Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0982600	06/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Infant Botulism Program Laboratory	850 Marina Bay Pkwy, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on 1 of 3 patient test result reports (IBTPP Tracking Number L-2268) reviewed, Jouan KR22i Centrifuge Records Chart (1/5/21-6/18/21) review, Water bath #1 (May 2021) temperature log record review, and interviews with Technical Supervisors (TS) #1 and #2 on June 25th, 2021 at 11:55 AM, the laboratory failed to document temperatures on each day of patient testing per laboratory requirements. Findings included: a) Review of patient test result report (IBTPP Tracking Number L-2268) on June 26th, 2021 indicated that testing for bacterial ID genus and species as well as neurotoxin detection were performed on May 19th, 2021. b) Review of written laboratory procedures for Infant Botulinum bacterial ID genus and species/neurotoxin detection as well as interview with TS #1 and #2 confirmed that required day of testing temperature monitoring on the Jouan KR22i Centrifuge Records Chart (1/5/21-6/18/21) and the Water bath #1 (May 2021) Temperature Log was required but not documented. c) At the time of the survey on June, 25th, 2021 according to laboratory records, the laboratory performed 250 Infant Botulinum bacterial ID genus and species /neurotoxin detection tests annually.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3)

	Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on 1 of 5 Sheep Blood Agar (SBA) Quality Control form (Lot#604652-1) and 1 of 5 Botulinum Selective Media (BSM) Quality Control form (Lot#0002727) record reviews, as well as interviews with the Laboratory Director (LD), Technical Supervisors (TS) #1, and TS #2 at 10:20 AM on June 25th, 2021 the laboratory failed to adhere to their quality control policy and had quality control performed by staff that did not qualify as Testing Personnel. Findings included: a) Review of Sheep Blood Agar (SBA) Quality Control forms (Lot#604652-1) and Botulinum Selective Media (BSM) Quality Control forms (Lot#0002727) on June 26th, 2021, indicated that Quality Control was performed on June 16th, 2021 by Laboratory Personnel (LP) #1. SBA and BSM are used to perform Infant Botulism bacterial ID genus and species, and neurotoxin detection tests. b) Review of the Form CMS-209, Laboratory Personnel Report (CLIA) submitted on June 25th, 2021 as well as interview with the Laboratory Director (LD), TS #1, and TS #2 at 10:20 AM on June 25th, 2021 confirmed that there was not a diploma, transcript, or other supporting evidence available which showed that LP #1 qualified as Testing Personnel for a CLIA High Complexity Laboratory and that the laboratory had not adhered to its quality control policy. c) At the time of the survey on June, 25th, 2021 according to laboratory records, the laboratory performed 250 Infant Botulinum bacterial ID genus and species /neurotoxin detection tests annually.