

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2105803	(X3) Date Survey Completed 02/08/2018
Name of Provider or Supplier Aim Laboratories	Street Address, City, State 19255 Park Row Dr, Ste 205, 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 resulting in immediate jeopardy for the following condition: 42 CFR 493.1771 Condition: Inspection The location was not an active clinical laboratory established to accept and test patient samples.
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> <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 was not a clinical laboratory. Cross refer to D8301</p>
D8301	<p>INITIAL INSPECTION OF CERT OF COMPLIANCE LABS CFR(s): 493.1777(a)</p> <p>(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</p>

any time during the laboratory's hours of operation.

This STANDARD 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 found on the 116 application which also includes the statement "...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 have functional laboratory equipment for patient testing. Findings were: At the time of the submission of the CLIA 116 application (received 11/03/15), the laboratory location on the 116 application was listed as 19255 PARK ROW DR, STE 205, Houston, TX 77084. The form had the laboratory owner's signature, with a signature date of 10/28/15. The effective date of the CLIA number was 12/03/15. Based on the CLIA application, the laboratory director requested a Registration Certificate of compliance for the specialty of chemistry for a total annual test volume of 600 tests and for the specialty of hematology for a total annual test volume of 600 tests. On February 8, 2018 an onsite initial inspection was conducted during their hours of operation of Sunday through Saturday of 0800 to 1700 hours. During a tour of the laboratory on 02/08/18 at 0915 hours, it was found that it was a specimen collection space for another business Biopharma Informatic Inc. The specimen collection space had laboratory equipment of an Abbott Picollo (SN 0000000P10203) and HemoPoint H2 Meter (SN 3011-14-0002) stored in the bottom drawer. Inspection of the refrigerator revealed no test kits and/or control materials to perform patient testing for the waived testing or for the non-waived testing. An interview with the facility phlebotomist on 02/8/18 at 0930 hours in the collection room confirmed that no patient testing has been performed in the laboratory since her hire date of 09/2017. She stated that there were lab supplies in the refrigerator when she began working, but they were all expired so she discarded them in 09/2017. She stated that she had not been trained nor did she know how to use either instrument. An interview with the finance manager on 02/08/18 at 1015 hours in his office confirmed that no patient testing had been performed since the laboratory started in 2015. An interview with a laboratory representative whose contact information was on the CMS116 on 02/08/18 at 0935 hours revealed he was unaware there were no patient testing performed at the above location. He stated the facility was attempting to get business to the lab but have been unsuccessful thus far.