


VALIDATION		Doc #	VALSUMMARY – ReOpen Diagnostics – 0001
		Revision	1.1
	Sponsor: Concentric by Ginkgo	Effective	2/25/2021
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Summary of Results: ReOpen Diagnostics PRL SCV2 Test for Swab Pooling

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

Performance metric		Description	Performance
25-Swab Pool	Detection of weak positive swabs in a pool	Percent of swab pools positive at 1,500 copies/mL ¹ (with clinical matrix ²)	30 / 31 = 96.8%; 95% CI [83.3%-99.9%]
	Detection of strong positive swabs in a pool	Percent of swab pools positive at 1,000,000 copies/mL ¹ (with clinical matrix ²)	16 / 16 = 100%; 95% CI [79.4%-100%]

¹ Virus used to prepare swab samples: BEI Resources NR-52287, lot # 70035888

² Samples from the same individuals utilized to prepare the contrived samples were confirmed to be negative for the virus in the same experiment (results not shown).