

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2137150	(X3) Date Survey Completed 10/25/2019
Name of Provider or Supplier Commonwealth Diagnostics International, Inc	Street Address, City, State 4 Technology Way, Salem, 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 Commonwealth Diagnostics International, 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 record review and interview, 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: 1. The surveyor reviewed the written procedure manual on 10/25/19. Procedure MTD-120 named "Plate Reader Maintenance and Troubleshooting" stated "perform system test monthly" and "perform absorbance plate test monthly." 2. The surveyor reviewed maintenance records for the plate reader on 10/25/19. Maintenance on the plate reader was performed on 10/23/18 and on 10/23 /19. 3. The Chief Financial Officer confirmed in an interview on 10/25/19 at 9:00 AM that the laboratory failed to follow procedure MTD-120 named "Plate Reader Maintenance and Troubleshooting" and did not perform monthly maintenance on the plate reader for one year. 4. The laboratory performs 103 General Immunology tests annually.</p>