| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 05D0643850 | 05/05/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Viral & Rickettsial Disease 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 |
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| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>1. Based on general supervisor interview and Hanta EIA Plate Washer Maintenance record review on May 4, 2021, the laboratory failed to perform maintenance on an enzyme-linked immunosorbent assay (EIA) plate washer as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings included: a. In the Zoonotic & Vectorborne Diseases Section, the laboratory performed patient IgG and IgM Hanta virus testing using an EIA method that involved the use of a plate washer. b. The manufacturer of the plate washer required that for each day of use, the following maintenance be performed on the plate washer: "wash buffer prepared," "full system prime," "dispense test," 'evac. test," "wash plates," "day rinse," "rinse and soak," and "check and empty waste bottle." c. Laboratory records indicate that on April 13, 2021, the laboratory performed IgG and IgM Hanta virus testing on patient specimens V21B00003, V21S00063, and V21S00064. The laboratory maintained no documentation to indicate that plate washer maintenance had been performed on April 13, 2021. d. According to laboratory personnel, the laboratory tests approximately 20 patient specimens annually for IgG and IgM Hanta virus. 2. Based on general supervisor interviews and SARS-CoV-2 testing thermal cycler maintenance record review on May 5, 2021, the laboratory failed to perform maintenance on a thermal cycler as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings included: a. The laboratory performed patient SARS-CoV-2 testing using a polymerase chain reaction (PCR) method that involved the use of an Applied Biosystems thermal cycler. b. The manufacturer of the thermal cycler required that for |

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| | each month of use, the laboratory "perform a background calibration." c. Laboratory records indicate that on December 10, 2020, the laboratory performed SARS-CoV-2 PCR testing on 90 patient specimens. Within the month of the December 10, 2020 patient SARS-CoV-2 testing, the laboratory maintained no documentation to indicate that the monthly required thermal cycler maintenance had been performed. d. According to laboratory personnel, the laboratory has tested 42,976 patient specimens using their SARS-CoV-2 PCR test from March 2020 to May 5, 2021. |