


VALIDATION		Doc #	VALSUMMARY – NxGen MDx – 0001	
		Revision	1.1	
	Sponsor: Concentric by Ginkgo	Effective	2/15/2021	
	Contract Lab: NxGen MDx	Author	Vasiliki Tsakraklides	

Summary of Results: NxGen MDx - NxGen MDx SARS-CoV-2 Single-Well 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)	35 / 35 = 100%; 95% CI [90%-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)	11 / 11 = 100%; 95% CI [71.5%-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).