

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2111364	<b>(X3) Date Survey Completed</b>  08/08/2018
<b>Name of Provider or Supplier</b>  Codex Health Llc	<b>Street Address, City, State</b>  2700 Technology Forest Blvd, Suite 114, The Woodlands, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Intakes #TX00269401 An unannounced revisit was conducted on August 8, 2018. Based on the plan of corrections and allegation of corrections the facility submitted for the survey performed September 18-22, 2017, the facility was given approval to resume patient testing. As of the date of the onsite revisit, the laboratory had not restarted patient testing, and therefore compliance could not be determined. The laboratory remains to be OUT OF COMPLIANCE with the CLIA regulations at: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor ***** Intakes #TX00269401 The laboratory was found to be out of compliance with the CLIA regulations. Immediate jeopardy findings were identified. The conditions not met were: D3000 - 42 C.F.R. 493.1100 Condition: Facility administration D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>