Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2212715	07/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Luxe Mobile Iv	806 Leavenworth Ave, Houston, 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	An unannounced investigation in response to complaint TX00375359 was attempted on 6/24/21. Facility was a mobile lab and was unavailable for survey. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D1002 42 CFR 493.41Condition: Reporting of SARS-CoV-2 test results. Complaint TX00375359 was substantiated. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory records from 02/2021 to 06/2021, and confirmed in interview the laboratory failed to report 16 positive and negative SARS-Co-V-2 test results as required for 11 of 11 days reviewed from February 2021 to June 2021. Findings include: 1. Review of the laboratory records emailed on 6/28/21 revealed the laboratory started SARS-Co-V-2 on 2/10/21 using the AccessBio CareStart Covid-19 Antigen Rapid diagnostic test. 2. Review of the Instructions for Use for the AccessBio CareStart Covid-19 Antigen Rapid diagnostic test (IFU-RCHM71-E Revision number: E Effective date: Apr. 15, 2021) under CONDITIONS OF AUTHORIZATION FOR THE LABORATORY revealed "authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. Review of the laboratory records from 02/2021 to 06/2021 revealed

	no documentation the laboratory reported 16 positive and negative SARS-Co-V-2 test results as required for 11 of 11 days reviewed from February 2021 to June 2021. Refer to patient alias list 4. An interview with the medical consultant on 7/2/21 at 0840 hours via phone confirmed the above findings.