

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2036126	(X3) Date Survey Completed 11/18/2025
Name of Provider or Supplier Consultants In Medical Oncology & Hematology	Street Address, City, State Crozer Medical Plaza Ii Cancer Center, Glen Mills, PA	
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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to evaluate twice a year the relationship between automated white blood cell (WBC) count differentials performed on 1of 1 Sysmex XN-430 hematology analyzer and manual microscopic WBC differentials performed in 2024. Findings include: 1. On the day of survey, 11/18/2025 at 11:47 am, the laboratory failed to provide documentation of the biannual comparison of test results between the automated WBC differentials performed on 1 of 1 Sysmex XN-430 hematology analyzer (s/n 11779) and manual microscopic WBC differentials performed in 2024. 2. Review of the laboratory's test logs revealed the laboratory performed 125 manual microscopic WBC differentials in 2024. 3. The TC confirmed the findings above on 11 /18/2025 at 1:18 pm.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p>

This STANDARD is not met as evidenced by:

Based on review of quality assurance (QA) records, lack of documentation, and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure an established QA program was maintained and documented to ensure the quality of services provided by the laboratory for 6 of 10 months when hematology testing was performed in 2025. Findings include: 1. The laboratory's Quality Assurance plan stated, "Purpose: To ensure high quality test results that accurately reflect the status of the patient. To identify and correct issues through an ongoing review and education process. All related supporting documentation must be retained for at least two years." 2. On the date of survey, 11/18/2025 at 10:10 am the laboratory failed to provide documentation of the ongoing review used to evaluate and assess the laboratory's pre-analytical, analytical, and post-analytical processes for the following 6 of 10 months in 2025: - May 2025 - June 2025 - July 2025 - August 2025 - September 2025 - October 2025 3. The TC confirmed the findings above on 11/18/2025 at 1:18 pm.