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Video: The Antibody Deception

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The world has been fixated for months on novel-coronavirus PCR testing, contact tracing and vaccination.

Meanwhile, another major part of the Covid biomedical complex has received far less attention: the use of antibodies for detecting, diagnosing and treating infection with the novel coronavirus.

Hundreds of antibodies have been approved for these purposes since January 2020. And hundreds more are poised to start being marketed soon.

This is part of the biomedical gold rush: by last summer already, antibodies were on track to become the most lucrative medical product, with global revenue projected to reach nearly half a trillion dollars by 2024. Profit margins in the range of 67% aren't uncommon.

Pharma giants such as AstraZeneca, Novartis, GlaxoSmithKline and Eli Lilly are among the companies grabbing the largest chunks of the novel-coronavirus-antibody market. And some of the most muscular government agencies, including Anthony Fauci's US National Institute of Allergy and Infectious Diseases and the US's Defense Advanced Research Projects Agency, are part of the action (see, for example, the second-last section of this article, on antibodies used to treat Covid).

Virtually every study and piece of marketing material related to Covid is premised on scientists having positively and correctly identified the presence of the novel coronavirus (also known as SARS-CoV-2) in the material they're working with.

The job of that identification is usually given to antibodies that are said to bind to the novel coronavirus. The assumption is these antibodies are able to pick out the virus and only the virus from among every other organism and substance surrounding it.

Unfortunately it turns out that the antibodies rarely (if ever) do that. This is because of, among other things, inadequate verification of the antibodies' accuracy in targeting the virus by the companies that manufacture and sell them. And there's even less verification by government regulators.

Let's take a 30,000-foot tour of a couple of the main features of the antibody-industry landscape, which is awash in complexity and cash.

Can Antibodies be Created That Only Bind to One Type of Virus or Another?

Antibodies are tiny, finely-tuned, parts of our immune system. One of their main functions is to seek out viruses and bacteria that may have the potential to cause disease. Antibodies bind to and neutralize these microbes so they can't multiply and spread.

Humans and our ancestors have been making antibodies in our bodies to fend off infections for millions of years. Then a few decades ago companies got involved in the discovery and manipulation of antibodies, partnering with university labs.

There are two main categories of antibodies. One is 'polyclonal' antibodies. These are garden-variety antibodies that bind to a variety of different substances and/or organisms.

The other is monoclonal antibodies. As the name implies, cloning is involved in their creation. First an antibody that is specific to a particular amino-acid sequence (amino acids are the building blocks of proteins) of interest – for example, one from a protein on the surface of a virus or bacterium — is identified. Then the immune-system cell which produced that antibody is 'cloned' in the lab. As a result, each set of monoclonal antibodies binds to that particular amino-acid sequence.

I emailed one of the English-speaking world's leading authorities on monoclonal antibodies, Harvard Medical School professor Clifford Saper, to get clarity on this. I asked him if it's true that, as most in the antibody-commercializing arena claim, a monoclonal antibody can be created that's specific for (that is, binds to) just one type of virus or just one other type of organism.

Saper replied [bolding and italics added by me for emphasis]:

> "**No, there is no such thing as a monoclonal antibody that, because it is monoclonal, recognizes only one protein or only one virus**. **It will bind to any protein having the same (or a very similar) sequence."**

The implication of Saper's statement is that any attempt to use a monoclonal antibody to verify the presence of the novel coronavirus will yield a large rate of false-positive results. That is, they will indicate that the novel coronavirus is detected when in fact it hasn't been. That's because there's a high probability that the monoclonal antibody is binding to something else besides the virus (this is known as 'cross-reacting').

(I recommend this review paper by Saper, and this one and this one co-authored by Yale pathology professor David Rimm, to anyone wishing to learn about antibody validation.)

J Histochem Cytochem. 2009 Jan; 57(1): 1–5.
doi: 10.1369/jhc.2008.952770
PMCID: PMC2605712
PMID: 18854594

A Guide to the Perplexed on the Specificity of Antibodies

Clifford B. Saper

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Abstract

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Many investigators are unaware of the potential problems with specificity of antibodies and the need to document antibody characterization meticulously for each antibody that is used. In this review, I consider the principles of antibody action and how they define a set of rules for what information should be obtained by the investigator before using an antibody in a serious scientific investigation. **(J Histochem Cytochem 57:1–5, 2009)**

Keywords: immunohistochemistry, immunocytochemistry, controls

And in fact, the vast majority of antibodies and monoclonal antibodies marketed as being specific for the novel coronavirus were developed years ago for detecting SARS-CoV-1. They were then simply repurposed for identifying SARS-CoV-2 — with very few if any checks for whether they also cross-react to other organisms or substances.

I sought confirmation of this repurposing from Zhen Lu. She's the North American marketing manager for Sino Biological, a Beijing-headquartered company that develops and sells, among other things, hundreds of antibodies. Lu replied to me via email, "Yes, antibodies are repuposed [sic]."

I also checked and received confirmation from Pratiek Matkar, a senior staffer from BenchSci, an antibody-database company. And to see for myself, I logged into the BenchSci database (Matkar granted me a guest account), selected all antibodies for the novel coronavirus, and looked to see which organisms had been used in cross-reactivity tests for them. SARS-CoV-1 was the only one that came up in this check.

This all explains something I observed last week: Sino Biological had just changed the content of its home page for the section of their website on antibodies against SARS-CoV-2. The page now announces that they've introduced new **"matched antibody pairs"** that work better at finding the virus. The pair consists of a "**capture antibody**" and a "**detection antibody**."

And they claim these pairs are more accurate at finding the novel coronavirus: that they "have high specificity without cross-reactivity with MERS-CoV, [or with the common human coronaviruses] 229E, NL63, HKU1, [and] OC43."

The only way I can interpret that is they know the antibodies they've been marketing for months as being specific for the novel coronavirus bind to other things, such as common human coronaviruses.

How Are Antibodies Harnessed in Tests for the Novel Coronavirus?

One of the main types of tests for the virus contains antibodies that are ostensibly specific for the novel coronavirus. The way they're designed to work is that if the virus is present in a blood sample the antibodies bind to it and, as a result, the test gives a positive signal.

The other type of test contains sequences of protein from the novel coronavirus; if antibodies to the virus are present in a blood sample, they bind to the protein sequences and produce a positive result.

The manufacturers are supposed to conduct accuracy checks of their test kits before they put them on the market. These checks largely consist of estimation of the rates of false positives and false negatives (the latter is a negative result when the antibody or protein of interest is contained in the sample being tested by the kit).

However, companies do this cursory accuracy check with only very few samples of a small number of viruses — and rarely on bacteria or any other of the millions of biological substances that can be present in the blood.

Despite this very inadequate validation and the strong incentive for the companies to make their products look good, **as documented last May by David Crowe, the manufacturers often record a significant rate of false positives. The false positives are to everything from West Nile virus to various types of human coronaviruses.**

Usually the companies and governments wave that off as insignificant. Occasionally though, the test kits are so bad that they're taken off the market.

For example, an antibody-testing kit sold by a company called Chembio Diagnostics was launched on March 31, 2020. It was almost immediately granted Emergency Use Authorization (EUA) by the US Food and Drug Administration (FDA). An EUA allows companies to rush products onto the market with very minimal oversight. Brazil and the European Union also gave the nod for the Chembio test to be sold in their jurisdictions in April and May 2020, respectively.

Then in June 2020 the FDA pulled it off the market. The agency said "this test generates a higher than expected rate of false results." (Note that the top table on page 13 of the product insert for that "revoked" Chembio test indicates it cross-reacts to the human coronavirus 229E.)

But in November 2020 the Chembio antibody test again was approved for use in Brazil. And on January 14, 2021, the test got the nod in the European Union, the UK and Ireland.

Is it identical to the rest that was so inaccurate it was pulled off the market last June? It's hard to tell. There is no product insert for it that I could find. In fact there's very little information about it on the webpage for the test; you have to request the information. I

submitted a request on Jan. 23 and haven't received it yet.

Two of the heads of the FDA branch that approves testing devices penned a February 18, 2021, *New England Journal of Medicine* article. In it, the pair admitted that the FDA's EUAs allowed too-loose approvals for serology tests.

They indicated the FDA has tightened its criteria for approval of these tests. They also point to efforts by other government agencies to evaluate serology tests. **But the pair don't say a word about the need to move toward objective, thorough test validation. They also are mute on the fact that EUAs are still being issued.**

(Also note that the FDA and Health Canada listings of the 65 serology tests approved to date in the US and 19 approved to date in Canada continue to give the sensitivity [correct identification of positive samples] of the tests by 'positive percent agreement' and specificity [correct identification of negative samples] by 'negative percent agreement.' These are relative measures of accuracy – that is, compared to other tests – rather than objective/absolute accuracy, and therefore are poor facsimiles of accuracy.)

One of the many major figures in the Covid-biomedical complex who are priming the pump of the antibody pipeline is Ian Lipkin. He's director of the Center for Infection and Immunity at Columbia University in New York. Lipkin is involved at high levels in many global organizations including the World Health Organization and the Bill & Melinda Gates Foundation, as well in pharmaceutical companies. (And he is quoted in a 'fact-check' of a July 2020 article I co-authored with Patrick Corbett titled, "No one has died from the coronavirus." Lipkin states, among other things, in the fact-check piece that "Conspiracy theorists are not persuaded by data.")

Lipkin co-authored a Feb. 12, 2021, paper in which he and his team claimed to have identified, using a new 'peptide-microarray' technology they invented, 29 amino-acid sequences unique to the novel coronavirus. They assert that antibodies specific to the sequences could be created – and that these in turn could be harnessed "to facilitate diagnostics, epidemiology, and vaccinology" for Covid. (The only conflict Lipkin and some of his co-authors disclose in the 'competing interests' paragraph at the end of article is that they invented the peptide-microarray technology described in the article.)

Do Antibodies Used to Treat Covid Fare Any Better?

Antibodies are also being marketed to treat Covid. Some are sold singly (known as 'monotherapy') and others in pairs. They are deemed to confer 'passive immunity.'

Among the most-reported-on set of antibodies for treating Covid is the Regeneron monoclonal antibodies casirivimab and imdevimab. This pair reportedly was used in October 2020 to treat then-U.S. President Donald Trump. The combo subsequently was granted an EUA by the FDA on November 21, 2020. It also is being considered for approval by Health Canada.

I'd like to focus on a somewhat lesser-known monoclonal antibody called bamlanivumab. It's being used both singly and as one half of a pair for treatment of symptomatic Covid patients early in the course of their infection. The antibody was discovered, and clinical study of it started, by the US National Institute of Allergy and Infectious Diseases (which is headed by Anthony Fauci) and a Vancouver, British Columbia-based company called AbCellera

Diagnostics. The antibody is being manufactured and sold by Eli Lilly. It costs more than $1,200 a vial.

AbCellera is developing a significant pipeline of other antibodies. Its capabilities for this were developed over the past two-plus years as part of the Defense Advanced Research Projects Agency (DARPA) Pandemic Prevention Platform program.

(AbCellera also has received hundreds of millions of dollars from the Canadian government, including for building an antibody-manufacturing plant. And Peter Thiel, who co-founded both PayPal and Palantir, is a board member. So is John Montalbano, who's also on the board of the Canada Pension Plan Investment Board and until 2015 was CEO of RBC [Royal Bank of Canada] Global Asset Management. This and significant positive media coverage helped propel the company to the biggest Canadian-biotech-company Initial Public Offering to date, on Dec. 11, 2020.)

Bamlanivumab was given an EUA by the FDA on November 9, 2020, for treatment of mild to moderate Covid. And Health Canada gave the monotherapy an interim authorization on November 17. It's **not getting much traction in clinical practice so far in Canada, though, perhaps because of the less-than-stellar results from clinical trials (see below).**

But this hasn't deterred the Canadian and US federal governments, which combined have purchased close to half a million of these tests. For example, most recently, on February 26, the US government bought 100,000 vials.

The only study on bamlanivimab made public prior to the November 9 FDA approval was one posted October 1, 2020, on the website of the online-only journal *bioRχiv.* [My Feb. 3, 2021, and Feb. 11, 2021, articles — on the new variants and the associated modelling papers, respectively – noted that the journal and its sister publication *medRχiv* contain only non-peer-reviewed articles and were created by an organization headed by Mark Zuckerberg and his wife.]

The study used rhesus monkeys and provided very extensive details about how the antibody was discovered and checked for specificity to the novel coronavirus. The researchers concluded that the antibody – at that time known as LY-CovV555 — has "potent neutralizing activity" against SARS-CoV-2.

On January 14 I emailed the lead author of that paper, Bryan Jones. He's a researcher in Lilly's Biotechnology Research Program. I asked Jones where in their paper is the proof the antibody is specific to SARS-CoV-2 (and therefore isn't binding to something else instead of, or in addition to, the novel coronavirus).

He responded promptly, as follows [bolding added by me for emphasis]: "While we did determine that LY-CoV555 is specific to SARS-CoV-2 (and doesn't bind to the spike protein of SARS-CoV), **that is not specified or detailed in any of the figures or tables [in the paper]**."

Jones pointed me to several parts of the paper and supplemental material published with it that he said show, **via indirect extrapolation**, that the antibody is specific for the novel coronavirus.

That's not exactly convincing.

Then on December 22 a study in the *New England Journal of Medicine* gave a thumbs-down to the usefulness of bamlanivimab in people hospitalized after receiving a Covid diagnosis. The paper noted that in late October the study was stopped because the antibody didn't help the patients any more than did placebo.

But this didn't deter Lilly.

On January 21, 2021, the company issued a news release about a study of bamlanivumab in residents and staff of nursing homes. They claimed their research showed that the antibody "significantly reduced the risk of contracting symptomatic COVID-19."

However, they didn't back this up with much information. The study hasn't been published in a journal or presented at a scientific/medical meeting. And there's no word on when it will be.

Despite that, on the same morning the release was sent out by Lilly, glowing articles appeared in major media outlets stating that the study showed bamlanivumab appears to significantly reduce Covid symptoms in the frail elderly.

For example a Bloomberg article was posted at 8 a.m. on Jan. 21 with the headline, "Eli Lilly Antibody Cuts Covid-19 Risk Up to 80% in Nursing Home Study." The article was carried in many other media outlets such as the *Globe & Mail*.

The article quoted Lilly's Chief Scientific Officer Daniel Skovronsky as saying, "This is an urgent situation. Where there's an outbreak in nursing homes and people haven't yet received the vaccine, this could be a potential way to protect them before they get it."

And January 21 *New York Times* piece by senior science journalist Gina Kolata quotes a vaccine expert at Boston Children's Hospital, Ofer Levy, who wasn't one of the scientists involved in the study, as saying, "I see only positives here. This is a win."

Kolata also reported that **Lilly plans to ask the FDA for an EUA for bamlanivimab for prevention of Covid in the frail elderly, focusing on those in nursing homes and long-term-care homes.**

In parallel, Lilly is pivoting to using bamlanivumab in combination with another monoclonal antibody called etesevimab. A study on this combination in people with mild or moderate Covid was published on January 21, 2021. The results indicate it doesn't reduce symptoms, but only lowers the viral load of people.

This didn't deter Lilly either; it's spinning this in the media as a very positive result. And so is the FDA: on February 9 the agency issued an EUA for the combination of the two antibodies for treating mild or moderate COVID.

Then the next twist in the plot happened, on February 16: a paper published that day in *bioRχiv* indicated that bamlanivumab doesn't neutralize the South African and Brazilian variants of the novel coronavirus.

I'll Leave the Last Words to Scott Adams

Dilbert-cartoon creator Scott Adams makes this observation on page 13 of his book *Loserthink*:

> “One thing I can say with complete certainty is that it is a bad idea to trust the majority of experts in any domain in which both complexity and large amounts of money are involved.”

This perfectly describes the situation with antibodies for the novel coronavirus.

Buyer beware, follow the money, and stay tuned.

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