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DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

Helping people. It's who we are and what we do.

Lisa Sherych
Administrator

Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer

Technical Bulletin

Date: April 5, 2022
Topic: BioPlex 2200 Syphilis Total & RPR Test Kit Recall
Contact: Elizabeth Kessler, MPH, STD Program Manager, Nevada Division of Public and Behavioral Health, Office of Public Health Investigations and Epidemiology
To: Health Care Providers, Medical Facilities, and Correctional Facilities

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Situation:

On February 8, 2022, BioRad issued a voluntary recall for the rapid plasma reagin (RPR) portion of the BioPlex 2200 Syphilis Total & RPR Test Kit due to current concerns related to COVID-19 vaccine interference and false reactive RPR results, as well as intermittent manufacturing challenges to produce the RPR reagents that consistently meet stability specifications. The U.S. Food and Drug Administration (FDA) classified this as a Class 2 Device Recall on March 16, 2022. BioRad Laboratories, Inc. has disabled the RPR portion of the Syphilis Total and RPR panels until further notice. Customers are instructed to:

1. Dispose of the reagents according to local waste management procedures.
2. If they have further distributed or transferred the product to other customers, or labs from their site, notify those customers of this field action.
3. Complete a customer response form and email or fax it to local Bio-Rad Technical Support. (techsupport.ussd@bio-rad.com or 1-888-228-0688)

Individuals who need syphilis testing should continue to get tested and receive the full testing algorithm. Testing locations can be found at Nevada 2-1-1: https://www.nevada211.org/std-syphilis-testing/

Resources:

We encourage you to review this recall notice in detail:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=192210&ACSTrackingID=USCDC_2146-DM78416&ACSTrackingLabel=Lab%20Alert%3A%20FDA%20Recalls%20BioPlex%202200%20Syphilis%20Total%20%26%20RPR%20Test%20Kit&deliveryName=USCDC_2146-DM78416

Questions:

For updated guidance, please review the DPBH Technical Bulletin website. For questions about this technical bulletin, contact Elizabeth Kessler at (775) 447-4494 or ekessler@health.nv.gov or the Laboratory Outreach Communication System (LOCS) at LOCS@CDC.gov.

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