Table 9: Symptomatic at time of collection, >14 days since symptom onset

		Clinician Collected Nasopharyngeal Swab (in RNA preservative)		
		Positive	**Negative**	**Total**
Self-Collected Oral Fluid Swab (Non-HCW observed/directed) in RNA preservative	**Positive**	4	1	5
	Negative	3	0	3
	Total	7	1	8
Positive Agreement		57.1 % (95% CI 25.0-84.2%)		
Negative Agreement		0/1		

When testing is limited to asymptomatic individuals at time of collection, but not observed and directed by HCW during collection, the test performance is as follows:

Table 10: Asymptomatic at time of collection

		Clinician Collected Nasopharyngeal Swab (in RNA preservative)		
		Positive	**Negative**	**Total**
Self-Collected Oral Fluid Swab (Non-HCW observed/directed) in RNA preservative	**Positive**	0	3	3
	Negative	3	14	17
	Total	3	17	20
Positive Agreement		0/3		
Negative Agreement		82.4 % (95% CI 59.0-93.8%)		

*1 oral fluid swab sample was QNS (quantity not sufficient) and was excluded from analysis

In the table above, all three false negatives were from individuals tested as asymptomatic at time of collection, but previously symptomatic, within 17 days of symptom onset (7, 14, and 17 days).

The data above does not support use of the Curative SARS-CoV-2, for any individuals for self-collected oral fluid samples when not directly observed and directed by a trained healthcare worker during collection and at the site of collection. A modification to the original clinical study acceptance criteria was made. Subjects more than 14 days from symptom onset at time of collection, and subjects who were no longer symptomatic, were excluded from the final clinical study. A total of 52 subjects were enrolled. Upon obtaining consent, a clinician drove to the subjects' home with a testing kit, the written research study information form, and the sample collection materials. Testing kits included components for collecting 4 different sample types and all samples were collected into DNA/RNA Shield (Zymo Research).

Subjects were instructed to complete self-collection of the oral fluid specimen and nasal specimen while observed and directed by the study clinician and package the sample into the collection bag. Then the clinician collected a nasopharyngeal sample from the subject. All three specimens were collected in the same visit within a 30-minute window.

There was 100% positive and negative agreement between the results obtained from testing of clinician observed and directed, self-collected oral fluid swabs put into Zymo