2022 and 1-3 events 2023) of 5 events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing documentation on 1/11/2024 at 9:49 am revealed a lack of review of results performed by the testing personnel for 5 of 5 events reviewed as follows: a. 2022 i. 2nd and 3 event. b. 2023 i. 1st, 2nd, and 3rd event. 2. An interview on 1/11/2024 at 12:50 pm, the Office Manager and Testing Personnel #2 and TP#7 confirmed the Laboratory Director had not ensured the proficiency testing reports were reviewed by the testing personnel.