State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

# CALIFORNIA DEVICE RECALL INFORMATION SHEET

**Bio-Rad Laboratories Recall Bioplex 2200 For Incorrect Packaging Of Conjugate Leading To Potentially False Test Results**

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|---|---|---|---|
| 5/17/2023 | **Bioplex 2200**<br>REF 665-2050, APLS IgM Pack, APLS IgM Reagent Pack | **BIO-RAD LABORATORIES, INC.**<br>Redmond, Washington | APLS IgM reagent kits were packaged with the incorrect conjugate, which could lead to an increase in false-positive and false-negative results. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|---|---|---|---|
| II | **Bioplex 2200**<br>Lot Code: 301538; UDI-DI: (00)847865000666 | 154 Units<br>in California | January 2023 to Febuary 2023 |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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