


VALIDATION		Doc #	VALSUMMARY – Quest Pittsburgh – 0001
		Revision	1.1
	Sponsor: Concentric by Ginkgo	Effective	6/1/2021
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Summary of Results:

Quest Diagnostics Pittsburgh - Roche cobas® SARS-CoV-2 Method with 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)	24 / 24 = 100%; 95% CI [85.7%-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)	12 / 12 = 100%; 95% CI [73.5%-100%]

Quest Diagnostics Pittsburgh - Aptima SARS-CoV-2 Method with 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 ¹ (with clinical matrix ²)	44 / 44 = 100%; 95% CI [92%-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)	24 / 24 = 100%; 95% CI [85.7%-100%]

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

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).