From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Fri, 6 Mar 2020 04:01:59 +0000
To: James Krellenstein
Subject: RE: 2019-nCoV Testing for Public Health Labs

James:
Thanks for the note. Be assured that I am trying to break this log jam.
Best,
Tony

From: James Krellenstein (b) (6)
Sent: Wednesday, March 4, 2020 6:46 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b) (6)
Subject: Re: 2019-nCoV Testing for Public Health Labs

Tony:

I am loath to contact you given that I am sure you are overwhelmed. However, we are now being contacted by sources at tertiary academic hospitals with CLIA-high complexity clinical labs who are alarmed about their inability to scale up SARS-CoV2 qRT-PCR testing in their facilities in the time frame they feel is neccesary, even after Saturday's FDA regulatory guidance and the availability of Integrated DNA Technology's testing reagents. (An example of such an email is below.) I am passing this along with the hopes that if you can do something about it, you will. From an email:

> "We have experience bringing up laboratory developed tests. We have never submitted an EUA before. For our current LDTs, they are typically for pathogens that we have some experience with, positive clinical samples are readily available, and/or appropriate control materials (e.g. bacteria, viral genomes) are readily commercially available. None of those are true for SARS-CoV2. There is tremendous concern about deploying a suboptimal test into a challenging environment.
>
> The EUA guidance from FDA is not unreasonable for the validation of a new respiratory virus test, and it gives an accurate picture of the amount of testing that is required to bring on a new test by the lab. Federal law requires us to perform accuracy, reproducibility, analytical sensitivity / LOD, and analytical specificity (cross reactivity) studies. Those studies require positive control material *including*intact virus or RNA. Clinical labs are not prepared to generate RNA transcript, and we don't usually source these ourselves. We can't get the virus without filling out extensive paperwork that requires multiple signatures. Getting control material for validation one of the biggest issues.