Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0929489	06/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cancer And Hematology Centers, The	12460 Riley Street, Holland, 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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to test its peripheral blood smear staining materials for predictable staining characteristics at least each day of patient testing for 2 (June 2021 to June 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Manual Differential Procedure" revealed a section titled "Quality Control" stating, "When a new lot of stain is put into use, a slide is reviewed to make sure the cells are stained appropriately." 2. A review of the laboratory's "Wright Stain Log Sheet" revealed the laboratory only documented stain quality when it put a new lot of staining materials into use. 3. An interview on 6/20/23 at 11:37 am with the Technical Supervisor confirmed the laboratory had not established a practice of documenting its peripheral blood smear staining materials for predictable staining characteristics each date of patient testing.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory failed to follow its policy to immediately report critical results for 1 (Patient 129758) of 12 patient test reports reviewed. Findings include: 1. A review of the laboratory's "Laboratory Test Documentation" policy revealed a section stating, "If any critical results are obtained as defined on the critical values chart, do the following: a. Repeat to confirm results b. Notify the physician or designee ASAP by sending a task in the EMR (electronic medical record). Include date, time and initials of the sender in the task." 2. A review of patient test reports and the critical values chart revealed Patient 129758 had a Complete Blood Count (CBC) performed on 7/25/22 with a critically high white blood cell count. 3. The surveyor requested documentation showing Patient 129758's white blood cell result was reported according to the laboratory's policy on 10:41 am and it was not made available. 4. An interview on 6/20/23 at 10:41 am with the Technical Supervisor revealed the laboratory had not reported the critical result according to its policy.