

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0947663	(X3) Date Survey Completed 09/09/2026
Name of Provider or Supplier Consultants In Medical Oncology & Hematology	Street Address, City, State Bryn Mawr Hospital Hlth Ctr, Newtown Square, 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
D0000	A recertification survey was conducted by the Pennsylvania State Agency for Consultants in Medical Oncology & Hematology on 09/09/2026. The laboratory was found out of compliance with the following conditions: 493.1250 Condition: Analytic systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation in the laboratory, review of laboratory temperature records, and interview with the Clinical Coordinator (CC), the laboratory failed to meet applicable analytic systems requirements in 493.1251(b) for 17 of 17 months from 03/27/2025 to 09/09/2026. Refer to 5413.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and

interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

A. Based on observation in the laboratory, review of laboratory temperature records, and interview with the Clinical Coordinator (CC), the laboratory failed to monitor refrigerator and room temperatures to ensure proper storage temperatures of reagents was maintained for 165 of 531 days when the Sysmex XN 430 was not in use from 03/27/2025 to 09/09/2026. Findings include: 1. On the day of survey, 09/09/2026, at 10:00 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - Sysmex Cell Pack. Storage requirements 2C to 35C. - Sysmex LyserCell. Storage requirements 15C to 35C. - Sysmex Cell Clean. Storage requirements 1C to 30C. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document refrigerator and room temperatures for 165 of 531 days from 3/27/2025 to 09/09/2026. 3. The laboratory performed 4,512 Hematology tests in 2025 (CMS 116, estimated annual volume, dated 8/27/2026). 4. The CC confirmed the findings above on 09/09/2026 at 11:00 am. *Repeat Deficiency

B. Based on review of the laboratory's temperature logs, lack of documentation and interview with the Clinical Coordinator (CC), the laboratory failed to monitor and document room humidity (RH) to ensure reliable test system operation and test result reporting for 1 of 1 Sysmex XN430 used to perform Hematology testing from 03/27/2025 to date of survey. Findings include: 1. The Sysmex user manual stated: "Relative humidity should be within the range of 20 to 85%" 2. On the date of the survey, 09/09/2026 at 10:00 am, review of the laboratory's temperature logs revealed the laboratory failed to document room humidity (RH) to ensure operating conditions were met for 1 of 1 Sysmex XN430 used for hematology testing from 3/27/2025 till day of survey. 3. The laboratory performed 4,512 Hematology tests in 2025 (CMS 116, estimated annual volume, dated 8/27/2026). 4. The CC confirmed the findings above on 09/09/2026 at 11:00 am.