

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2109691	(X3) Date Survey Completed 11/30/2023
Name of Provider or Supplier Ridgewood Diagnostic Laboratory	Street Address, City, State 126 State St, 2nd Floor, Hackensack, NJ	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: An unannounced complaint survey was performed on 11/30/23 to determine if Ridgewood Diagnostics Laboratory was in compliance with CLIA regulations 42 C.F.R. 493. Based on surveyor interview with the laboratory technical/general supervisor (TGS) and an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain a NJCLL for 2022 and 2023. The findings include: 1. The TGS stated that their NJCLL had been denied for 2022 and 2023 by the NJ State Clinical Laboratory Licensure Program (NJCLLP). 2. The NJCLLP Manager confirmed on 11/29/23, prior to the complaint survey, that the laboratory was denied their NJCLL license for 2022 and 2023. 3. The laboratory performed Toxicology testing on 4,480 patient specimens from 1/1/22 to 12/31/22. 4. The laboratory performed Toxicology testing on 4,259 patient specimens from 1/1/23 to 11/28/23. 5. The laboratory performed allergy testing under Diagnostic Immunology on 37 patient specimens from 1/7/22 to 12/5/22. 6. The laboratory performed allergy testing under Diagnostic Immunology on 252 patient specimens from 1/12/23 to 7/7/23. 7. The TGS confirmed on 11/30/23 at 11:00 am that the laboratory did not maintain a NJCLL for 2022 and 2023.</p>