Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2277833	08/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cancer And Hematology Centers, The	15100 220th Avenue, Big 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
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 general supervisor, the laboratory failed to verify that the manufacturer's reference intervals were appropriate for the patient population for two new reagents (Alkaline Phosphatase and Aspartate Aminotransferase) implemented since June 2024. Findings include: 1. A review of the laboratory's "Method Evaluation Policy" revealed a lack of information about how the laboratory verifies reference intervals provided by the manufacturer prior to reporting patient test results. 2. A review of the verification of performance specifications for the laboratory's Cobas Pure chemistry instrumentation revealed Alkaline Phosphatase (ALT) and Aspartate Aminotransferase (AST) changed reagent generations in June 2024 to "ALPTP2" and "ASTP2" respectively. The documentation failed to include verification of the reference intervals. 3. An interview on 8/27/25 at with the general supervisor revealed the laboratory had changed their reference intervals for ALT to 0-50 U/L for males and 0-35 U/L for females and the reference intervals for AST were changed to 0-50 U/L for males and 0-35 U/L once the new reagents were put into use. The general supervisor confirmed the laboratory had not verified the manufacturer's reference intervals for its ALT and AST testing.
D5775	COMPARISON OF TEST RESULTS

	CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: . Based on record review and interview with the general supervisor, the laboratory failed to evaluate the relationship between its automated differential and its manual differential at least twice annually for one (August 2024 to August 2025) of two years reviewed. Findings include: 1. A review of the laboratory's test menu revealed the laboratory uses an automated white blood cell differential using its Sysmex SN 1000 PR analyzer and a manual white blood cell differential. 2. The surveyor requested documentation of twice annual comparisons between the automated and manual white blood cell differentials performed by the laboratory on 8/27/25 at 1:05 pm and it was not made available. 3. An interview on 8/27/25 at 1:05 pm with the general supervisor revealed the laboratory performed a comparison between the automated and manual differential methods upon installation of the Sysmex SN 1000 PR analyzer but had not performed them twice annually between August 2024 and August 2025.