FDA -- CDC virus not isolated

https://www.fda.gov/media/134922/download

pg. 39

The analytical sensitivity of the rRT-PCR assays contained in the CDC 2019 Novel Coronavirus (2019- nCoV) Real-Time RT-PCR Diagnostic Panel were determined in Limit of Detection studies. **Since no quantified virus isolates of the 2019-nCoV are currently available,** assays designed for detection of the 2019-nCoV RNA were tested with characterized stocks of in vitro transcribed full length RNA (N gene; GenBank accession: MN908947.2) of known titer (RNA copies/µL) spiked into a diluent consisting of a suspension of human A549 cells and viral transport medium (VTM) to mimic clinical specimen. Samples were extracted using the QIAGEN EZ1 Advanced XL instrument and EZ1 DSP Virus Kit (Cat# 62724) and manually with the QIAGEN DSP Viral RNA Mini Kit (Cat# 61904). Real-Time RT-PCR assays were performed using the ThemoFisher Scientific TaqPath™ 1-Step RT-qPCR Master Mix, CG (Cat# A15299) on the Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument according to the CDC 2019-nCoV RealTime RT-PCR Diagnostic Panel instructions for use.