

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2303146	(X3) Date Survey Completed 02/25/2025
Name of Provider or Supplier Salient Diagnostics, Llc	Street Address, City, State 5650 N Washington St, C9, Denver, CO	
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	Based on an on-site initial certification survey conducted on February 25, 2025, deficiencies were cited for Salient Diagnostics, LLC in Denver, Colorado.
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assessment plan (QA plan), the laboratory's policies and procedures manual, and an interview with testing personnel 1 (TP1), the laboratory failed to establish a policy or procedure to document all complaints and problems reported to the laboratory, and to investigate complaints when appropriate, since the laboratory began patient testing in August 2024. The laboratory performs approximately 277,200 tests annually. Findings include: 1. A review of the laboratory's QA plan revealed the laboratory failed to establish a policy or procedure to document all complaints and problems reported to the laboratory, and to investigate complaints when appropriate. 2. A review of the laboratory's policies and procedures manual revealed the laboratory failed to establish a policy or procedure to document all complaints and problems reported to the laboratory, and to investigate complaints when appropriate. 3. An interview with TP1, on February 25, 2025, at approximately 11:15 PM, confirmed that the laboratory failed to establish a policy or procedure to document all complaints and problems reported to the laboratory, and to investigate complaints when appropriate.</p>