

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2083645	<b>(X3) Date Survey Completed</b> 04/10/2018
<b>Name of Provider or Supplier</b> Haider Diagnostic Services Llc	<b>Street Address, City, State</b> 10019 S Main St A-1, Houston, 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>	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."
<b>D8100</b>	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 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. Finding were: 1. Observation of the location at 10019 S MAIN ST A-1 Houston, TX 77025 on 04/10/2018 at 0855 hours revealed a sign on the building "One Stop Medical Care". 2. Review of the CMS-116 signed by the laboratory director on 4/25/2016 revealed the laboratory requested a certificate of compliance for the specialty of chemistry with an estimated test volume of 5000. A review of the "LISTING OF TESTS PERFORMED IN THE FACILITY" dated 5/11/2016 revealed the laboratory would perform routine chemistry testing on the Liasys 330 chemistry analyzer. 3. During a tour of the facility on 4/25/2018 at 0945 hours it was determined that the location had no chemistry analyzer for patient testing. 4. In an interview of the physician in her office on 4/10/2018 at 0915 hours she stated that Haider Diagnostic Services LLC had never performed testing in her offices. 5. Review of the CMS-116 signed by the laboratory director on 4/25/2016 revealed a mailing address of 2000 Crawford Street Suite 1125 Houston, TX 77002. An internet search for Haider Diagnostic Services NPI (National Provider Identifier) number listed the 2000 Crawford Street Suite 1125 Houston, TX 77002 address. 6. Observation of the location at 2000 Crawford Street Suite 1125 Houston, TX 77002 revealed a reference laboratory send-out lockbox on the floor next to the suite door entrance with the "Haider Diagnostic STE 1125" written on the box. Observation of the instrument in the waiting room revealed it was a Liasys chemistry analyzer. Further observation revealed the instrument was not plugged in and several cables / connectors were laying on top of the analyzer. Observation of the signage on the door to suite 1125 revealed 3 entities listed: "SPRING CLINICAL RESEARCH" "SUMMER DIAGNOSTICS LLC" "CARE AND CURE CLINIC" 7. During a tour of the facility suveyor observed an Abacus 5 hematology analyzer and an Indiko chemistry analyzer used for toxicology testing for SUMMER DIAGNOSTICS LLC CLIA 45D2093191. No other instrumentation was observed. 8. In an interview of the CEO on 04/20/2018 at 1315 hours in his office revealed Haider Diagnostics had not performed any testing since it received its CLIA certificate in 2016. Key: CMS-Centers for Medicare & Medicaid Services