Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2109691	(X3) Date Survey Completed 04/09/2025
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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on survey review of the Procedure Manual (PM), Proficiency Testing Reports, Alternative Assessment Records and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of all analytes for Urine Confirmation Toxicology (UCT) testing from from 1/1/24 to 4/9/25. The findings include: 1. The PM states "when PT surveys are not available through a CAP and CMS approved PT provider, the laboratory must participate in an alternative assessment program for the test every 6 months/ semi-annually." "Laboratory manager documents and evaluates the new results on the original alternative assessment form." 2. The laboratory performed a method comparison for the analytes not covered by the proficiency testing provider, but there was no evaluation of the results by the laboratory. 3. The GS confirmed on 4/9/25 at 1:30 pm, the laboratory failed to verify the accuracy of all analytes for UCT.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with

	General Supervisor (GS), the laboratory failed to perform and document two levels of external controls on each day of patient testing for Urine Creatinine (CREAT) and urine Potential of Hydrogen (pH) run on the AU 680 from 7/19/18 to 4/9/25. The findings include: 1. The laboratory did not select control material that correlated with the abnormal patient range. 2. The Patient Range (PR) for Urine CREAT was 20-300 mg/dL. a) The high QC mean was 26.11 mg/dL 3. The PR for pH was 5.0-8.0 a) The high QC mean was 6.11 4. The laboratory performed approximately 7000 urine pH and CREAT tests. 5. The GS confirmed on 4/9/25 at 12:20 pm that laboratory did not select control material that correlated with the abnormal patient range for the above mentioned analytes.