Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2111127	**(X3) Date Survey Completed** 05/10/2018
Name of Provider or Supplier Precision Molecular Labs, Llc	**Street Address, City, State** 11240 Fm 1960 Road West, Suite 402, 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	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 current 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."
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 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.

	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 was not 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 05/10/2018. Finding were: 1. Observation of the laboratory location at 11240 FM 1960 ROAD WEST, SUITE 402 Houston, TX 77065 on 05/10 /2018 at 1155 hours revealed a sign on posted the door "Lockout Notice. Your doors have been locked due to violations of the lease. For reentry, please contact the management office." The door was locked and the lights were out. 2. Review of the facility CMS-116 application signed by the laboratory director on 02/15/2016 revealed the stated hours of operation were 8:30 am-5pm Monday through Friday. 3. The property management representative allowed the surveyors entry to the laboratory. Surveyor observations revealed no electricity to the laboratory. There was one Synermed IR-500 tabletop chemistry analyzer on a counter. The refrigerator contained LinZhi toxicology reagents, calibrators, and controls. All reagents were warm to the touch. Please refer to the photos. The sink had FedEx and UPS mailer bags. Surveyor observed mailer bags were opened and revealed unprocessed urine specimens from November and December 2017." Please refer to the photos. A stack of requisitions from November and December 2017 was on the counter. An overview of the laboratory records revealed the laboratory director last reviewed the quality control for the Synermed IR-500 on 06/13/2017. 4. In an interview with the property management representative on 5/10/18 at 1120 hours, she stated that she had changed the locks to the property "some time ago." She stated that she had only seen 1 woman coming and going to the facility location. Key: CMS- Centers for Medicare & Medicaid Services