

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2114553	(X3) Date Survey Completed 12/12/2023
Name of Provider or Supplier Reproductive Medicine Associates	Street Address, City, State 109 Professional View Drive, Freehold, 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: Based on surveyor interview with the laboratory technical supervisor (TS), review of the laboratory directors (LD) credentials and an in-office review of the laboratory's requirements for LD with New Jersey State Clinical Laboratory Licensure (NJCLL) under New Jersey Administrative Code: N.J.A.C. 8:44-2.3 Laboratory Director Qualifications, the laboratory failed to maintain a qualified LD who meets NJCLL requirements since 7/27/21. The findings include: 1. The laboratory failed to maintain a LD who holds a NJ Bioanalytical Laboratory Director (NJBALD) License which is required by NJCLL. 2. The laboratory type is indicated as Independent, not Physician Office Laboratory (POL) which does have an exemption for the NJBALD License requirement, on the CMS-116 form provided at the time of the survey. 3. The TS confirmed on 12/12/23 at 11:00 am that the laboratory performs testing on patients outside of the practice and is therefore an Independent laboratory and that the LD does not hold a NJBALD License.</p>