


VALIDATION		Doc #	VALSUMMARY – One Health Labs – 0001
		Revision	1.1
	Sponsor: Concentric by Ginkgo	Effective	1/24/2021
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Summary of Results: Biomeme SARS-CoV-2 Real-Time RT-PCR 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 1,000 copies/mL ¹ (with clinical matrix ²)	40 / 40 = 100%; 95% CI [91.2%-100%]
	Detection of strong positive swabs in a pool	Percent of swab pools positive at 667,000 copies/mL ¹ (with clinical matrix ²)	20 / 20 = 100%; 95% CI [83.2%-100%]
	Evaluation of performance at low viral concentration ³	Percent of swab pools positive at 1,000 copies/mL ¹ (without clinical matrix)	30 / 30 = 100%; 95% CI [88.4%-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).

³ These samples are included as an experimental control to verify that clinical matrix does not interfere with virus detection at low virus concentrations in case detection of weak positive swabs in a pool fails.