

## California Device Recall Information Sheet

### Food and Drug Branch – Device Recalls

#### Beckman Coulter Mishima K.K. Sample Probe

Recall Date	Product Description	Recalling Firm	Recall Reason
06/04/2025	Sample probe sucks a sample dispensed into a tube or cup and discharges the appropriate amount into a cuvette. Lot 178713114 - 179433670	Beckman Coulter Mishima K.K.	A manufacturing defect in the sample probe (S probe). The corners of the tip of the defective S probe are rounded and chamfered, which can prevent the proper formation of the "air layer" required for normal dispensing. The air layer is the air space that separates the cleaning water filled in the probe from the sample sucked into the probe. Maintaining this air space prevents the cleaning water and the sample from mixing. In the defective S probe, the "air layer" was not properly formed, causing the cleaning water and the sample to mix diluting the sample. As a result, the sample mixture dispensed into the cuvette has a lower concentration than the original sample, and the analyte

			<p>concentration measured is lower than expected results. Sample probes with defective probe tips, when used with clinical chemistry analyzers, may lead to a lower concentration being dispensed, which may not be detectable by QC checks, which could lead to the reporting of false low test results (Max 34% error at 1.0 microliters and 7% error at 1.6 microliters sample dispensing volume), which may lead to delayed recognition and treatment.</p>
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Recall Class	Product Identification	Distribution	Affected Dates
II	AU680 REF: B12185 UDI-DI: 14987666540732 REF: B12186 UDI-DI: 14987666540688 REF: B12187 UDI-DI: 14987666540701 REF: B12188 UDI-DI: 14987666540725 REF: B96694 UDI-DI: 14987666542989 REF: B96695 14987666542996 REF: B96696 UDI-DI: 14987666543009 REF: C02656 UDI-DI: 14987666543306 REF: C02657 UDI-DI: 14987666543313 REF: N3147700	264 units in California	April and prior

	<p> UDI-DI: 15099590346249  REF: N3662000  UDI-DI: 14987666535301  REF: N3662100  UDI-DI: 14987666535318  REF: N3662200  UDI-DI: 14987666535325  REF: N3662700  UDI-DI: 14987666535615  REF: N3663000  UDI-DI: 14987666535646  REF: N3910200  UDI-DI:  14987666535790N3910400,  14987666535813  REF: N3910500  UDI-DI: 14987666535820  REF: N3910600  UDI-DI: 14987666535912  REF: N3910800  UDI-DI: 14987666535936  REF: N3910900  UDI-DI: 4987666535946  REF: N3911200  UDI-DI: 14987666535974  REF: N3911700  UDI-DI: 14987666536575  REF: N3911900  UDI-DI: 14987666536599  REF: N3147100, N3147200,  N3147300, N3147400,  N3147600, N3148100,  N3149400, N3149800  Lots: 10436 - 2022087656   Sample Probe  REF: MU993400, B66752  UDI-DI: 04987666522939  Lots: 178713114 - 179433670 </p>		
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For additional information, please visit: [FDA Website \(1\)](#) and [FDA Website \(2\)](#).