

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1040440	(X3) Date Survey Completed 03/29/2019
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 the Imgen Diagnostics, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the laboratory failed to follow policies and procedures in place for all tests, assays, and examinations performed by the laboratory as evidenced by the following: The surveyors reviewed the written procedure manual on 3/29/19. The review revealed that the laboratory failed to follow the procedure named Formaldehyde/Xylene Safety Monitoring for two (2) testing persons (TP) out of 2 TP performing gross descriptions. The procedure stated that TP be monitored for formaldehyde/xylene exposure on an annual basis. There was no evidence of monitoring for calendar years 2017, 2018, and 2019. The laboratory added histopathology on 10/15/17. The laboratory owner confirmed in an interview at 10:36 A.M. that annual safety monitoring was not performed since adding histopathology.</p>