

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2112676	(X3) Date Survey Completed 06/22/2021
Name of Provider or Supplier Ca Dept Of Public Health, Drinking Water &	Street Address, City, State 850 Marina Bay Pkwy, Rm G-164, Richmond, CA	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and PerkinElmer NexION 350D operations manual record review on March 22, 2021 at 10:15 am, the laboratory failed to maintain documentation to indicate that the laboratory performed manufacturer required daily maintenance on the PerkinElmer NexION 350D. Findings included: a. The laboratory's chemical terrorism testing protocols included the use of the PerkinElmer NexION 350D to perform patient CDAA, HG-U, TES, and VM tests. b. According to the operations manual for the NexION 350D, PerkinElmer required that daily maintenance included "daily cleaning." c. The laboratory maintained no documentation to indicate that the laboratory had performed the manufacturer required daily maintenance of "daily cleaning" each day the PerkinElmer NexION 350Ds were used.</p>