


<b>VALIDATION</b>		<b>Doc #</b>	VALSUMMARY – Helix – 0001
		<b>Revision</b>	3.0
	<b>Sponsor:</b> Concentric by Ginkgo	<b>Effective</b>	4/1/2021
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## Summary of Results:

### Helix Diagnostics - Helix COVID-19 Test (without RNA Extraction) 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> )	80 / 80 = 100%; 95% CI [95.5%-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> )	40 / 40 = 100%; 95% CI [91.2%-100%]

<sup>1</sup> Virus used to prepare swab samples: BEI Resources NR-52287, lot # 70039067

<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).