


VALIDATION		Doc #	VALSUMMARY – Dascena – 0001
		Revision	1.1
	Sponsor: Concentric by Ginkgo	Effective	01/05/2021
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Summary of Results: Validation of Dascena PCR-based Lab Developed Test (LDT) 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 2250 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 2250 copies/mL (with clinical matrix)*	39 / 40 = 97.5%; 95% CI [86.8%-99.9%]
	Detection of strong positive swabs in a pool	Percent of swab pools positive at 1,968,750 copies/mL (with clinical matrix)*	20 / 20 = 100%; 95% CI [83.2%-100%]

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