


V A L I D A T I O N		Doc #	VALSUMMARY – LifeScan – 0001
		Revision	1.1
	Sponsor: Concentric by Ginkgo	Effective	1/14/2021
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Summary of Results: Validation of LifeScan Labs of Illinois - CDC 2019-Novel Coronavirus (2019-nCoV) for Swab Pooling

Table 1. Validation of pooling test performance with 25 dry swabs per pool.

Performance metric		Description	Performance
25-Swab Pool	Confirmation of performance at low viral concentration	Percent of swab pools positive at 1500 copies/mL (without clinical matrix)*	30 / 30 = 100%; 95% CI [88.4%-100%]
	Confirmation of performance at intermediate viral concentration	Percent of swab pools positive at 4500 copies/mL (without clinical matrix)*	30 / 30 = 100%; 95% CI [88.4%-100%]
	Detection of weak positive swabs in a pool	Percent of swab pools positive at 1500 copies/mL (with clinical matrix)*	30 / 30 = 100%; 95% CI [88.4%-100%]
	Detection of intermediate positive swabs in a pool	Percent of swab pools positive at 4500 copies/mL (with clinical matrix)*	40 / 40 = 100%; 95% CI [91.2%-100%]
	Detection of strong positive swabs in a pool	Percent of swab pools positive at 1,000,000 copies/mL (with clinical matrix)*	10 / 10 = 100%; 95% CI [69.1%-100%]

*Virus used to prepare swab samples: BEI Resources NR-52287, lot # 70035888