



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Bio-RAD recalls BioPlex 2200 Syphilis Total and RPR Kit

Recall Date	Product Description	Recalling Firm	Recall Reason
2/8/2021	BIO-RAD BioPlex 2200 Syphilis Total & RPR Reagent Pack REF 12000650 The BioPlex Syphilis Total & RPR kit is a multiplex flow immunoassay intended for the qualitative detection of total (IgG/IgM) antibodies to Treponema pallidum and the qualitative detection and/or titer determination of nontreponemal reagin antibodies in human serum or plasma	Bio-Rad Laboratories, Inc. Redmond, Washington	Due to current concerns related to COVID-19 vaccine interference with the RPR portion of the BioPlex 2200 Syphilis Total & RPR panel, as well as intermittent manufacturing challenges to produce RPR reagents that consistently meet stability specifications
2/8/2021	BIO-RAD BioPlex 2200 Syphilis Total & RPR Calibrator REF 12000651	Bio-Rad Laboratories, Inc. Redmond, Washington	COVID-19 Vaccine interference and stability problem.

Recall Class	Product Identification	Distribution	Affected Dates
II	BIO-RAD BioPlex 2200 Syphilis Total & RPR Reagent Pack	537 Units in California	September 2021 and prior
II	BIO-RAD BioPlex 2200 Syphilis Total & RPR Calibrator	37 Units in California	September 2021 and prior

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