

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2140447	(X3) Date Survey Completed 07/12/2018
Name of Provider or Supplier Goto Lab Express Texas, Llc	Street Address, City, State 1902 Country Club Drive, Suite 160-A, Carrollton, 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>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>
D8100	<p>INSPECTION REQUIREMENTS 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 observation it was revealed the facility was not an active clinical laboratory conducting patient testing. The finding were: 1. Review of the facility's CMS-116 form revealed its current location to be: 1902 Country Club Drive, Suite 160-A Carrollton, Tx 75006 2. Observation of the facility at 1902 Country Club Drive Suite 160-A revealed empty offices. The location was locked, the rooms were dark, pictures were removed and left leaning against the walls, and there was no furniture. 3. An interview with the building manager on 07/12/2018 at 1600 hours revealed the facility had moved out of the location in November 2017 or December 2017 (he couldn't remember exactly which) due to its inability to pay rent. He stated he was not aware facility was currently operating in a new location.
Key: CMS- Centers for Medicare & Medicaid Services