

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1085290	<b>(X3) Date Survey Completed</b>  07/12/2018
<b>Name of Provider or Supplier</b>  Strategic Laboratory Services	<b>Street Address, City, State</b>  1000 N Davis Drive , Suite E, Arlington, 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>The laboratory was found out of compliance with the CLIA regulations for the following condition: D8100 - 42 C.F.R. 493.1771 Condition: Inspection requirements applicable to all CLIA certified and CLIA-exempt laboratories. This was not an active laboratory. There was no evidence of patient testing at this site. This location does not meet the definition of a laboratory under the CLIA regulations. "42 CFR 493.1 Basis and Scope. This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861(e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under "laboratory" in 493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification. 42 CFR 493.2 Definitions. Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories."</p>
<b>D8100</b>	<p><b>INSPECTION REQUIREMENTS</b> CFR(s): 493.1771</p> <p>Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.</p>

This CONDITION is not met as evidenced by:  
Under section 42 CFR 493.55 (c ) Application format and contents "...(2) states the application must be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and...". In addition, this statement is also on the 116 application which "determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with the CLIA regulations". The laboratory owner and laboratory director failed to adhere to this requirement because the location for the CLIA number did not contain an active clinical laboratory conducting patient testing. (refer to D8301)

**D8301**

**INITIAL INSPECTION OF CERT OF COMPLIANCE LABS**  
CFR(s): 493.1777(a)

(a) Initial inspection. (a)(1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of this part before CMS issues a certificate of compliance. (a)(2) The inspection may occur at any time during the laboratory's hours of operation.

This STANDARD is not met as evidenced by:  
Based on review of the facility CMS-116 and surveyor observation, it was revealed the facility was not an active clinical laboratory conducting patient testing. The findings were: 1. A review of the laboratory's CMS-116 form identified the facilities original address as: 1000 N Davis Drive, Suite E Arlington, Texas 76012 2. Observation of the location on 07/12/2018 at 1300 hours revealed 1000 N Davis Drive, Suite E was occupied by another business. An interview with staff revealed the company had occupied Suite E for years and no one had hear of the laboratory which was supposed to be located there. 3. A review of the laboratory's CMS-116 form notifying of a change of address for the facility revealed the new address to be: 2029 E Levee Street Dallas, Texas 75207 The effective date of the address change was listed as: 02/22/2018 4. Observation of the location on 07/12/2018 at 1400 hours revealed 2029 E Levee Street was a vacant building currently undergoing renovations. Interviews with occupants next door revealed the location had previously been occupied by an Architecture firm but was currently empty and undergoing renovations. 5. Located on the outside of the building at 2029 E Levee Street was a sign which stated the building was for lease and indicated the contact person. A call to the contact person confirmed the location was not rented to a facility at the current time. He stated he hadn't heard on Strategic Laboratory Services. Key: CMS- Centers for Medicare & Medicaid Services