

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2130956	(X3) Date Survey Completed 04/03/2018
Name of Provider or Supplier Rectified Laboratory Llc	Street Address, City, State 10303 Northwest Fwy Suite 536, 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	<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 observation, review of the facility CMS-116 and confirmed in interview the laboratory was not an active clinical laboratory conducting patient testing at the time of the initial inspection on 04/03/2018. Finding were: 1. Observation of the laboratory location at 10303 Northwest Fwy Suite 536 Houston, TX 77092 on 04/03/2018 at 0855 hours revealed a sign on the door "RECTIFIED LABORATORY, LLC". The door was locked and the lights were out. During the time period of 0855 hours to 1015 hours on 04/03/2018 no persons were observed entering or leaving suite 536. A series of 6 phone calls from 0911 hours to 1011 hours were placed to the phone number listed on the application, the phone number on the laboratory website and other contact numbers with no answer or a message the phone number was not in service (website number). 2. Review of the facility CMS-116 application signed by the laboratory director on 02/20/2017 revealed the stated hours of operation were 8 am-5pm Sunday- Saturday. 3. In an interview of the building manager in his office on 4/3 /2018 at 1025 hours he stated the suite was leased in November or December of 2017 and rent was paid 3 months in advance. He stated that rent for April 2017 was due. In addition, he stated the lessee was not the individual listed on the Disclosure of Ownership as the Authorized Representative for Rectified Laboratory LLC dated 02 /25/2017. (Please refer to Alias List) Key: CMS- Centers for Medicare & Medicaid Services