

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2265661	(X3) Date Survey Completed 08/08/2024
Name of Provider or Supplier Hartford Healthcare Cancer Institute At	Street Address, City, State 2800 Main St, Suite 3-Nb-7, Bridgeport, CT	
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. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to have a system to monitor and evaluate testing performed on multiple instruments twice annually in the specialty of hematology. Finding includes: 1. Record review on 8/8/2024 of the laboratory's "QC 2023" binder revealed lack of documentation of complete blood counts (CBC) comparison in 2023 between Sysmex XN 450 Serial # 12312 and Sysmex XN 450 Serial #12452. 2. Staff interview on 8/8/2024 at 1:30 PM with the Technical Consultant and Testing Personnel #1 (TP#1) confirmed the above finding. TP#1 further commented that the instrument-to-instrument comparison was not performed in 2023. 3. The laboratory performs 60,000 CBC annually in the specialty of hematology. .</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview the technical consultant (TC) failed to evaluate testing personnel competency semiannually during the first year of employment in the specialty of hematology. Findings include: 1. Record review on 8/8/2024 of the "CMS Laboratory Personnel Report 209" CMS 209 form revealed the laboratory have employed 4 testing personnel (TP) in 2023. 2. Record review on 8/8/2024 of the laboratory's "Competency Assessment_HHC_Cancer Institute ONC 10002" policy revealed "during the first year of an individual's duties, competency must be assessed at least semi-annually". 3. Review on 8/8/2024 of the laboratory's employee competency records revealed the following for TP#1: a. Initial training completed on 6/16/2023. b. Lack of documentation of semi-annual competency assessment. c. Annual competency completed on 5/22/2024. 4. Staff interview on 8/8/2024 at 10:15 AM with the TC confirmed the above findings. 5. The laboratory performs 60,000 complete blood counts annually in the specialty of hematology.