


<b>VALIDATION</b>	 <b>GINKGO BIOWORKS</b> <small>THE ORGANISM COMPANY</small>	<b>Doc #</b>	VALSUMMARY – MedArbor – 0001	
		<b>Revision</b>	1.1	
	<b>Sponsor:</b> Concentric by Ginkgo	<b>Effective</b>	4/15/2021	
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## Summary of Results:

### MedArbor - ThermoFisher 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
25-Swab Pool	Detection of weak positive swabs in a pool	Percent of swab pools positive at 1,500 copies/mL <sup>1</sup> (with clinical matrix <sup>2</sup> )	40 / 40 = 100%; 95% CI [91.2%-100%]
	Detection of strong positive swabs in a pool	Percent of swab pools positive at 1,000,000 copies/mL <sup>1</sup> (with clinical matrix <sup>2</sup> )	20 / 20 = 100%; 95% CI [83.2%-100%]

### MedArbor - LabTurbo™ AIO COVID-19 qPCR Testing Kit for Swab Pooling

**Table 2.** 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 <sup>1</sup> (with clinical matrix <sup>2</sup> )	40 / 40 = 100%; 95% CI [91.2%-100%]
	Detection of strong positive swabs in a pool	Percent of swab pools positive at 1,000,000 copies/mL <sup>1</sup> (with clinical matrix <sup>2</sup> )	20 / 20 = 100%; 95% CI [83.2%-100%]

<sup>1</sup> Virus used to prepare swab samples: BEI Resources NR-52287, lot # 70039068

<sup>2</sup> 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).