

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2120621	(X3) Date Survey Completed 03/06/2018
Name of Provider or Supplier Primary Pinnacle Diagnostic, Llc	Street Address, City, State 1903 Central Drive Suite 215, Bedford, 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	An onsite complaint investigation was conducted on 03-06-2018. The allegation regarding certification/unauthorized testing was substantiated and cited.
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: Based on an onsite investigation, the laboratory was found to have been closed. The State Agency was not notified, resulting in an active CLIA certificate assigned to a non-existent laboratory. Refer to D8105.</p>
D8105	<p>BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(e)(f)(g)</p> <p>(e) Reinspection. CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results. (f) Complaint inspection. CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part. (g) Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor observation and staff interview, the laboratory failed to notify the State Agency of laboratory closure as required. Findings: 1. An unannounced visit was made at 1000 CDT 06 March 2018. Entry was granted by the office manager for another business located at the same address. In an interview at the site, the office manager stated that the laboratory had been planned to operate as an independent laboratory by its owner in 2016, but due to financial considerations was never put into operation and that the equipment had been removed. An inspection of the site revealed an empty suite on the second floor which the office manager indicated to have been intended for use as a laboratory testing space. No testing equipment was found. The owner was not present at the time of the visit. Documents supplied during the visit showed that the laboratory had been sold on 27 September 2017. 2. The former director of the laboratory was contacted by telephone at 0956 AM CDT 15 March 2018. At that time the former laboratory director stated that no testing for that laboratory had ever been performed at that location.