

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2144408	(X3) Date Survey Completed 09/02/2021
Name of Provider or Supplier Elm Tree Clinic Llc	Street Address, City, State 21 School St, Quincy, MA	
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
D0000	A CLIA recertification survey was conducted for the Elm Tree Clinic LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on proficiency testing (PT) record review and an interview with the Laboratory Director (LD) on 9/2/21, the laboratory failed to enroll and participate in a HHS approved proficiency testing (PT) program commensurate with the services offered as evidenced by the following: The surveyor requested to review PT records on 9/2/21 for calendar years 2019, 2020, and 2021. The review revealed that the laboratory enrolled late in a HHS approved PT testing program for 2020 for the subspecialty performed. The laboratory failed to participate in CAP-UT-A 2020 Urine Toxicology Event #1. The LD confirmed in an interview on 9/2/21 at 10:47A.M. that the Technical Supervisor enrolled the laboratory late in a HHS approved PT program for 2020 and therefore the laboratory failed to participate in CAP-UT-A 2020 Urine Toxicology Event #1. The laboratory performs approximately 561,600 Toxicology tests annually. (Refer to D6116) .</p>

D6116

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(3)

The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered.

This STANDARD is not met as evidenced by:

. Based on proficiency testing (PT) record review and an interview with the Laboratory Director (LD) on 9/2/21, the Technical Supervisor (TS) failed to enroll and participate in a HHS approved PT program commensurate with the services offered as evidenced by the following: The surveyor requested to review PT records on 9/2/21 for calendar years 2019, 2020, and 2021. The review revealed that the TS enrolled the laboratory late in a HHS approved PT testing program for 2020 for the subspecialty performed. The laboratory failed to participate in CAP-UT-A 2020 Urine Toxicology Event #1. The LD confirmed in an interview on 9/2/21 at 10:47A.M. that the TS enrolled the laboratory late in a HHS approved PT program for 2020 and therefore did not participate in the CAP-UT-A 2020 Urine Toxicology Event #1. The laboratory performs approximately 561,600 Toxicology tests annually. (Refer to D2000)