

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2085134	(X3) Date Survey Completed 03/30/2018
Name of Provider or Supplier East Texas Clinical Laboratory	Street Address, City, State 9301 N Central Expressway Tower 2 Suite 335, Dallas, TX	
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	<p>An unannounced onsite revisit was conducted 03/26/18 through 03/30/18 for complaint TX00263877. Based on the onsite survey, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493.1240 Preanalytical Systems 493.1403 Moderate Complexity Laboratory Director 493.1409 Moderate Complexity Technical Consultant 493.1441 Laboratory Director High Complexity 493.1447 Technical Supervisor, High Complexity</p> <p>----- An unannounced investigation of complaint TX00263877 conducted on site. An entrance conference was held with the Technical Supervisor on 07/10/17 to explain the purpose and process of the survey. Based on the onsite survey conducted on 07/10/17 through 07/14/17, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493.1240 Preanalytical Systems 493.1250 Analytic Systems 493.1403 Moderate Complexity Laboratory Director 493.1409 Moderate Complexity Technical Consultant 493.1441 Laboratory Director High Complexity 493.1447 Technical Supervisor, High Complexity 493.1461 General Supervisor, High Complexity 493.1487 Testing Personnel, High Complexity An exit conference was held with Technical Supervisor #1, #2, Regulatory and Compliance Coordinator, Vice President Operations, Technical Supervisor for Pharmacogenetics, Chief Compliance Officer, CFO, CEO, President, VP of Human Resources, Laboratory Director and Supervisor of Toxicology on 07/14/17. Survey findings were discussed. Complaint TX00263877 was substantiated 2567 report to be sent to Regional CMS office.</p>