

Table 5: Clinical Evaluation of the LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel

2019-nCoV Real-Time RT-PCR Diagnostic Panel	FDA EUA Real-Time RT-PCR Test		Total	% Performance Agreement	95% CI
	Detected	Not Detected			
Detected	30	0	30	PPA 100%	88.7-100%
Not Detected	0	30	30	NPA 100%	88.7-100%
Total	30/30	30/30	60		

Warnings:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by the authorized laboratory;
- This test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

REMOVED