Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2112676	(X3) Date Survey Completed 03/29/2023
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	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on laboratory procedure review, maintenance and performance record review, and laboratory personnel interview, the laboratory failed to maintain documentation to indicate that all ICP-MS required daily instrument maintenance activities were performed. Findings include: a. According to the laboratory's protocol titled "Standard Operating Procedures for Measuring Toxic Elements in Human Blood by Inductively Coupled Plasma Mass Spectrometry (SOP 010)," analysts are expected to perform all required daily maintenance and performance checks listed on the Perkin Elmer NexION 350D, Inductively-Coupled Plasma Mass Spectrometer (ICP-MS) instrument daily maintenance and performance checklist, and indicate by checkmark on the checklist that the activity was performed. b. Review of ICP-MS Instrument-B and Instrument-C daily maintenance and performance checklists, showed that the laboratory maintained no checkmark documentation to indicate that nebulizer and spray chamber cleaning was performed for both instruments on October 12, 2021, October 19, 2021, October 20, 2021, October 22, 2021 and October 28, 2021. d. The checkmark spaces on the checklists for the listed dates were blank. e. The technical supervisor confirmed on March 29, 2023 at 3.40 p.m. that the laboratory maintained no documentation to indicate that all required daily maintenance was performed. f. The laboratory reports an annual test volume of 100.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on laboratory procedure review, maintenance and performance record review, and laboratory personnel interview, the laboratory failed to maintain documentation to indicate that all ICP-MS required daily instrument function checks were performed. Findings include: a. According to the laboratory's protocol titled "Standard Operating Procedures for Measuring Toxic Elements in Human Blood by Inductively Coupled Plasma Mass Spectrometry (SOP 010)," analysts are expected to perform all required daily maintenance and performance checks listed on the Perkin Elmer NexION 350D, Inductively-Coupled Plasma Mass Spectrometer (ICP-MS) instrument daily maintenance and performance checklist, and indicate by checkmark on the checklist that the activity was performed. b. Review of ICP-MS Instrument-B daily maintenance and performance checklists, showed that the laboratory maintained no checkmark documentation to indicate daily function checks for: i. Tuning (Smart Tune Manual (dual detector calibration)) on April 6, 2022, April 7, 2022, April 19, 2022, April 20, 2022, and May 17, 2022. ii. Chiller turn off after plasma turn off on October 19, 2021. iii. Vacuum in Torr reading on October 20, 2021. c. Review of ICP-MS Instrument-C daily maintenance and performance checklists, showed that the laboratory maintained no checkmark documentation to indicate daily function checks for: i. Tuning (Smart Tune Manual (dual detector calibration)) on October 20, 2021, October 28, 2021, April 19, 2022, August 10, 2022, August 22, 2022, August 23, 2022 and December 23, 2022. ii. Vacuum in Torr reading on October 22, 2021. iii. Exhaust duct connection and function check on December 19, 2022. iv. Chiller turned on check on December 19, 2022, December 20, 2022, and December 23, 2022. d. The checkmark spaces on the checklists for the listed dates were blank. e. The technical supervisor confirmed on March 29, 2023 at 3.40 p.m. that the laboratory maintained no documentation to indicate that all required daily function checks were performed. f. The laboratory reports an annual test volume of 100.