Antibodies and COVID-19

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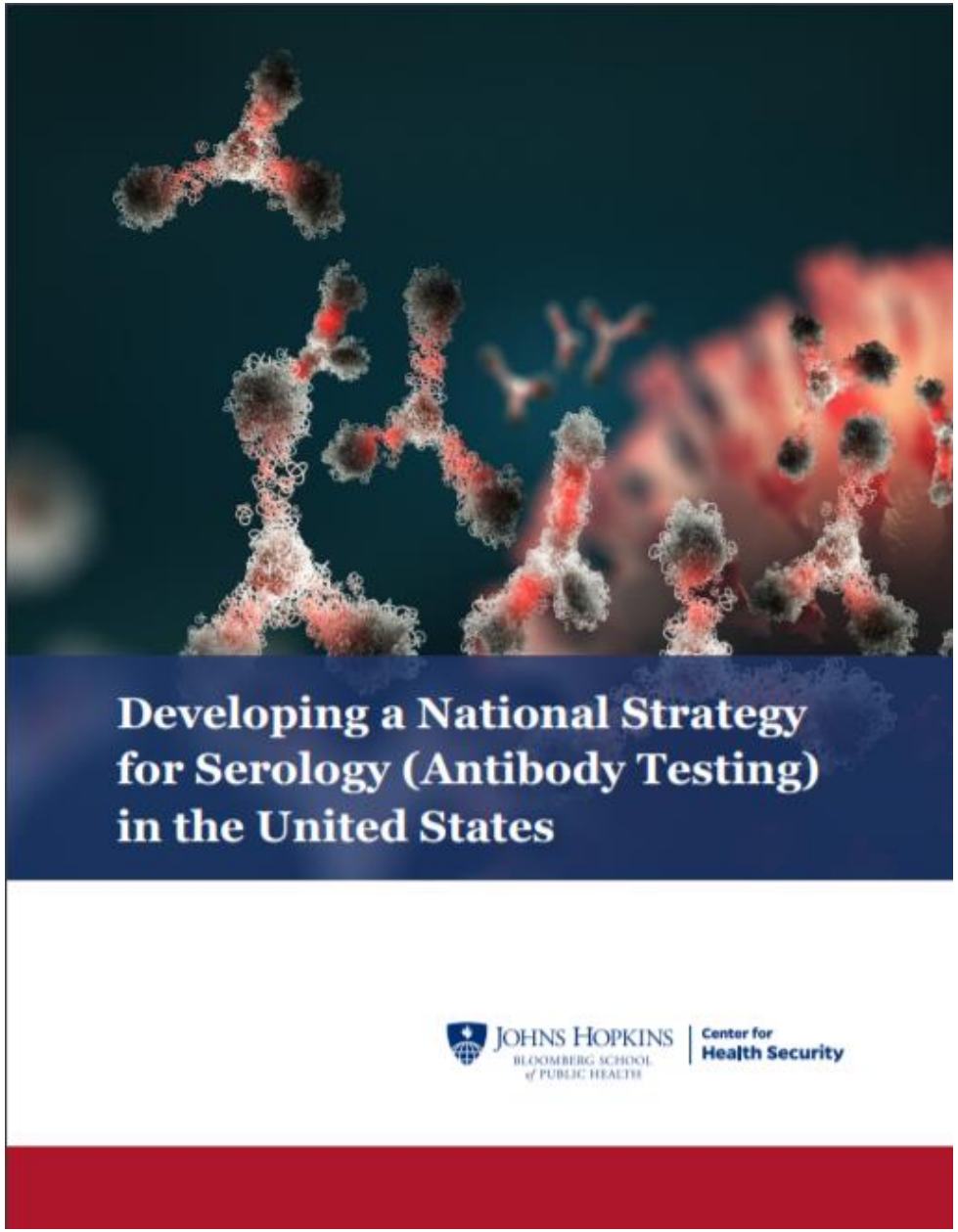
Strategy Document

April 22, 2020

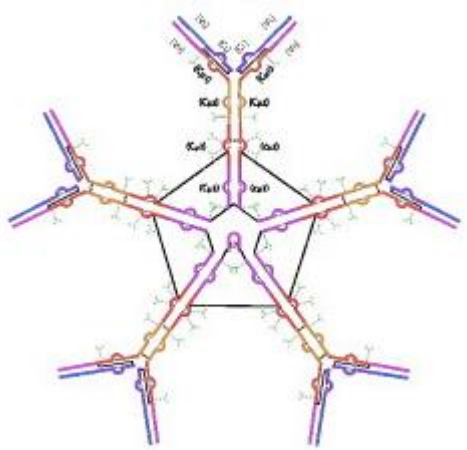
Intended to present the latest science to policymakers

https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200422-national-strategy-serology.pdf



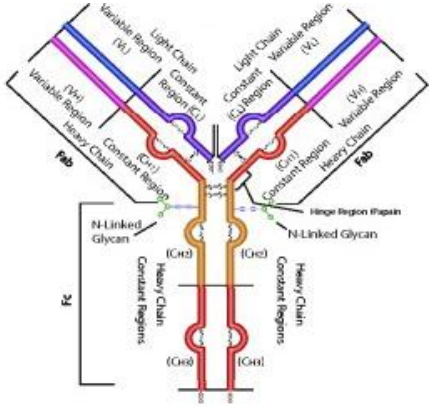
Serology testing provides important disease prevalence information

- Serology tests are a type of blood test that detects an immune response to SARS-CoV-2
- The presence of **antibodies** in the serum can indicate if a person was once infected with the virus, even if they have cleared the virus



IgM: The early responders (5-10 days post symptom onset)

IgG: Emerge later, but are more specific (10+ days symptom onset)



Sigma Aldrich

What serology can tell us

Serology results can be used to understand the true prevalence of an infection.

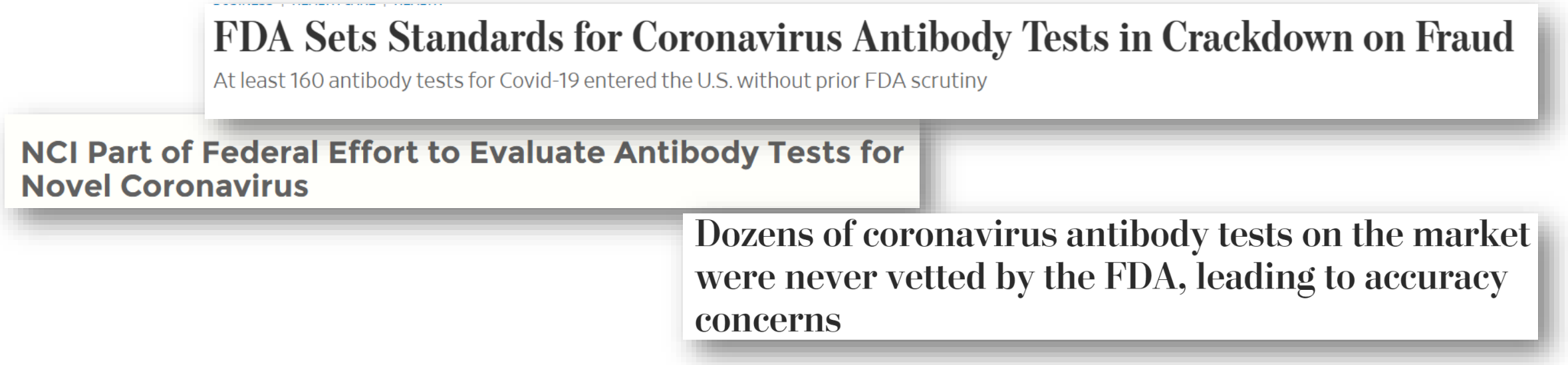
- Individuals with no symptoms have antibodies to the virus, but may not have been tested using molecular methods
- Serology testing can capture all individuals, no matter the type or range of symptoms, who were infected
- Seroprevalence studies may be used to determine the case fatality rate
- Fill in gaps left by contact tracing

Limits of serology test results

*Serology test results **alone** cannot tell us if a person is immune to reinfection*

- We do not know what **levels** or **longevity** of antibodies are necessary for protective immunity to SARS-CoV-2
- Serology tests cannot tell us if a person's immune system has **memory**, or the immune system's ability to recognize a previously encountered pathogen and produce a rapid, strong response
- Depending upon the seroprevalence, may be less useful for individual decision making (assuming durable immunity)

What makes a good serology test?



- ✓The test must have high **sensitivity** and **specificity** to prevent false negatives or positives
- ✓The test must be validated by independent, unbiased sources (such as the NCI)
- ✓The FDA is currently regulating test development in the US, with recent policies providing more stringent approval criteria

Sensitivity and specificity can have large impacts on test accuracy

Population	1 million
15% Infected	150,000
Sensitivity	95%
Specificity	95%

	Infected	Not Infected	
Seropositive	142,500	42,500	185,000
Seronegative	7,500	807,500	815,000
	150,000	850,000	

Total Infected	150,000
Total Positive Tests	185,000
False Positives	42,500
Percent of Positive Tests that Were Inaccurate	22.97%
False Negatives	7,500
Positive Predictive Values	77.03%

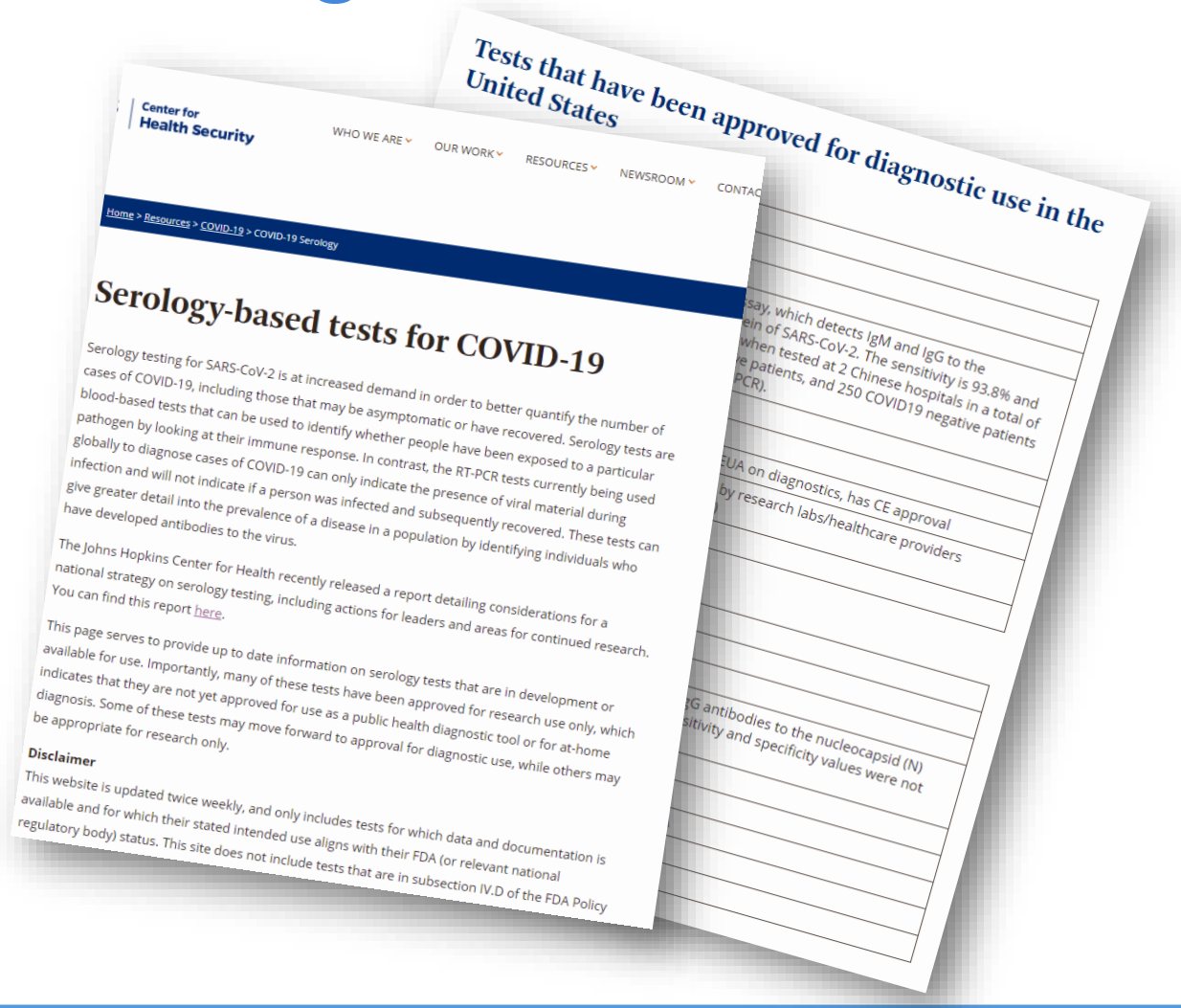
Seemingly high sensitivities and specificities can lead to false negatives and positives depending on disease prevalence

Serology test types

	RDT	ELISA	NA
	Rapid Diagnostic Test	**Enzyme-Linked Immunosorbent Assay**	**Neutralization Assay**
	-Takes 10-30 minutes	-Takes 2-5 hours	- Takes 3-5 days
	-Qualitative (yes/no)	-Quantitative (antibody levels)	-Quantitative (antibody levels)
	-Small and portable	-Requires lab space and trained personnel	-Requires lab space and trained personnel
	-Requires a fingerstick	-Requires blood sample	-Requires blood sample and live virus
What it provides	**Quick yes or no results**	**Levels, but not efficacy**	**Levels of effective antibodies**

The Global Serology Testing Tracker

- The Center for Health Security has created a **serology test tracker** to provide information on available serology tests around the world
- Tests are categorized by health agency approval status
- Updated twice weekly



Thank you!

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