

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2144408	(X3) Date Survey Completed 07/17/2019
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	An initial CLIA certification survey was conducted for Elm Tree Clinic LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturer for the following performance characteristic: reportable range as evidenced by the following: The surveyor reviewed the validation study for the Beckman Coulter AU480. The review revealed that reportable range validation was not performed prior to implementing the test system for patient testing and reporting. The laboratory director interviewed on 7/17/19 at 10:36 A.M. confirmed that the reportable range validation for the above system had not been completed. The laboratory performs 182,000 toxicology tests annually.</p>