Overview of the Diagnosis of COVID-19 And Overview Stage 4 Protocol for LTCF

Carolyn Buxton Bridges, MD, FACP

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Governor's Coronavirus Working Group
Idaho Department of Health and Welfare, Consultant
Carolyn.bridges@dhw.Idaho.gov

Disclosure

- I have no financial conflicts of interest
- The information and any errors are mine
- This information was based on published data available as of mid-June 2020. As COVID-19 information is rapidly evolving, healthcare personnel are reminded to consider additional information that has come to light since this presentation.

Introduction

- Goals
  - Provide overview of COVID-19 epidemiology in Idaho
  - Introduce Stage 4 protocol
  - Provide overview of COVID-19 testing and information on terms used in the protocol

Epidemiology of SARS-CoV-2

- Symptoms may appear 2-14 days after exposure to the virus
  - Cough
  - Shortness of breath or difficulty breathing
  - Fever
  - Chills
  - Muscle pain
  - Sore throat
  - New loss of taste or smell
- Less common symptoms like nausea, vomiting, or diarrhea
- Other novel presentations, e.g. back pain, lethargy, decreased appetite, stroke (thrombi/clot in arteries or veins)

https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

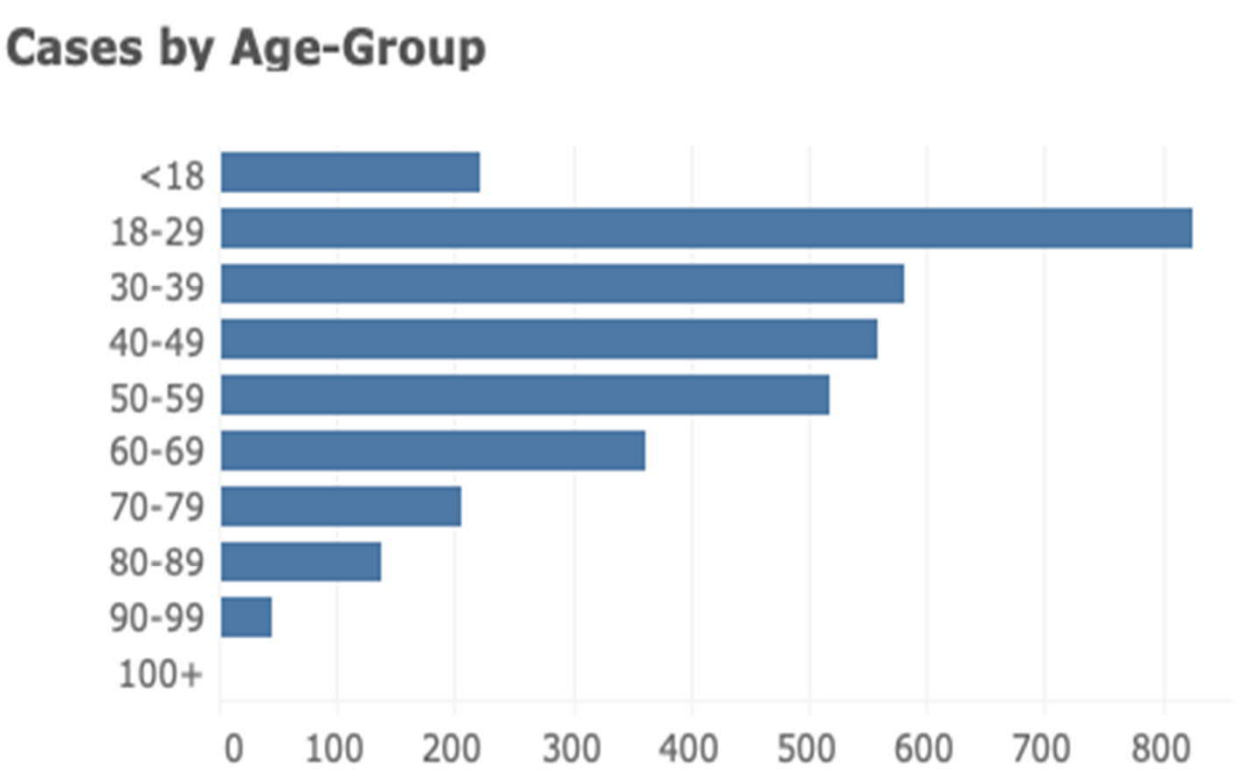
Risk factors for severe disease

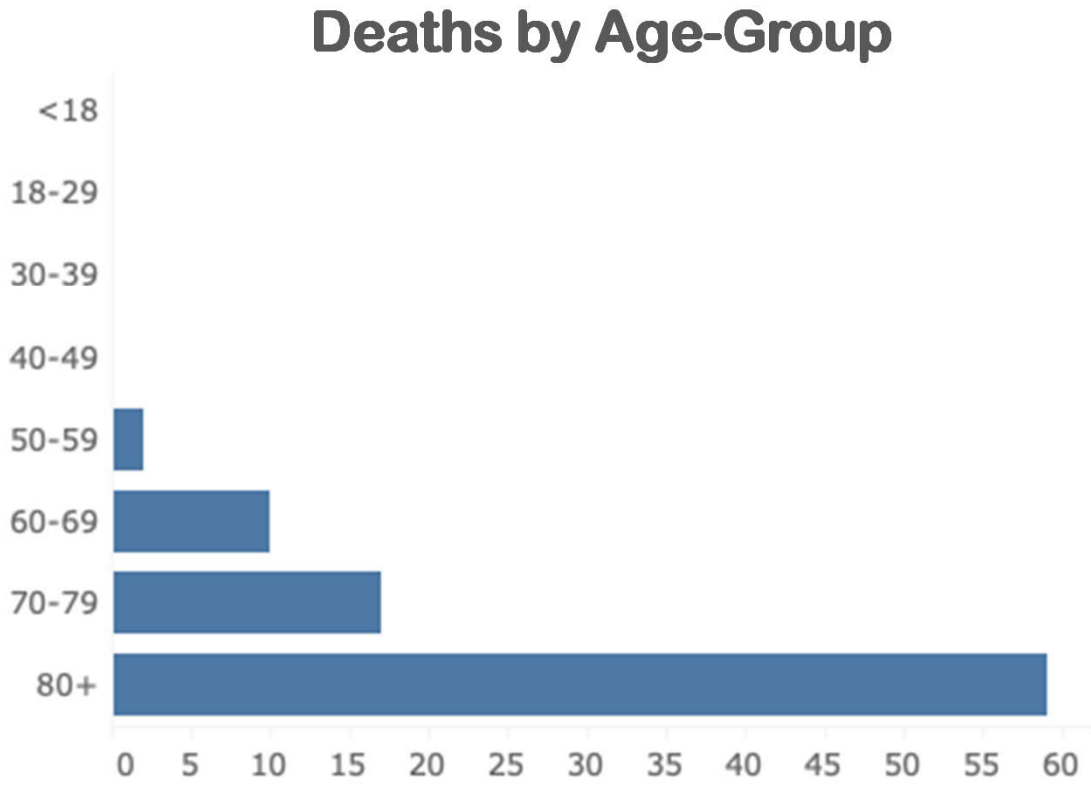
- Age 65+
- Live in LTCF
- Hypertension
- Other cardiovascular disease
- Metabolic disease (diabetes)
- Chronic lung disease and asthma
- Immune suppression
- Obesity
- Neurologic disease
- Chronic renal or liver disease
- Hemoglobin disorders

About 2 out of every 3 COVID-related deaths in Idaho have been among LTCF residents

https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/surveillance-data-analytics.html

Idaho COVID-19 Cases and Deaths By Age-Group





https://public.tableau.com/profile/idaho.division.of.public.health#!/vizhome/DPHIdahoCOVID-19Dashboard_V2/Story1.

Overview of Stage 4 Protocol for LTCF

- https://rebound.idaho.gov/wp-content/uploads/stage4-protocols-long-term-care-facilities.pdf.
- Requires written plans, adequate PPE supplies, arrangements for laboratory testing, no cases of COVID among staff or residents in 28 days in order to begin to allow visitors.
- Plans for allowing visitors and easing restrictions
  - Can be submitted to Division of Licensing and Certification for review.
    - Approval is not required.
  - Should be posted on website and/or provided in hardcopy to families and patients
  - Requirements displayed clearly in facility
  - Communicated with staff, residents and families/visitors

Minimum Criteria for Allowing Visitors

- No COVID-19 cases among residents or HCP within the previous 28 days.
- If feasible, baseline SARS-CoV-2 PCR testing of all HCP, regardless of any symptoms, completed for facilities located in counties with community spread
- Facility has adequate personal protective equipment (PPE) for direct care HCP for the care of all residents for at least three days. And has a plan to obtain additional PPE, if needed.
- HCP have been trained in proper use of PPE and other infection and control prevention measures.
- Procedures in place to conduct daily surveillance to identify any new illnesses among HCP and residents, and to screen anyone who enters the facility for illness.
- Infection prevention and control plan for COVID-19 has been developed and includes policies for admissions and readmissions to the facility.
- Plan to rapidly implement testing of all HCP and all residents if confirmed case identified among residents or HCP. The plan should address access to testing supplies and a laboratory agreement.
- Plan to manage suspected or confirmed cases of COVID-19 among HCP or residents.
- Staffing contingency plan to mitigate any staffing shortages.
- Communication plan to notify HCP, residents and residents' families/ representatives if a suspected or confirmed case of COVID-19 among HCP or residents.

Screening of Visitors and When to Reinstate Restrictions

- Protocol describes procedures recommended to reduce COVID-19 from being introduced by visitors or staff
  - Screen staff, residents and visitors for fever or other symptoms of COVID
  - Includes recommendations on PPE and other infection control measures
- Stop allowing visitors and reinstate restrictions (e.g. communal dining, group activities) if…
  - COVID-19 infection suspected or confirmed among any HCP or resident
- If COVID-19 confirmed, reopen after minimum criteria are again met
- Minimum criteria do not need to be met for surveyors, ombudsmen, adult protective services (APS) or representatives of other services vital to the health and safety of the residents

Information on Testing

- Ensure working relationship with laboratory that can supply test kits and rapid turn-around for results
- PCR is recommended test to be used
- Priority 1 recommendations”
  - Test all symptomatic residents and healthcare personnel (HCP) and all new resident admissions to facilities.
    - Test right before or on admission. Consider repeat testing at 7 and 14 days, if testing would influence infection control and prevention actions
  - Conduct facility-wide testing of all HCP and residents in facilities with one or more newly confirmed cases of COVID-19

https://coronavirus.idaho.gov/wp-content/uploads/2020/06/LTCF-Testing-Strategy-FINAL-2020_6_3.pdf.

Information on Testing

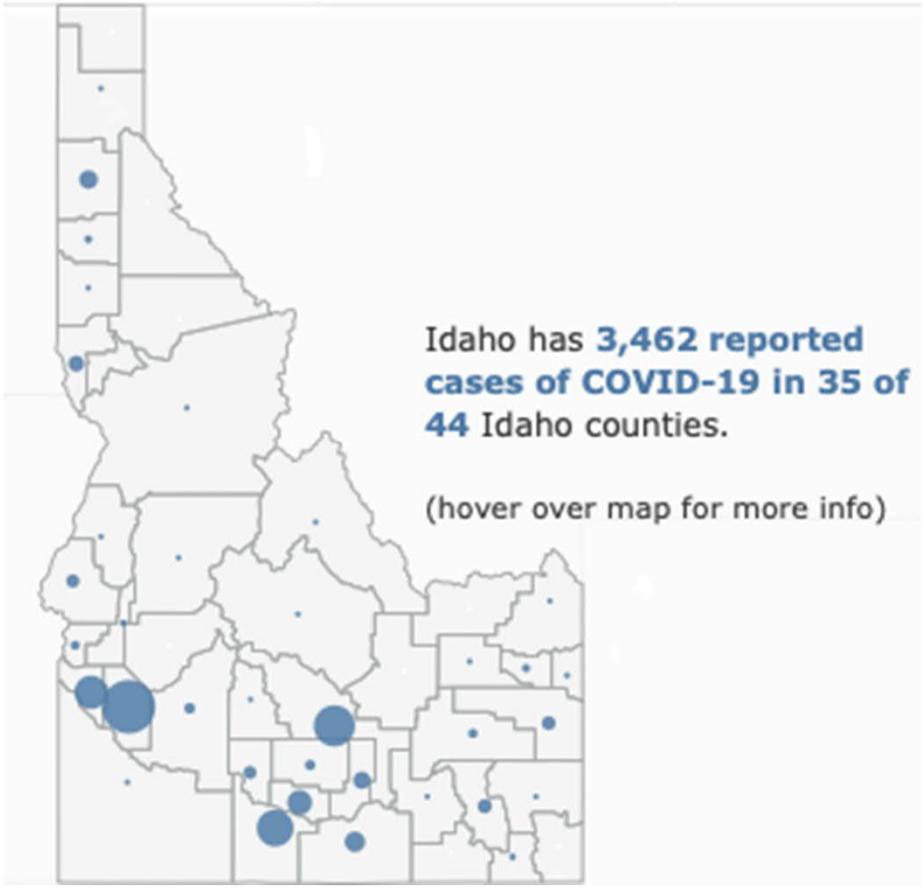
- Retest residents and HCP in facilities with confirmed COVID-19, per CDC guidance.
  - Retest as quickly as possible any resident or staff who develops symptoms consistent with COVID-19.
  - Retest all residents who previously tested negative at some frequency (e.g., weekly) to detect those with newly developed infection, until no further cases are identified, and it has been at least 14 days since the most recent positive result.

Information on Testing – Priority Group 2

- Upon their return, consider testing all residents who leave the facility for non-medically necessary outings.
  - Test as if new admission (i.e., on reentrance and about 7 and 14 days later).
- Test all HCP at some regular interval (e.g., every 7-14 days).
- If testing capacity is limited, test those HCP who reside or work in counties with known community spread of SARS-CoV-2 or who work in other healthcare facilities with cases of COVID-19.

Definition of Terms: Community Spread

- Community spread = when cases occurring and source of infection cannot be determined
- Different from cases linked to defined, recognized outbreaks
- Contact your local public health district to find out if your county has community spread



https://public.tableau.com/profile/idaho.division.of.public.health#!/vizhome/DPHIdahoCOVID-19Dashboard_V2/Story1.

Asymptomatic, Pre-symptomatic and Symptomatic Persons

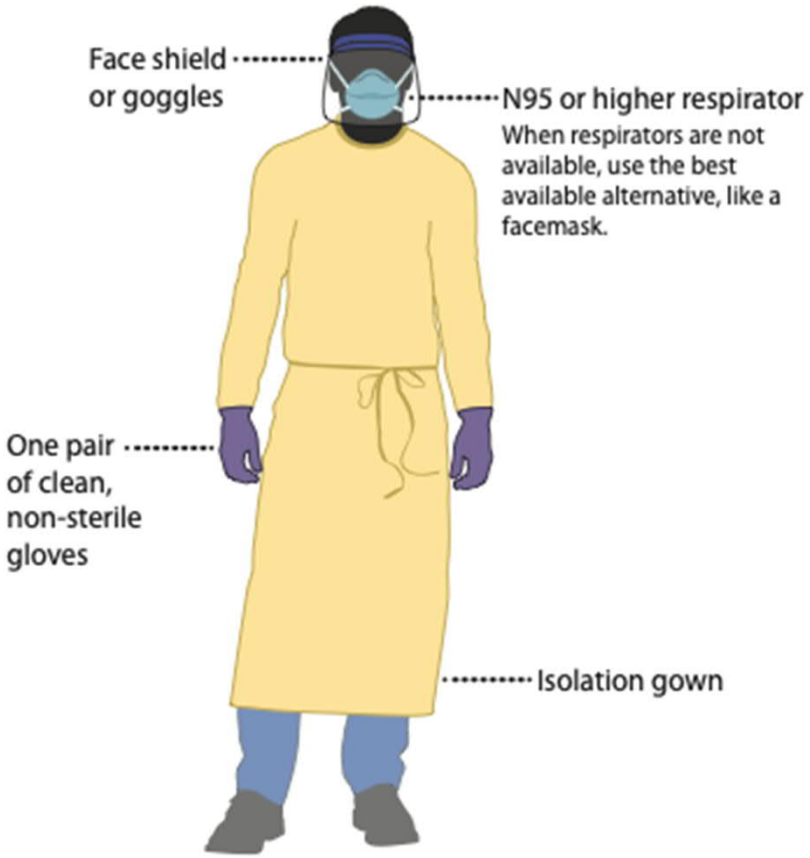
- People infected with SARS-CoV-2, the virus that causes COVID-19, may be:
- Asymptomatically infected – be infectious to others, have virus that can be detected on testing, but do not show symptoms
- Pre-symptomatically infected - be infectious to others, have virus that can be detected by testing before symptoms start, and later go on to have symptoms
- Symptomatically infected – infected with the virus AND have symptoms

Universal and Transmission-based Precautions

- Universal assumes everyone is potentially infectious.
- Because of the potential for asymptomatic and pre-symptomatic infected persons to unknowingly spread SARS-CoV-2, CDC recommends respiratory transmission-based precautions
- All staff in facility should wear a facemask
- Strict adherence to hand hygiene before and after each patient contact
- Use N95, gowns, eye protection, and gloves for any of the following:
  - Collecting specimens for SARS-CoV-2 testing
  - Caring for persons suspected or confirmed COVID
  - New admissions into a facility for first 14 days
  - Aerosol generating procedures like nebulizer treatments
- When N95 not available, facemasks are acceptable alternative

COVID-19 Personal Protective Equipment (PPE) for Healthcare Personnel

Preferred PPE – Use **N95 or Higher Respirator**



Acceptable Alternative PPE – Use **Facemask**

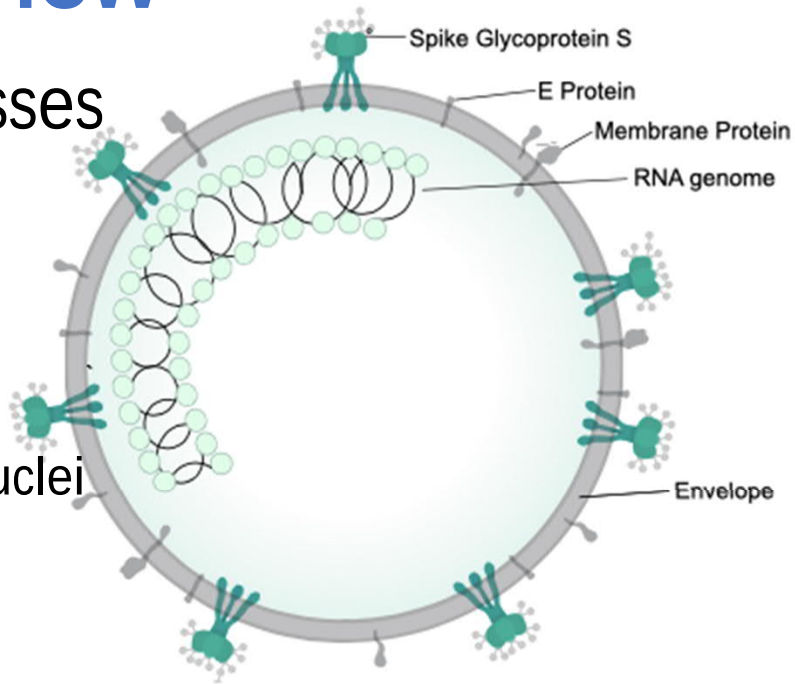
CDC

cdc.gov/COVID19

- Ensure staff are trained in appropriate donning and doffing of PPE

Tests for COVID-19 Diagnosis: An Overview

- Different kinds of tests to help diagnose COVID-19 illnesses caused by SAR-CoV-2 virus
  - Virus detection test
    - Usually detect either the virus'
      - Genetic material - PCR = polymerase chain reaction or NAAT= nuclei acid amplification test OR
      - Antigen = virus' protein, like the Spike protein
    - Swabs of nasopharynx (NP), nasal, posterior pharynx, or saliva
  - Point of care test = can be done in CLIA waved lab
    - E.g. Abbot ID NOW test
    - But, less accurate than PCR or NAAT tests which require more complex lab procedures



Coronavirus Virion Structure

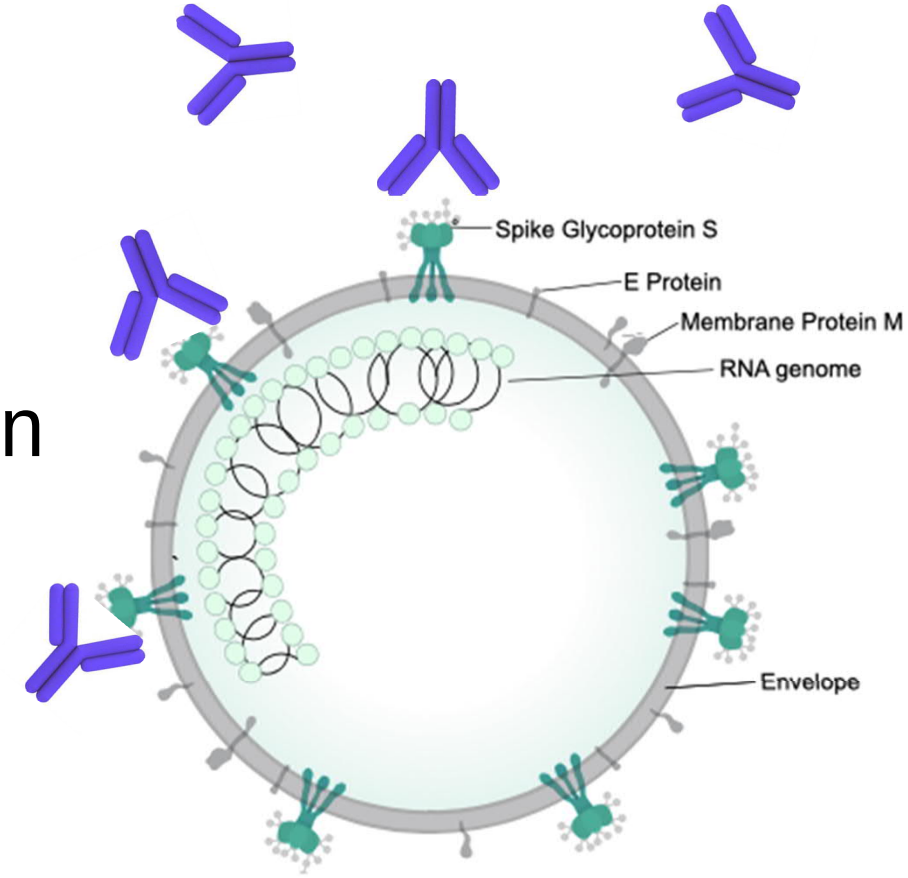
(Cross Section Diagram)

By SPQR10Binte altaf - Own work, CC BY-SA 4.0, https://commons.wikimedia.org/w/index.php?curid=88349537

https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html.

Antibody Tests for COVID-19: An Overview

- Serology = antibody test
  - Blood sample must be collected
  - Identifies antibody made by a person's immune system in response to an infection
  - Identifies past infection (although person may still also be infectious depending on when a specimen is collected)



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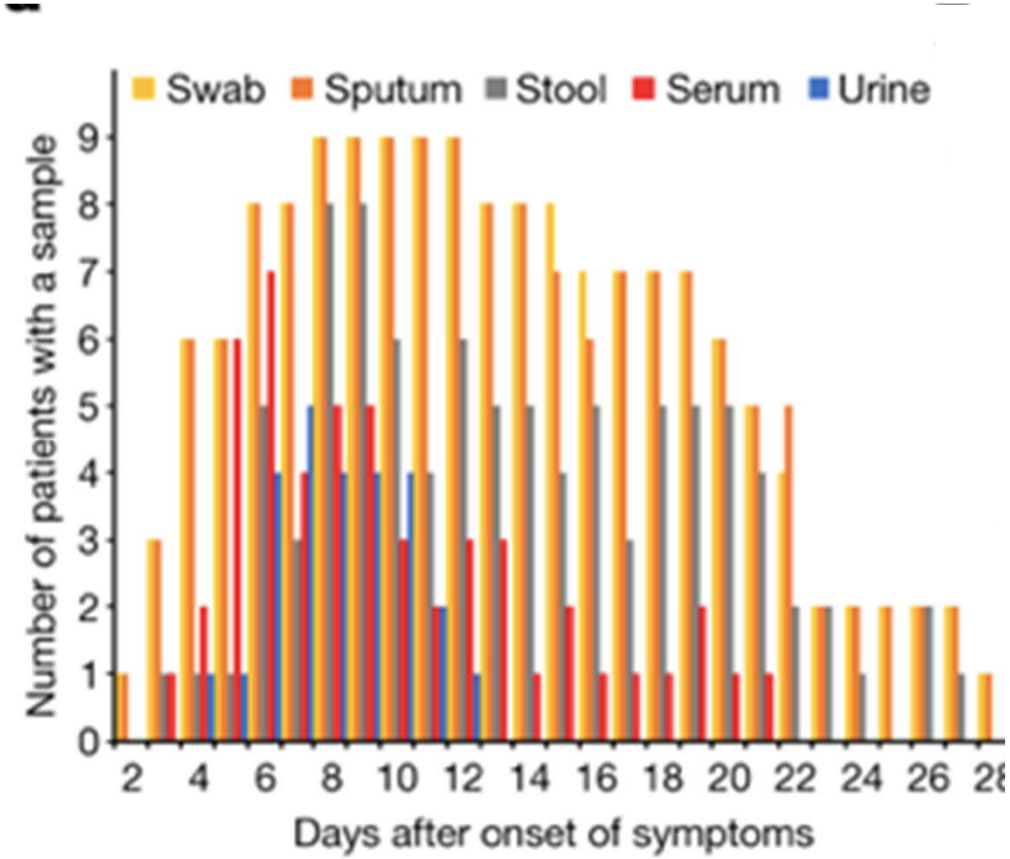
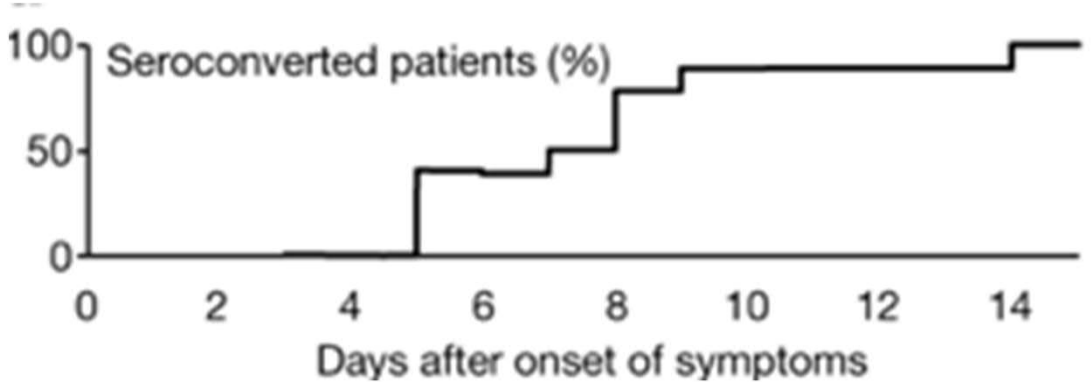
SARS CoV-2 Virus Detection in Hospitalized Patients

Wölfel, R., Corman, V.M., Guggemos, W. et al. Virological assessment of hospitalized patients with COVID-2019. Nature 581, 465–469 (2020).





- Viral RNA detected from NP (nasopharyngeal) swab samples, sputum, stool, serum, and urine among patients in Germany identified through contact tracing
- No serum, urine or stool samples were culture-positive
- No throat or sputum samples were culture-positive after day 8 of illness onset

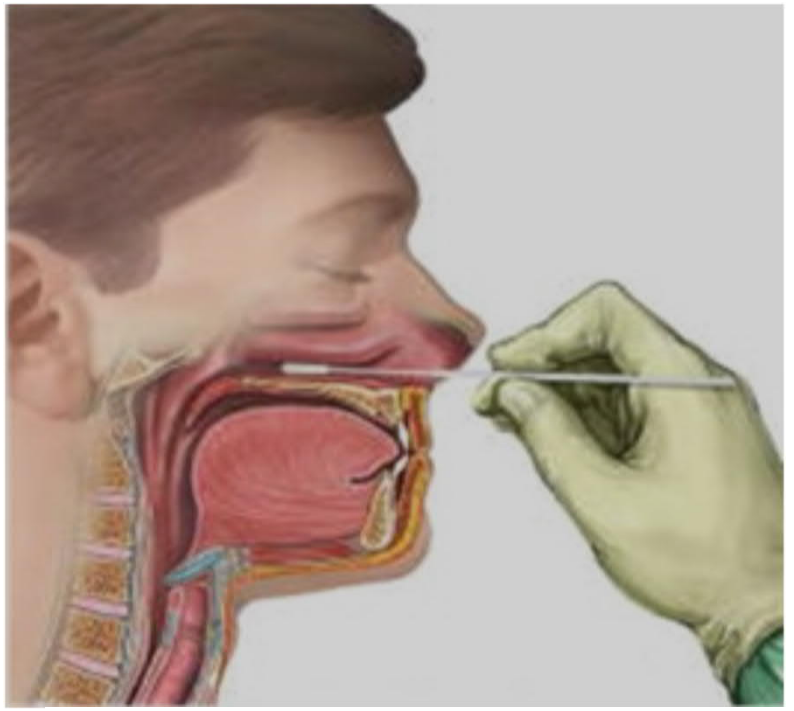
Collecting Specimens To Test for Virus Infection

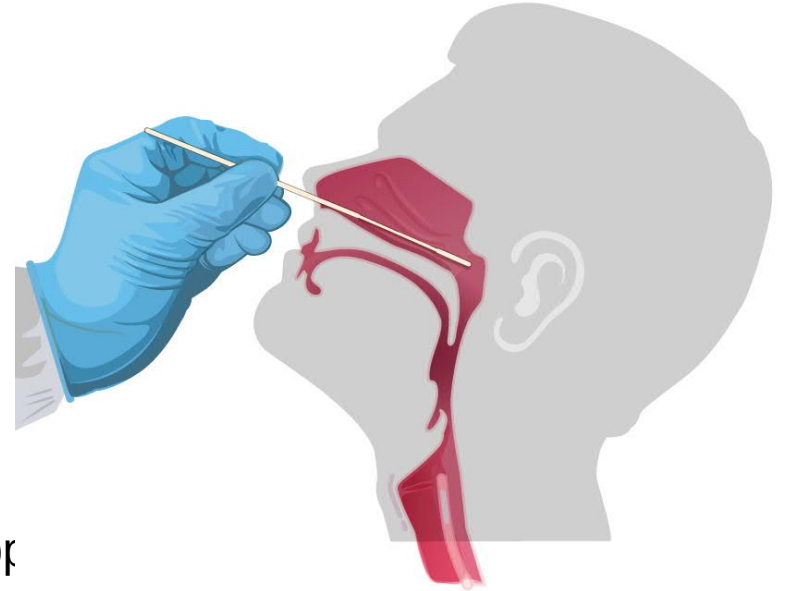
- Decide on type of specimen
  - Nasopharyngeal (NP) swabs most sensitive
  - Other types: deep nasal, oropharyngeal, nasal mid-turbinate swab using a flocked tapered swab; or anterior nares (nasal swab) specimen using a flocked or spun polyester swab
- Determine materials needed based on specimen and your lab
  - Sterile swab, dacron tip with plastic or wire shaft for NP swab (not wooded or calcium alginate)
  - Usually sterile transport tube with 2-3 ml of viral transport media (check with lab)
- Prepare materials
  - Label specimen with patient name, date and time of collection, and other information requested by the laboratory
- Prepare the room and have PPE on
  - Use room with closed door and minimize number of people in the room
  - Gown, gloves, N-95 (facemask if not available), and eye protection

Collecting Nasopharyngeal Specimens To Test for Virus Infection

- With the person's head in a neutral position or tilted ~ 70^0
  - Insert the dry swab through one nostril straight back (NOT upwards), along the floor of the nasal passage, holding gently
  - Stop when get resistance
  - Rotate the swab gently then leave in place a few seconds
  - Carefully remove the swab without touching the sides of the nostril

- Open the transport vial and place the swab in the transportation medium.



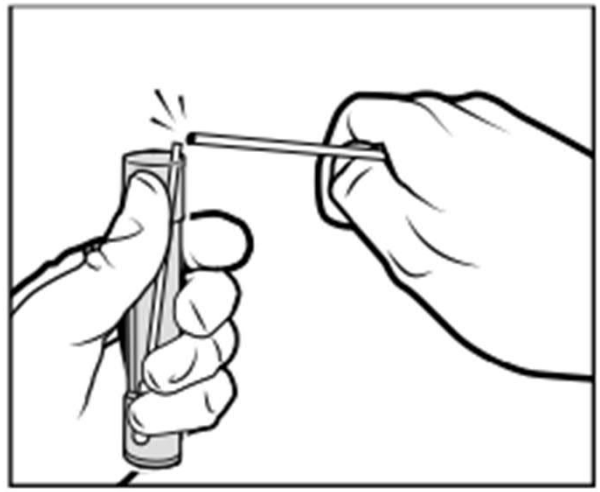


https://www.ottawapublichealth.ca/en/professionals-and-partners/how-to-collect-a-nasop

https://www.youtube.com/watch?v=DVJNWefmHjE

General Steps To Prepare Specimens For Referring Lab – Important – Check Your Lab's Instructions

- Break the swab at the scored line; recap transport vial.
- Place the specimen in the big inner pocket of the plastic biohazard bag provided.
- Remove your gloves and perform hand hygiene; remove your mask and perform hand hygiene.
- Place the requisition form in the small outer pocket of the plastic biohazard bag.
- Place the entire plastic biohazard bag in a separate clean paper bag or zip-lock bag.
- Refrigerate the specimen as directed by testing lab.
- Perform hand hygiene.



https://www.ottawapublichealth.ca/en/professionals-and-partners/how-to-collect-a-nasopharyngeal--np--swab.aspx

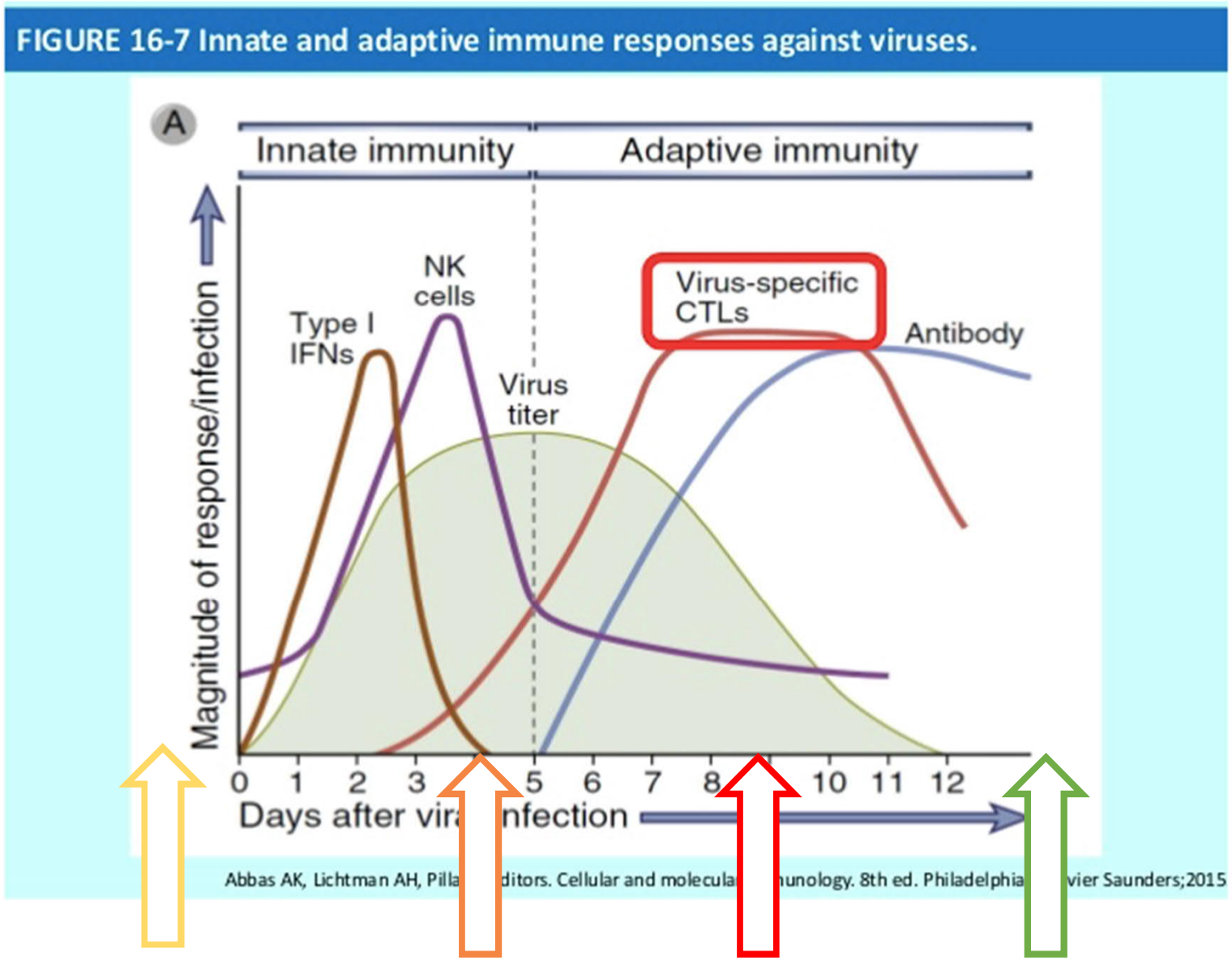
Theoretical Example of Antibody Response Relative to Viral Shedding

Pre-symptomatic
Antibody - / PCR +/-
+/-Infectious

Symptomatic
Antibody - /PCR +
Infectious

+/- Symptomatic
Antibody + / PCR +
Infectious

No symptoms
Antibody + / PCR –
Not infectious



Abbas AK, et al. Cellular and molecular immunology. 8th ed. Philadelphia. Elsevier Saunders; 2015

Serologic Testing Recommendations

- Limited usefulness for decision making for individual persons tested
- Antibody (serology) results currently should not impact return to work or use of PPE decisions
  - Level and duration of protection from detected antibody unknown
- Studies to estimate the percent of the population with antibody can help understand how many have likely been infected

https://rebound.idaho.gov/wp-content/uploads/testing-recommendations.pdf.

Updated CDC Serologic (Antibody) Testing Recommendations May 23, 2020

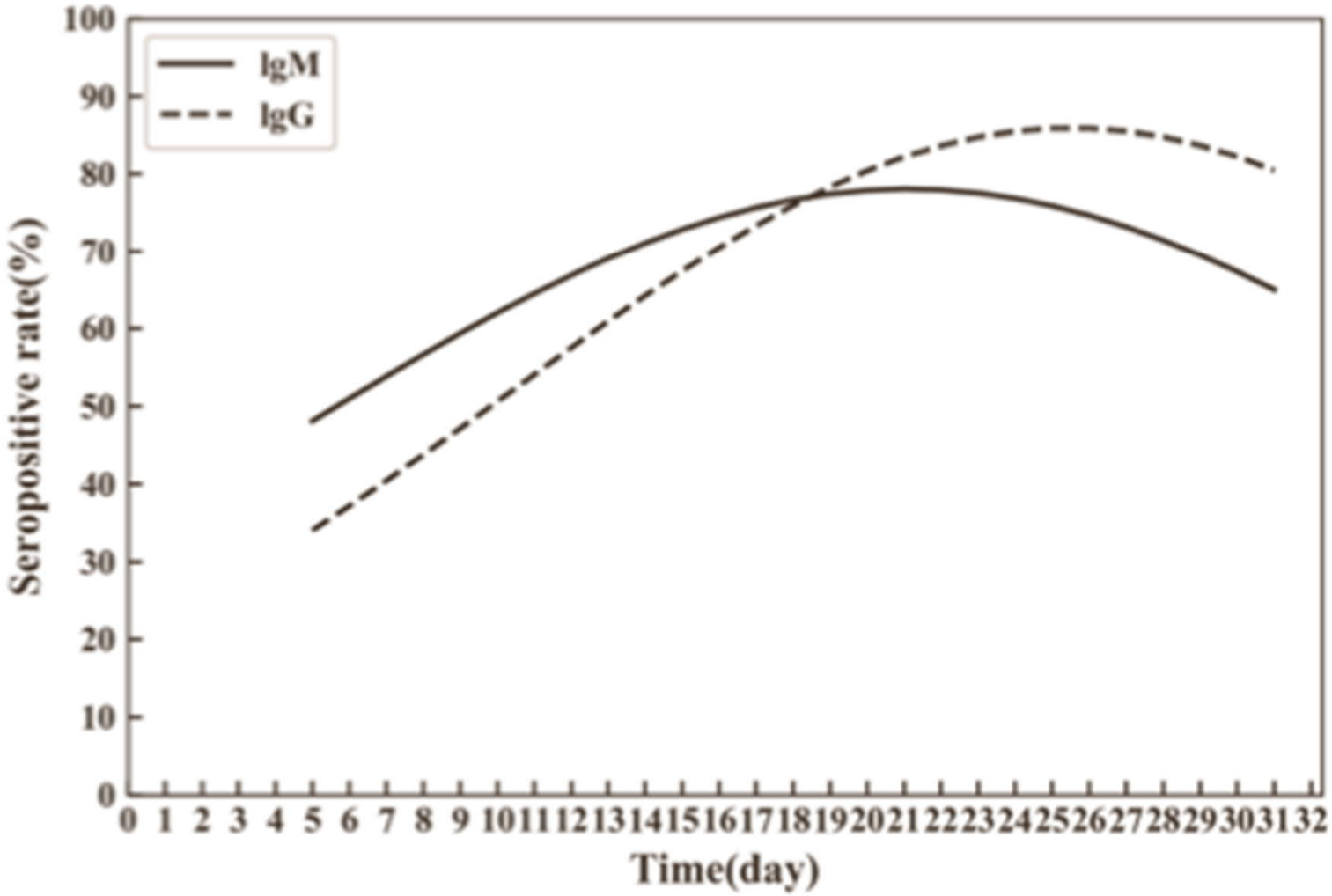
- No advantage of IgM vs IgG tests

- Serologic testing can support diagnosis of acute COVID-19 illness for people who present late along with PCR testing.
  - Persons presenting 9-14 days after illness onset
  - To help establish diagnosis for patients with late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children.

https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html.

Xiang F, et al. Antibody Detection and Dynamic Characteristics in Patients with COVID-19. Clin Infect Dis. 2020 Apr 19 doi: 10.1093/cid/ciaa461

Detection of IgM and IgG antibodies in different periods. A log-distribution was used to describe the distribution time period of seropositive rate of the two types of antibodies. Serological IgM and IgG antibodies tested by ELISA in patients with confirmed diagnosis. The IgM and IgG antibodies were detected as positive as early as on the 4th day after onset, the seropositive rate of IgM increased gradually; however, IgG was increased sharply on the 12th day after onset.



Serologic Testing

- If used, important to have a highly sensitive and specific antibody test
- Sensitivity = the percentage of people who have had the infection who actually test positive. (Number testing positive ÷ Number actually positive)
- Specificity = percentage who test negative among persons who are truly negative (Number testing negative ÷ number actually negative)
- Positive predictive value – among those that test positive, how likely a positive test represents an actual positive
  - Influenced by sensitivity, specificity, and level of antibody in the population

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance.

Positive Predictive Value (PPV) for different test sensitivity and specificity and antibody levels in tested population

	sensitivity	specificity	prevalence	PPV
Test A	90%	90%	0.1%	0.9%
			0.5%	4.3%
			1%	8.3%
			5%	32%
			10%	50%
			20%	69%
Test B	99%	99%	0.1%	9%
			0.5%	33%
			1%	50%
			5%	84%
			10%	92%
			20%	96%

Serologic Testing

- FDA now with new independent verification of test sensitivity, specificity

Abbott Architect SARS-CoV-2 IgG

Developer: Abbott
Test: Architect SARS-CoV-2 IgG
Technology: High Throughput CMIA
Target: Nucleocapsid

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgG	Sensitivity (PPA)	100% (88/88)	(95.8%; 100%)
IgG	Specificity (NPA)	99.6% (1066/1070)	(99.0%; 99.9%)
IgG	PPV at prevalence = 5%	92.9%	(83.4%; 98.1%)
IgG	NPV at prevalence = 5%	100%	(99.8%; 100%)

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance.