

8/28/2020



Edcgov.us Mail - Re: COVID-19: Moving Ahead on Proposed Test, etc. f/ TERRY KAYES

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Re: COVID-19: Moving Ahead on Proposed Test, etc. f/ TERRY KAYES

1 message

Terry Kayes <kayes.gov@gmail.com>

Thu, Aug 27, 2020 at 8:10 PM

To: "Dr. Ann Cornell-Bell" <ann.cornellbell@gmail.com>

Cc: John Hidahl <bosone@edcgov.us>, Shiva Frentzen <bostwo@edcgov.us>, Brian Veerkamp <bosthree@edcgov.us>, Lori Parlin <bosfour@edcgov.us>, Sue Novasel <bosfive@edcgov.us>, Kim Dawson <kim.dawson@edcgov.us>, Don Ashton <don.ashton@edcgov.us>, Creighton Avila <creighton.avila@edcgov.us>, David Livingston <david.livingston@edcgov.us>, Don Semon <don.semon@edcgov.us>, Karen Feathers <karen.feathers@edcgov.us>, "Dr. Nancy Williams" <nancy.williams@edcgov.us>, Lynnann Svensson <edcgov.us>, michael.ungeheuer@edcgov.us, Greg Stanton <greg.stanton@edcgov.us>, Dave Johnston <dave.johnston@edcgov.us>, Laura Lyons <lyonsl@edso.org>, Josh Sprague <spraguej@edso.org>, Scott.Lindgren@fire.ca.gov, corderot@eldofire.com, McKayb@eldofire.com, oganl@eldofire.com, Tiffany Schmid <tiffany.schmid@edcgov.us>, Rafael Martinez <rafael.martinez@edcgov.us>, edc.cob@edcgov.us

Greetings Dr. Ann Cornell-Bell (COVID-19 Products Consultant, Oasis Therapeutics, LLC (California); and President and CEO of Perseus Sciences Group, LLC (Connecticut),

Re: **FAST, Accurate, Precise, Inexpensive COVID-19 Test**

I received and am studying your email messages of August 21 and August 24. I'll need a few days to "digest" the information that you sent me, and will get back to you as soon as I can.

Things for me in the Placerville-Camino area have been for days in a state of almost constant chaos, due to prolonged outages of electric-power and Internet services, a health-threatening heat-wave and high smoke levels coming from very large wildfires (so far largely to the west of us), with the seasonal prevailing eastward air movement bringing the smoke directly here, with little chance of the air clearing to healthy levels anytime soon.

Consequently, for both health and safety reasons, I am staying temporarily at a lower less wildfire- and smoke-prone elevation in Rancho Cordova (near Sacramento) at daughter Amy's place, in large part to take advantage of her consistent electric power and high-efficiency air-conditioning system. The public and individual health and safety situation for those living along or near 5 Mile Road (as historically too-often a fact) is **intolerable**, due to high-levels of wildfire smoke, on top of high-levels of highway motor-vehicle noise and air pollution, coming from an adjacent heavily-traveled, four-lane U.S. highway to Lake Tahoe -- with no sign of any efforts on the part of any state or county government agencies to take the well-known steps needed to properly

mitigate against these and other life-threatening, overt health hazards. El Dorado County by more than one standard is not a safe place to live -- far from it, based on my experience.

Regarding the "rapid-serology" test now available for COVID-19 IgM/IgG antibodies, from Orion Therapeutics, my (preliminary) understanding from our telephone conversations and from the information you have sent me by email is that it is intended for use as an inexpensive (\$25/test), highly-accurate and precise, "point-of-care" (no-lab-work-needed) very rapid (approximately 15 minutes from start of test to final results) screening tool to be used in advance of getting a RT-PCR test done for the SARS CoV-2 virus, a testing process that requires laboratory analysis and can take over a week or more to obtain final results.

(I believe it is correct to assert that the ongoing logistical slow-down in sample-collection and laboratory-testing protocols has for many weeks now been a major "choke point" in our nation and state's getting control of the COVID-19 pandemic.)

The "rapid-serology" test available from Oasis Therapeutics has been [FDA approved](#). As noted in your email message of August 24 "Specificity of the assay was independently assessed by the French National Research Center for Science and Technology" -- *[with specificity being measured as false positives]*.

For the "rapid-serology" test, "Both IgM and IgG showed 100% specificity, so they provide essentially 0% false positives."

(Added comment from you relevant to the above: "The RT-PCR test works well in early days of the infection (0-7 days), by day 10 the sensitivity of the PCR test goes down to 50%, explaining the increase in false positive and false negative results." **This latter point in my view is an especially important fact weighing in favor of having a rapid serological antibody test for initial and follow-up evaluations.)**

Other information pertinent to the "rapid-serology" test:

> Relative Accuracy by antibody: **IgM: 93% IgG: 99%**

("Accuracy is the ability of a test to measure the true amount or concentration of a substance in a sample.")

> Relative Sensitivity (i.e., the true positive rate) of the assay by antibody: **IgM 85% IgG 99.9%**

> Sample size: a single drop of blood

- > "Point of care" test development time: 15 minutes
- > Test endpoint: sample "colloidal-gold" color change
- > Cost: \$25/test
- > Common uses: COVID rapid screening at K-12 schools, colleges, universities, hospitals and clinics, businesses, government-agency work places, and similar locations, where some dozens, hundreds or thousands of people frequently or routinely congregate or come together in close proximity (< 6 feet) for longer than is desirable (i.e., more than about 5 minutes) -- as prescribed by public-health COVID-19 distancing guidelines.
- > Other possible uses: widening the narrow testing "time-window" to confirm laboratory RT-PCR test for the SARS CoV-2 virus (which can be a serious problem), as well confirming RT-PCR testing over extended time periods after onset of initially undiagnosed infection; testing in the field by paramedics of emergency responders (e.g. firefighting crews, etc.)??? . . . (Yes or No?)

(Note: I agree with your statement "The issues of false-positive or false-negative readings, cost, and processing time are likely to be critical considerations to any future decisions on test usage in the county" -- as well as most other places.)

To confirm a point you made in your August 24 email message to me, your primary areas of expertise as a long-experienced PhD-level scientist are: diagnostic development, "point of care" testing, neurochemistry, receptor physiology, high throughput screening. To this list I would respectfully add -- based on our last conversation -- a very good working knowledge of immunology and applied immunochemistry, two areas of work that I was directly or indirectly involved in, for years.

Over the next week or so, it is my intention to identify those decision-makers in El Dorado County government, as well as key contacts in the county's school systems, larger hospitals and clinics, business community, etc., to alert them of your interest in the county's COVID-19 problems, which are many -- and how to contact you. To do this, as I stated in our last telephone conversation, I will do my best to forward them copies of your recent "contents-rich" email messages to me

(including Power-Point attachments, etc.)

If there is anything that I wrote above that is conspicuously wrong and needs correction -- or if you would prefer that I not forward either of the two email message you sent to me on August 21 and 24 -- please so inform me before Monday, 8/31/2020, with whatever changes you think apply.

At the professional level, I think that El Dorado County, as a whole, could well benefit from your experience and input, and that it's governmental and institutional leaders should give you a fair and objective hearing, with regards to how you, and those you are affiliated with, might be able to help the county through the now increasingly-dangerous, fast-growing COVID-19 pandemic.

What is essential for all to understand is that this situation has long been predicticted by many top public-health and biomedical scientists, and that denialism, "wishful thinking" and taking ill-considered shortcuts won't make it go away soon. Like it or not, it is a serious "reality check," which in the long term one can hope may have some unanticipated benefits, such as people learning that ignoring such predictions can have dire, often devastating, consequences.

Thank you for your efforts, and best wishes,

Terrence B. Kayes, PhD
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On Thu, Aug 20, 2020 at 12:24 AM Terry Kayes <kayes.gov@gmail.com> wrote:

Greetings Dr. Ann Cornell-Bell (Westbrook, Connecticut),

Starting tomorrow morning (8/20/2020, 8:00 a.m.) and continuing for a day or so, PG&E will be turning off the electrical power in the area where I live, to replace a utility pole, make several significant power-line repairs, and do some essential tree trimming along the the back side of my property. Because of this and the ongoing heat wave and "rolling power outages" in California, I will likely not have

any Internet or telephone service until this upcoming weekend.

Next week, I would like to move forward on trying to identify who in El Dorado County government might be interested in the COVID-19 antibody test, improved face masks, and other products (or services) you mentioned, as they pertain to the ongoing pandemic. Aside from Dr. Nancy Wilson, the county's health officer, and possibly certain of her county public-health associates, there is the possibility of trying to establish a contact with key lead clinicians, senior administrators, or member of the Board of Directors of the Marshall Medical Center, the county's largest hospital and medical services provider. See the following for your information:

> <https://www.marshallmedical.org/About-Us.aspx>

<https://www.marshallmedical.org/About-Us/Leadership.aspx>

<https://www.marshallmedical.org/About-Us/Board-of-Directors.aspx>

<https://www.edcgov.us/Government/BOS>

<https://www.edcgov.us/Government/PublicHealth>

https://www.edcgov.us/government/publichealth/Communicable%20Disease/pages/communicable_diseases.aspx

<https://www.edcgov.us/Government/hhsa/edccovid-19>

<https://www.edcgov.us/Government/directory/Documents/Department-Directory-8-2020.pdf>

Please send me the following information:

- > the full name, postal mailing address, Internet address, etc. of the company with which you are affiliated;
- > your formal title and affiliation with that company, other pertinent affiliations, your final degree and its (specific) subject area and awarding institution;
- > your primary areas of scientific expertise and affiliations;
- > products/services: type of test, improved face masks, etc.

- > test's level of precision, accuracy, incidence of error (false positives or negatives), ease of use, start-to-finish mean processing time to final results, etc.

(The issues of false-positive or false-negative readings, cost, and processing time are likely to be critical considerations to any future decisions on test usage in the county.)

(I have a personal interest in the improved face masks -- and possibly the spray. Please send me more details on both.)

I will try to call you next week for further discussion.

My contact information on matters pertaining to government and the COVID-19 situation is as follows:

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