CALIFORNIA DEVICE RECALL INFORMATION SHEET

BioRAD Recalls Cytomegalovirus IgM In Vitro Diagnostic for Increased Positivity Rates

Recall Date	Product Description	Recalling Firm	Recall Reason
12/07/2022	**CMV IgM EIA** In Vitro Diagnostic	**BioRAD** Tukwila, Washington	Due to an unusual increase in the positivity rate with human IgM antibodies to cytomegalovirus (CMV) Enzyme Immunoassay (EIA).

Recall Class	Product Identification	Distribution	Affected Dates
II	Catalog Number: 25178 UDI-DI Code: 00847865010733 Lot Numbers: B02022 E10022 G05022	8 kits in California	October 2022 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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