Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1081376	01/06/2026
Name of Provider or Supplier	**Street Address, City, State**	
Cancer And Hematology Centers Of Western	6425 S Harvey St, Norton Shores, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the technical supervisor, the laboratory failed to label its hematology control materials with the expirations date reflecting its change in stability once opened for three (lot numbers 53361101, 53361102, and 53361103) of three control materials observed. Findings include: 1. The surveyor observed three XN CHECK lot numbers 53361101, 53361102, and 53361103 hematology controls on 1/6/26 at 9:13 am in the refrigerator with "O:12/22 /25" written on them, indicating the open date. 2. A review of the "XN Check" instructions for use included a section titled "Storage and shelf life after first opening" stating, "Open vials and vials which have been sampled by cap piercing will retain stability for 7 days if stored at 2-8 degrees C after being re-capped." showing a change in stability once a set has been put into use. 3. A review of the laboratory's "Quality Control Policy" included a section titled "Stability of Controls" stating, "The for Sysmex XN Control, Cancer& Hematology has proven by months of data collection that the controls are stable for 14 days once the control material is put into use. The 14 day stability will be standard operating procedure instead of the package insert stability recommendations." 4. An interview on 1/6/26 at 9:13 am with the technical supervisor confirmed the controls did not include the expiration date of the controls reflecting the change in stability for open vials.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the technical supervisor, the laboratory failed to ensure hematology control materials were not used beyond their expiration dates for three (lot numbers 53361101, 53361102, and 53361103) of three control materials observed. Findings include: 1. The surveyor observed three XN CHECK lot numbers 53361101, 53361102, and 53361103 hematology controls on 1/6 /26 at 9:13 am in the refrigerator with "O:12/22/25" written on them, indicating the open date. 2. A review of the "XN Check" instructions for use included a section titled "Storage and shelf life after first opening" stating, "Open vials and vials which have been sampled by cap piercing will retain stability for 7 days if stored at 2-8 degrees C after being re-capped." showing a change in stability once a set has been put into use. 3. A review of the laboratory's "Quality Control Policy" included a section titled "Stability of Controls" stating, "The for Sysmex XN Control, Cancer& Hematology has proven by months of data collection that the controls are stable for 14 days once the control material is put into use. The 14 day stability will be standard operating procedure instead of the package insert stability recommendations." 4. A review of the control results performed 1/6/26 revealed control testing was performed at 7:18 am. 5. An interview on 1/6/26 at 12:03 pm with the technical supervisor confirmed the controls listed above had exceeded the expiration date. A total of 63 patients were performed prior to the reanalysis of newly opened controls at 1:45 pm.