


V A L I D A T I O N		Doc #	VALSUMMARY – CIAN Dx – 0001
		Revision	1.0
	Sponsor: Concentric by Ginkgo	Effective	1/12/2021
	Contract Lab: CIAN Diagnostics	Author	Vasiliki Tsakraklides

Summary of Results: Validation of CIAN Diagnostics Modified Thermo Fisher TaqPath COVID-19 SARS-CoV-2 Method 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)*	40 / 40 = 100%; 95% CI [91.2%-100%]
	Detection of weak positive swabs in a pool	Percent of swab pools positive at 1500 copies/mL (with clinical matrix)*	64 / 64 = 100%; 95% CI [94.4%-100%]
	Detection of strong positive swabs in a pool	Percent of swab pools positive at 1,000,000 copies/mL (with clinical matrix)*	32 / 32 = 100%; 95% CI [89.1%-100%]

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