



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

Potential for Signal Amplification Delay in Simplexa COVID-19 Positive Control Pack

Recall Date	Product Description	Recalling Firm	Recall Reason
10/27/2021	<b>SIMPLEXA COVID-19 Positive Control Pack, REF MOL4160, IVD, Rx Only</b>  UDI: (01) 20816101027051  1690 kits	<b>DiaSorin Molecular LLC,</b> Cypress, California	Due to unapproved raw materials used in the manufacturing of Covid-19 control pack, there is the potential for delayed amplification signals.

Recall Class	Product Identification	Distribution	Affected Dates
Voluntary	<b>MOL4160 Lot# 12175N &amp; 12722N</b>	32 kits of 12175N 13 kits of 12722N in California	September 2021 and prior

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