

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1040440	(X3) Date Survey Completed 10/17/2023
Name of Provider or Supplier Imgen Diagnostics, Inc	Street Address, City, State 129 Morgan Drive, Norwood, MA	
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	A CLIA recertification survey was conducted for Imgen Diagnostics, Inc. pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the President/CEO and Testing Person (TP) on 10/17/2023, the laboratory failed to follow procedures and policies for twice annual verification of testing it performs that is not included in subpart I of this part as evidenced by the following: The surveyor reviewed the laboratory's procedure for histopathology urologic tissue slide case reviews. The review revealed that once per quarter within a calendar year, 10% of all histopathology cases performed by each of two TP-Pathologists would be reviewed by Laboratory Director for accuracy of diagnosis. A review of calendar years 2022 and 2023 quality assessment records for each of two TP-Pathologists revealed that no histopathology urologic tissue slide case reviews were performed at least twice annually between 1/22/22 and 4/26/23. The documented reviews were performed on 1/22/22, 4/26/23, 7/11/23, and 10/11/23. The President/CEO and TP interviewed on 10/17/23 at 11:02AM confirmed that twice annual accuracy verification for histopathology urologic tissue slide cases was not performed at least twice annually from February 2022 through April 2023. Laboratory performs 604 microbiology tests and 3351 pathology tests annually</p>