

	Doc #	VALSUMMARY – Sonora Quest – 0001	
	Revision	2.1	
	Sponsor: Concentric by Ginkgo	Effective	4/2/2021
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Summary of Results: Sonora Quest Laboratories – PerkinElmer® Coronavirus (SARS-CoV-2) Nucleic Acid Detection Kit for Swab Pooling

Table 1. Summary of test performance with 25 dry swabs per pool.

Performance metric		Description	Performance
25-Swab Pool	Detection of positive swabs in a pool	Percent of swab pools positive at 1,500 copies/mL ¹ (with clinical matrix ²)	60 / 60 = 100%; 95% CI [94.0%-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)	27 / 27 = 100%; 95% CI [87.2%-100%]

Table 2. Replicate results by sample.

Sample Number	Copies/mL ²	Expected Results	Replicates	Total Concordant Replicates	Invalid Replicates
1	0	Not Detected	10	9	1
2			10	9	1
3			7	7	0
4	1,500	Detected	10	10	0
5			10	10	0
6			10	10	0
7			10	10	0
8			10	10	0
9			10	10	0
10	1,000,000	Detected	7	7	0
11			10	10	0
12			10	10	0

Total Invalid: 2
Invalid Rate: 1.75%

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

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).