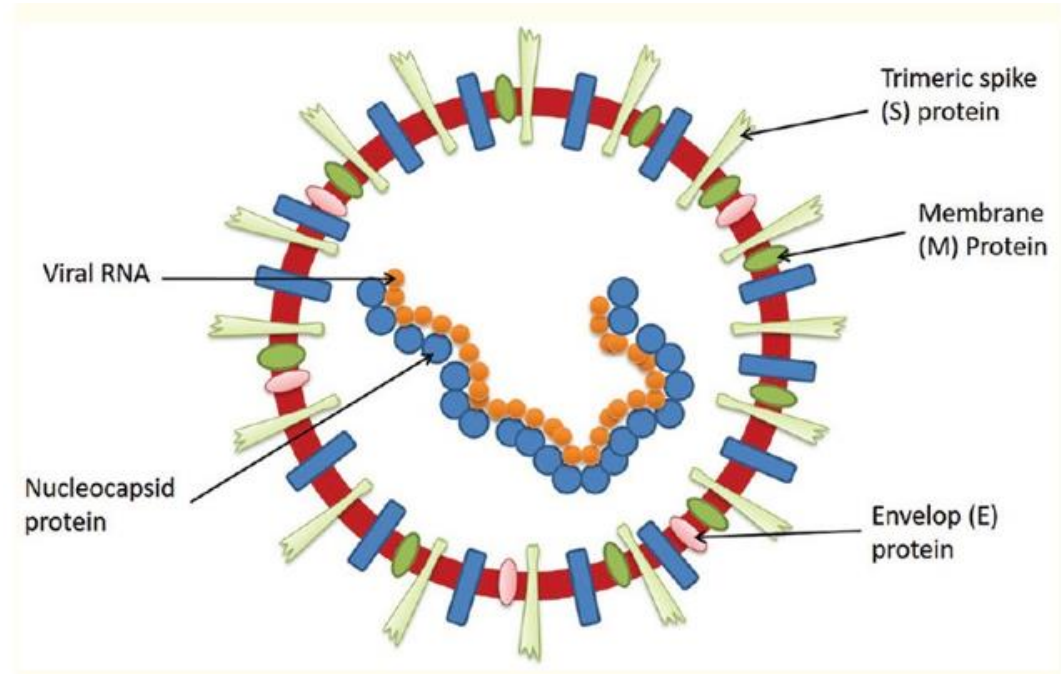


Four Ways to Detect Infection

1. RNA: virus' genetic material
2. Antibody: patient response to virus
3. Antigen: virus' proteins
4. Virus: infectious particles



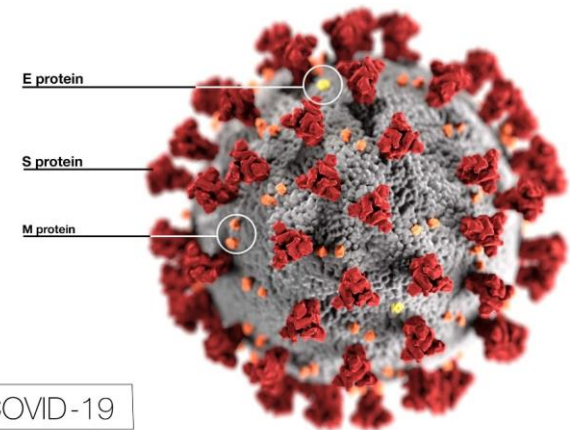


COVID-19

Antigen Testing

What Are Antigen Tests?

- Detect fragments of proteins on or within the virus
 - Intended to detect acute infection
- Advantages: cost less to manufacture (cost ~\$20), bulk availability, fast TAT, POC, positive results are highly accurate
- Disadvantage: higher probability of returning false negative results
 - Negative tests in suspected patients need to have PCR



Sofia 2 SARS Antigen FIA (Quidel)



- 10 May FDA issued EUA for use in CLIA labs and POC patient care settings under CLIA waiver
- NP or AN swab run on Sofia 2 analyzer
 - Already in use for flu and strep throat tests in >40,000 clinics/practices
- Results available in 10 minutes
- First EUA reported ~80% sens, 100% spec against PCR

<https://www.quidel.com/immunoassays/rapid-sars-tests/sofia-sars-antigen-fia>



Updating and Re-Thinking Quidel

- 17 July Quidel updated performance to 96.7% sensitivity against NP PCR if used within 5 d of symptom onset
- Negative tests no longer ‘presumptive’, needing PCR confirmation
- Duration of positivity not well studied but may be shorter than PCR and more closely reflect infectious state



BD Veritor

- July 10 FDA EUA for second Ag test granted for BD Veritor System for Rapid Detection of SARS-CoV-2 (Beckton, Dickinson and Company) for use in CLIA laboratories and POC patient care settings (under CLIA waiver)
- >10M tests to be produced by end Sept 2020
- Nasal swab specimen run on portable BD Veritor Plus Analyzer Instrument
 - In use in >25,000 hospitals, clinics, practices, retail pharmacies
 - Results in 15 minutes
- Against Quidel, pos agreement 84%, neg agreement 100%



HHS Antigen Test Roll Out

- [14 July the Trump Administration announced HHS](#) would embark on one-time procurement of antigen testing devices and tests to be distributed to 800 nursing homes
 - Intended for use on healthcare workers
- Each nursing home will receive either Quidel Sofia 2 Instrument (2k) or Veritor Plus system (2k) with associated tests (750k each)
 - Nursing homes then procure additional tests directly from manufacturer
- All nursing homes must have capability to screen and test residents at baseline, and test staff on weekly basis (or acc to state guidance)
 - Will also enable testing of visitors if appropriate for that facility



Which Facilities are Eligible?

- Distribution will begin with nursing homes prioritized by CMS, based on CDC epi hotspot data, and nursing homes that have reported to CDC by July 5th:
 - ≥ 3 confirmed or suspected new cases within last 7d
 - ≥ 1 new case in last 7d after having 0 previous cases
 - Inadequate access to testing within last 7d
 - ≥ 1 new resident death within last 7d
 - ≥ 1 new confirmed or suspected case among staff within last 7d
- Facilities that do not have CLIA Waiver will not receive until they obtain a CLIA waiver
 - Nursing homes can follow [CMS guidance](#) to obtain Waiver



3 Uses of Ag Testing in LTCF

- Symptomatic staff and residents in LTCFs
 - Within 5 days of symptom onset
- Asymptomatic staff and residents in LTCFs experiencing outbreaks
 - Batch testing possible
- Asymptomatic staff screening weekly in non-outbreak LTCFs (CRSSSP)



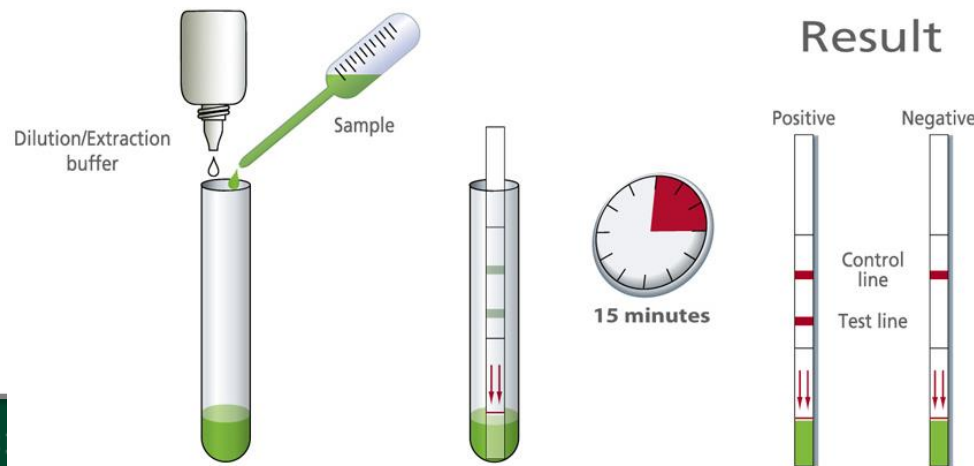
Remaining Questions

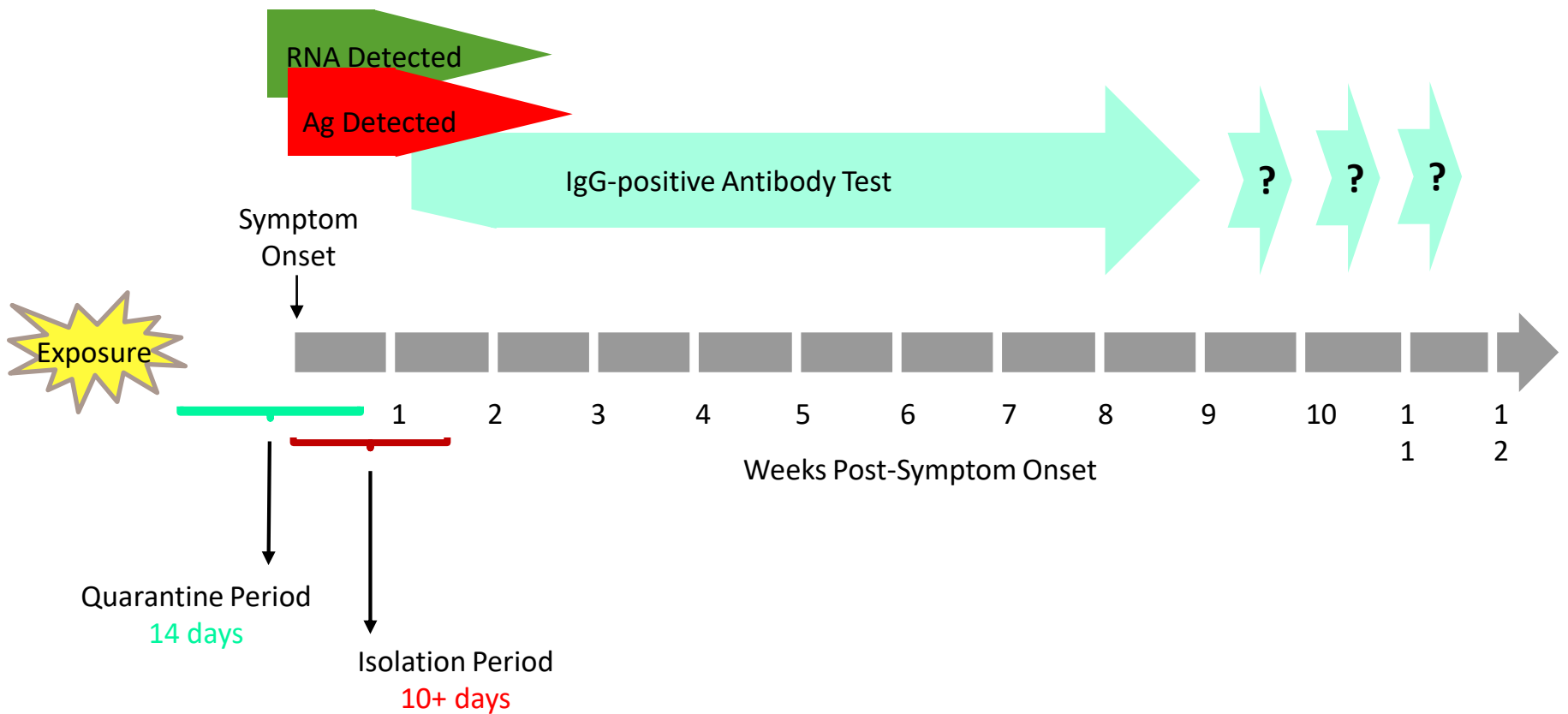
- When does a facility repeat testing in a previously positive person?
- Logistics: who is trained how, and who is available to use them?
- How will quality assurance occur?
- Reporting: someone has to generate the test result and transmit to DHHS



Coris BioConcept COVID-19 Ag Respi-Strip

- Pending EUA
- True POC test repurposed SARS-CoV-1 test
 - Lateral flow test (immunochromatographic)
 - Positive if colored band appears at marked test line
- Sensitivity against RT PCR among 328 symptomatic patients only 57.6%
- Nonmedical use? Ex international travel requirements







GUIDANCE ON INTERPRETING COVID-19 TEST RESULTS

	RESULT	INTERPRETATION	RECOMMENDED ACTION
VIRAL TESTING† (testing for current infection)	Positive	<i>Most likely*</i> you DO currently have an active COVID-19 infection and can give the virus to others.	<u>Stay home*</u> and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Negative	<i>Most likely*</i> you DO NOT currently have an active COVID-19 infection.	If you have symptoms, you should keep monitoring symptoms and seek medical advice about staying home and if you need to get tested again. If you don't have symptoms, you should get tested again only if your medical provider and/or workplace tells you to. <u>Take steps to protect yourself and others.</u>
ANTIBODY TESTING‡ (testing for past infection with the virus)	Positive‡	You <i>likely*</i> have HAD a COVID-19 infection.	You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. <u>Take steps to protect yourself and others.</u>
	Negative	You <i>likely*</i> NEVER HAD (or have not yet developed antibodies to) COVID-19 infection.	You could still get COVID-19. <u>Take steps to protect yourself and others.</u>
BOTH (antibody and viral testing)	Viral Positive, Antibody Positive‡	<i>Most likely*</i> you DO currently have an active COVID-19 infection and can give the virus to others.	<u>Stay home*</u> and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Viral Positive, Antibody Negative	<i>Most likely*</i> you DO currently have an active COVID-19 infection and can give the virus to others.	<u>Stay home*</u> and follow CDC guidance on steps to take if you are sick. *If you are a healthcare or critical infrastructure worker, notify your work of your test result.
	Viral Negative, Antibody Positive	You <i>likely*</i> have HAD and RECOVERED FROM a COVID-19 infection.	You may be protected from re-infection (have immunity), but this cannot be said with certainty. Scientists are conducting studies now to provide more information. You should get tested again only if your medical provider and/or workplace tells you to. <u>Take steps to protect yourself and others.</u>
	Viral Negative, Antibody Negative	You <i>likely*</i> have NEVER HAD a COVID-19 infection.	You could still get COVID-19. You should get tested again only if your medical provider and/or workplace tells you to. <u>Take steps to protect yourself and others.</u>

**No test is ever perfect. All tests occasionally result in false positive results (the test result should be negative because you DO NOT have COVID-19 but comes back positive) or false negative results (the test result should be positive because you DO have COVID-19, but comes back negative). Sometimes the results are not definitive (the result is unclear, and you don't know if it is positive or negative). For this and other reasons, results should always be reviewed by a healthcare professional.*

