

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0093009	(X3) Date Survey Completed 04/14/2021
Name of Provider or Supplier Hartford Healthcare Cancer Institute	Street Address, City, State 183 North Mountain Rd, New Britain, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure laboratory procedures reflect the review and approval by the current laboratory director (LD) when a change of laboratory directorship occurred. Findings include: 1. Record review on 4/14/2021 of the CMS-116 application received at the state agency on 10/16/2020 revealed a LD change effective 11/1/2020. 2. Record review on 4/14/2021 of the CMS-209 form signed on 4/14/2021 revealed the LD is same person stated on the CMS-116 noted in line 1 above. 3. Record review on 4/14/2021 of the 'Axcel Chemistry Analyzer ONC-20010' procedure revealed the procedure was not signed and approved by the current LD. 4. Record review on 4/14/2021 of the 'Sysmex XS1000i ONC-20006' procedure revealed the procedure was not signed and approved by the current LD. 5. Staff interview with the LD on 4/14/2021 at 1:00 PM confirmed the above findings. 6. The laboratory performs 91,260 tests in the specialty of chemistry and 46,800 tests in the specialty of hematology annually.</p>