Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0857475	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Greenwich Dept Of Health Laboratory	**Street Address, City, State** 101 Field Point Rd, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to label reagents with the appropriate expiration dates in the specialty of toxicology. Findings include: 1. Surveyor observation of the current Magellan Diagnostics, Inc. LeadCare Ultra/Plus Lead control vials on 11/05/19 at 11:20 AM revealed: a. Control Level 1 Lot # 1910M with a manufacturer label stating target range 7.7 +/- 3.0 expiration 11/1/20. b. Control Level 2 Lot # 1910M with a manufacturer label stating target range 25.5 +/- 4.0 expiration 11/1/20. c. The above vials did not have documentation of the open date or new expiration date for Levels 1 or 2. 2. Record review of the current Magellan Diagnostics Lead Control Datasheet on 11/05/19 revealed: a. Test kit lot # 1910MU b. Levels 1 & 2 controls lot # 1910M, expiration date 11/01/20 with open vial stability of 90 days. 3. Record review of the laboratory excel testing worksheet on 11/5/19 revealed the current kit lot # 1910MU with control lot #s 1910M was opened on 9/27/19. 4. Record review of the ESA LeadCare Plus analyzer procedure on 11/5/19 revealed "controls are good for 90 days after opening" and "if controls run out, call Magellan for more." 5. Staff interview with the laboratory director on 11/5/19 at 11:20 AM stated he/she had forgotten the change in expiration dates for the controls once they are placed into service. 6. The laboratory performs 100 blood lead tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to use in date control material in the specialty of toxicology. Findings include: 1. Record review of the Magellan Diagnostics Lead Control Datasheet for test kit lot # 1714MU on 11/05/19 revealed Levels 1 & 2 controls lot # 1714M had an expiration date of 1/19/19. 2. Record review of the laboratory excel testing worksheet on 11/5/19 revealed: a. Kit lot # 1714MU with control lot # 1714M was in use until 9/20/19. b. 53 patients were tested and resulted from 2/13/19 through 9/9/19 after the 1/19/19 expiration date. 3. Staff interview with the laboratory director on 11/5/19 at 9:45 AM confirmed the above findings. The LD stated he/she did not keep the control datasheets and was unaware the kit and controls were used after the expiration date. 4. The laboratory performs 100 blood lead tests annually.