



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Siemens Healthcare Diagnostics Recalls Epoc BGEM Test Card For Discrepancy In Glucose Readings

Recall Date	Product Description	Recalling Firm	Recall Reason
9/6/2023	epoc BGEM BUN Test Card with epoc Host SW v3.37.3, epoc NXS SW v4.10.6, Sensor Configuration 41.1	SIEMENS HEALTHCARE DIAGNOSTICS INC. Norwood, Massachusetts	There is potential for discrepant high glucose results in samples with glucose results on the lower end of the reportable range.
9/6/2023	epoc BGEM Crea Test Card with epoc Host SW v3.37.3, epoc NXS SW v4.10.6, Sensor Configuration 41.1	SIEMENS HEALTHCARE DIAGNOSTICS INC. Norwood, Massachusetts	There is potential for discrepant high glucose results in samples with glucose results on the lower end of the reportable range.
9/6/2023	epoc BGEM Test Card (BUN & TCO2) Veterinary with epoc Host SW v3.37.3, epoc NXS SW v4.10.6, Sensor Configuration 41.1	SIEMENS HEALTHCARE DIAGNOSTICS INC. Norwood, Massachusetts	There is potential for discrepant high glucose results in samples with glucose results on the lower end of the reportable range.

Recall Class	Product Identification	Distribution	Affected Dates
II	epoc BGEM BUN Test Card UDI-DI: 00809708121860 Siemens Material Number: 10736515 Lots: 04-23003-60 (expiry 20- Jun-2023), 11-22337-60 (expiry 20-May-	3201 each Nationwide including California	June 2023 and prior

	2023), 04-23034-40 (expiry 21-Jul-2023), 04-23059-50 (expiry 15-Aug-2023), 04-23059-60 (expiry 15-Aug-2023), and 04-23069-40 (expiry 25-Aug-2023)		
II	epoc BGEM Crea Test Card UDI-DI: 00630414243788 Siemens Material Number: 10736516 Lots: 04-23043-51 (expiry 30-Jul-2023)	473 each Nationwide including California	June 2023 and prior
II	epoc BGEM Test Card (BUN & TCO2) UDI-DI: 00630414243788 Siemens Material Number: 10736516 Lots: 04-23043-51 (expiry 30-Jul-2023)	348 each Nationwide including California	June 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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