From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Mon, 3 Feb 2020 00:50:43 +0000

To: James Krellenstein

Subject: RE: 2019-nCoV Testing for Public Health Labs

James:

Thanks for the heads-up. I will see what I can do.

Best, Tony

From: James Krellenstein (b) (6)

Sent: Sunday, February 2, 2020 7:37 PM

To: Fauci, Anthony (NIH/NIAID) [E] (b) (6) >

Cc: David Barr (b) (6) >; Lord, Aaron (b) (6) Peter Staley

(b) (6)

Subject: 2019-nCoV Testing for Public Health Labs

## Tony:

I hope this email finds you well. Over the past 48 hours, PrEP4All has received multiple requests from leaders of public health departments and public health practitioners to begin publicly pressuring CDC/HHS to ensure that properly equipped public health labs (besides CDC's lab in Atlanta) can perform real time reverse transcription PCR (qRT-PCR) testing for 2019 Novel-Coronavirus (2019-nCoV).

Our understanding is that given the public health emergency declared by HHS, an emergency use authorization (EUA) from the FDA is required for public health labs to perform their own lab developed test for 2019-nCoV, even if it is using the CDC's published qRT-PCR protocol and primer/probe sequences (

https://www.cdc.gov/coronavirus/2019-ncov/downloads/rt-pcr-panel-for-detection-instructions.pdf ) , and the lab is capable of handling BSL3+ samples.

We understand the extreme delicateness of this situation, and also that it is outside of our normal wheelhouse. But given the concerns of our colleagues in the public health sector, we thought it was important to give you a heads up regarding this request.

Let us know if there is anyway we can help.

Sincerely,

James Krellenstein
Data, Science and Policy Committee
The PrEP4AII Collaboration
109 S 5th St, Brooklyn, NY 11249
(b) (6)

--