

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D2156547	<b>(X3) Date Survey Completed</b>  12/10/2025
<b>Name of Provider or Supplier</b>  Hartford Healthcare Cancer Institute	<b>Street Address, City, State</b>  376 Tolland Tpke, Ste 201, Manchester, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Proficiency Test (PT) desk review of the Hartford Healthcare Cancer Institute at Hartford Hospital was conducted on December 10, 2025, pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988. The laboratory was found out of compliance with the following conditions: 42 CFR 493.803 Proficiency Testing, Successful Participation 42 CFR 493.1403 Laboratory Director, Moderate complexity
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on record review of the Centers for Medicare &amp; Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reports</p>

	<p>(CASPER) 0155D and Wisconsin State Laboratory of Hygiene University of Wisconsin-Madison (WSLH) PT summary reports, the laboratory failed to successfully participate in the CMS approved PT program for two out three consecutive testing events in the Hematology specialty for the Hematocrit test analyte in 2025 resulting in unsuccessful performance. Refer to D2130.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review of the Proficiency Testing (PT) Certification and Survey Provider Enhanced Reports (CASPER) 0155D, graded results from Wisconsin State Laboratory of Hygiene University of Wisconsin-Madison (WSLH) PT, and staff interview the laboratory failed to achieve satisfactory performance score in two out three consecutive testing events in 2025 in the specialty of Hematology for the analyte of Hematocrit #0785 (HCT). Findings include: 1. Record review on 12/04/2025 of the Proficiency Testing (PT) data report CASPER 0155D revealed the laboratory is enrolled with WSLH PT program. 2. Record review on 12/04/2025 of the PT data CASPER Report 0155D revealed the laboratory failed to achieve satisfactory scores for two out of three PT events in 2025 for "HCT" analyte# 0785 as follows: a. WSLH 2025 Event 1 the score was 60% and was unsatisfactory. b. WSLH 2025 Event 3 the score was 40% and was unsatisfactory. 3. Record review on 12/10/2025 of the 'WSLH PT 2025-HemeReg3' PT evaluation report revealed the laboratory obtained an unsatisfactory score for 2 of 3 events in 2025 for HCT analyte as mentioned in line item 2 above. 4. A telephone interview with the Technical Consultant (TC) on 12/10 /2025 at 12:38 PM confirmed the above findings.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review of the Centers for Medicare &amp; Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Report (CASPER) 0155D and Wisconsin State Laboratory of Hygiene University of Wisconsin-Madison (WSLH PT) Proficiency Testing (PT) summary reports on 12/10 /2025, the laboratory director (LD) failed to provide overall management and direction of the laboratory services. Refer to D6016, D2016 and D2130.</p>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p>

This STANDARD is not met as evidenced by:  
Based on record review of the Proficiency Testing (PT) data CASPER Report 0155D, graded results from Wisconsin State Laboratory of Hygiene University of Wisconsin-Madison (WSLH) PT reports, the laboratory director failed to ensure PT samples were tested as required in the specialty of Hematology. The laboratory failed to achieve satisfactory performance score in two out of three consecutive testing events in 2025 in the Hematology specialty for the analyte of Hematocrit (HCT) and has sustained an unsuccessful participation in PT. Refer to D2130 and D2016.