

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2096977	<b>(X3) Date Survey Completed</b>  03/30/2018
<b>Name of Provider or Supplier</b>  Gulfstream Genomics Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Summary of Deficiencies from a Follow-Up Revisit of 03/26/2018 to 3/30/2018: During an onsite revisit completed on 3/30/2018 it was determined that the facility had abated immediate jeopardy to patients served by the laboratory by ceasing patient testing on 7/12/2017. The facility remains out of compliance and requires additional time to remediate patients and demonstrate compliance: 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; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. 36914 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; D6134 - 42 C.F.R. 493.1453 Condition: Laboratories performing high complexity testing; clinical consultant; The facility representative was 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>