


<b>VALIDATION</b>		<b>Doc #</b>	VALSUMMARY – Rapid Dx – 0001
		<b>Revision</b>	1.0
	<b>Sponsor:</b> Concentric by Ginkgo	<b>Effective</b>	1/7/2021
	<b>Contract Lab:</b> Rapid Dx	<b>Author</b>	Vasiliki Tsakraklides

## Summary of Results: Validation of Rapid Dx SARS-CoV-2: Thermo TaqPath™ COVID-19 Combo Kit for Swab Pooling

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

Performance metric		Description	Performance
<b>25-Swab Pool</b>	Confirmation of performance at low viral concentration	Percent of swab pools positive at 1500 copies/mL (without clinical matrix)*	30 / 30 = 100%; 95% CI [88.4%-100%]
	Confirmation of performance at intermediate viral concentration	Percent of swab pools positive at 4500 copies/mL (without clinical matrix)*	30 / 30 = 100%; 95% CI [88.4%-100%]
	Detection of weak positive swabs in a pool	Percent of swab pools positive at 1500 copies/mL (with clinical matrix)*	50 / 50 = 100%; 95% CI [92.9%-100%]
	Detection of intermediate positive swabs in a pool	Percent of swab pools positive at 4500 copies/mL (with clinical matrix)*	50 / 50 = 100%; 95% CI [92.9%-100%]
	Detection of strong positive swabs in a pool	Percent of swab pools positive at 1,000,000 copies/mL (with clinical matrix)*	20 / 20 = 100%; 95% CI [83.2%-100%]

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