

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0989347	(X3) Date Survey Completed 09/06/2023
Name of Provider or Supplier Greenwich Hospital West Putnam Laboratory	Street Address, City, State 500 West Putnam Ave, Greenwich, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to ensure quality control material had not exceeded their expiration dates for Complete Blood Count (CBC) testing prior to reporting patient results in the specialty of hematology. Findings include: 1. Record review on 9/6/2023 of the quality control (QC) material 'XN Check' manufacturer's package insert revealed "Storage and shelf life after first opening, open vials and vials which have been sampled by cap piercing will retain stability for 7days if stored at 2-8 degrees Celsius after being recapped." 2. Surveyor observation on 9/6/2023 at 11:15 AM of the in use XN CHECK Hematology Controls vials revealed Level 1 (L1), Level 2 (L2) and Level 3 (L3) lot # 3198 had handwritten open dates of 8/28/2023 and expiration dates of 9/4/2023. 3. Record review on 9/6/2023 of the daily quality control report for L1, L2, and L3 levels from 9/5/2023 and 9/6/2023 revealed all QC results were within the acceptable ranges for patient testing. 4. Staff interview on 9/6/2023 at 11:20 AM with the testing personnel #1 confirmed when performing QC on 9/5/2023 and 9/6/2023, the expired QC vials were used. 5. Staff interview on 9/6/2023 at 1:30 PM with General Supervisor confirmed 25 CBCs were reported on 9/5/2023 and 12 CBCs were reported on 9/6/2023 utilizing the expired QC.</p>