


VALIDATION		Doc #	VALSUMMARY – Ethos – 0001
		Revision	1.1
	Sponsor: Concentric by Ginkgo	Effective	2/08/2021
	Contract Lab: Ethos Laboratories	Author	Vasiliki Tsakraklides

Summary of Results: Ethos Laboratories SARS-COV-2 MALDI-TOF ASSAY 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)	39 / 39 = 100%; 95% CI [91%-100%]
	Detection of strong positive swabs in a pool	Percent of swab pools positive at 1,000,000 copies/mL ¹ (with clinical matrix ²)	20 / 20 = 100%; 95% CI [83.2%-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).