Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0973254	01/07/2026
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
D0000	A recertification survey was performed on January 7, 2026 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition-level deficiencies: 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. Based on observation, record review, and interview with the technical supervisor, the laboratory failed to notify the state agency when it added high complexity peripheral blood manual differentials within six months of initiating testing in accordance with 493.51 Notification requirements for laboratories issued a certificate of compliance for 32 (May 2024 to January 2025) of 32 months since testing initiated. Findings include: 1. The surveyor observed a microscope, staining supplies, observed testing personnel #1 make a patient blood smear during a tour of the laboratory on 1/7/26 at 9:00 am. 2. A review of the laboratory's survey Form CMS-116 and test menu showed a lack of testing using blood smears. 3. An interview on 1/7/26 at 9:24 am with the technical supervisor confirmed the laboratory was performing high complexity peripheral blood smears for manual differentials and slide reviews. 4. An interview on 1/7/26 at 10:21 pm with the technical supervisor revealed the laboratory installed the microscope and peripheral blood smear supplies just prior to the 5/1/24 date the laboratory started to offer testing for peripheral blood smears for manual differentials and slide reviews. 5. A review of the laboratory's previous survey's Form CMS-116, signed by the laboratory director on 5/19/25, did not include testing using blood smears. 6. An interview on 1/7/26 at 10:28 am with the technical supervisor confirmed the laboratory had not notified the state agency of the addition of peripheral blood smears for manual differentials and slide reviews within six months of initiating patient testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i)

	Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical supervisor, the laboratory failed to verify its peripheral blood manual differentials and slide reviews prior to patient testing for 21 (May 2024 to January 2026) of 21 months reviewed. Findings include: 1. The surveyor observed a microscope, staining supplies, observed testing personnel #1 make a patient blood smear during a tour of the laboratory on 1/7/26 at 9:00 am. 2. An interview on 1/7/26 at 10:21 pm with the technical supervisor revealed the laboratory installed the microscope and peripheral blood smear supplies just prior to the 5/1/24 date the laboratory started to offer peripheral blood smear testing for manual differentials and slide reviews. 3. A review of the laboratory's test procedures revealed the laboratory director approved the "Manual Differential Procedure" on 5/1/24. 4. A review of the laboratory's "Method Evaluation Policy" revealed a section stating, "Before a new method, procedure or analyzer is put into use in the laboratory, the performance of the method must be technically evaluated to make sure it meets quality standards." Under the section titled "Technical Evaluation" included "Precision", "Linearity", "Between-Run Precision", and "Patient Correlation". 5. An interview on 1/7/26 at 1:33 pm with the technical supervisor revealed documentation of the laboratory's verification for manual differentials and slide reviews was not present at the laboratory.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on observation, record review, and interviews, the laboratory failed to ensure the laboratory director met certification or experience requirements (refer to D6078), the laboratory director failed to notify the state agency when it added high complexity peripheral blood manual differentials within six months of initiating testing in accordance with 493.51 Notification requirements for laboratories issued a certificate of compliance (refer to D6079), and the laboratory director failed to ensure the laboratory verified its peripheral blood manual differentials and slide reviews prior to patient testing (refer to D6086).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory

director 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 (b)(2)(i) Be a doctor of medicine, a 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 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii) Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.

This STANDARD is not met as evidenced by:
. Based on observation, record review, and interview with the technical supervisor, the laboratory failed to ensure the laboratory director met certification or experience requirements for 21 (May 2024 to January 2026) of 21 months since the laboratory started high complexity testing. Findings include: 1. The surveyor observed a microscope, staining supplies, observed testing personnel #1 make a patient blood smear during a tour of the laboratory on 1/7/26 at 9:00 am. 2. A review of the laboratory's test procedures revealed the laboratory director approved the "Manual Differential Procedure" on 5/1/24, which includes the identification and reporting of abnormal cells. 3. A review of the laboratory director's qualification records showed a lack of either board certification by the American Board of Pathology or the American Osteopathic Board of Pathology or at least two years of experience directing or supervising high complexity testing. 4. The surveyor requested either the board certification or documentation of supervisory experience on 1/7/26 at 9:42 am and it was not made available. 5. An interview on 1/7/26 at 10:21 pm with the technical supervisor revealed the laboratory installed the microscope and peripheral blood smear supplies just prior to the 5/1/24 date the laboratory started to offer testing for peripheral blood smears for manual differentials and slide reviews. 6. An interview on 1/7/26 at 1:33 pm with the technical supervisor confirmed the laboratory director did not have either board certification by the American Board of Pathology or the American Osteopathic Board of Pathology or at least two years of experience directing or supervising high complexity testing.

D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the technical supervisor, the laboratory director failed to notify the state agency when it added high complexity peripheral blood manual differentials within six months of initiating testing in accordance with 493.51 Notification requirements for laboratories issued a certificate of compliance. Refer to D0000.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: . Based on record review and interview with the technical supervisor, the laboratory director failed to ensure the laboratory verified its peripheral blood manual differentials and slide reviews prior to patient testing. Refer to D5421.