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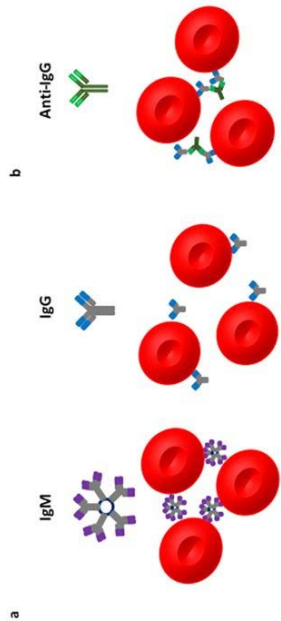
UPDATES ON SARS-COV-2 AND COVID19 | TESTING, VACCINES & TREATMENT

Swab Tests; COVID19 Disease



- Determines if active infection
- Nose, mouth swab
- 13 diagnostic manufacturers in market
 - 5 companies doing distribution kits
- Preferred method for diagnosing active disease/infection
- Point of Care (bedside) or Lab Based
- Uses fluorescent probe to identify nucleic acid of virus
- Fastest test 5 min +, 13 min -

Blood Tests; SARS-CoV-2 Antibodies

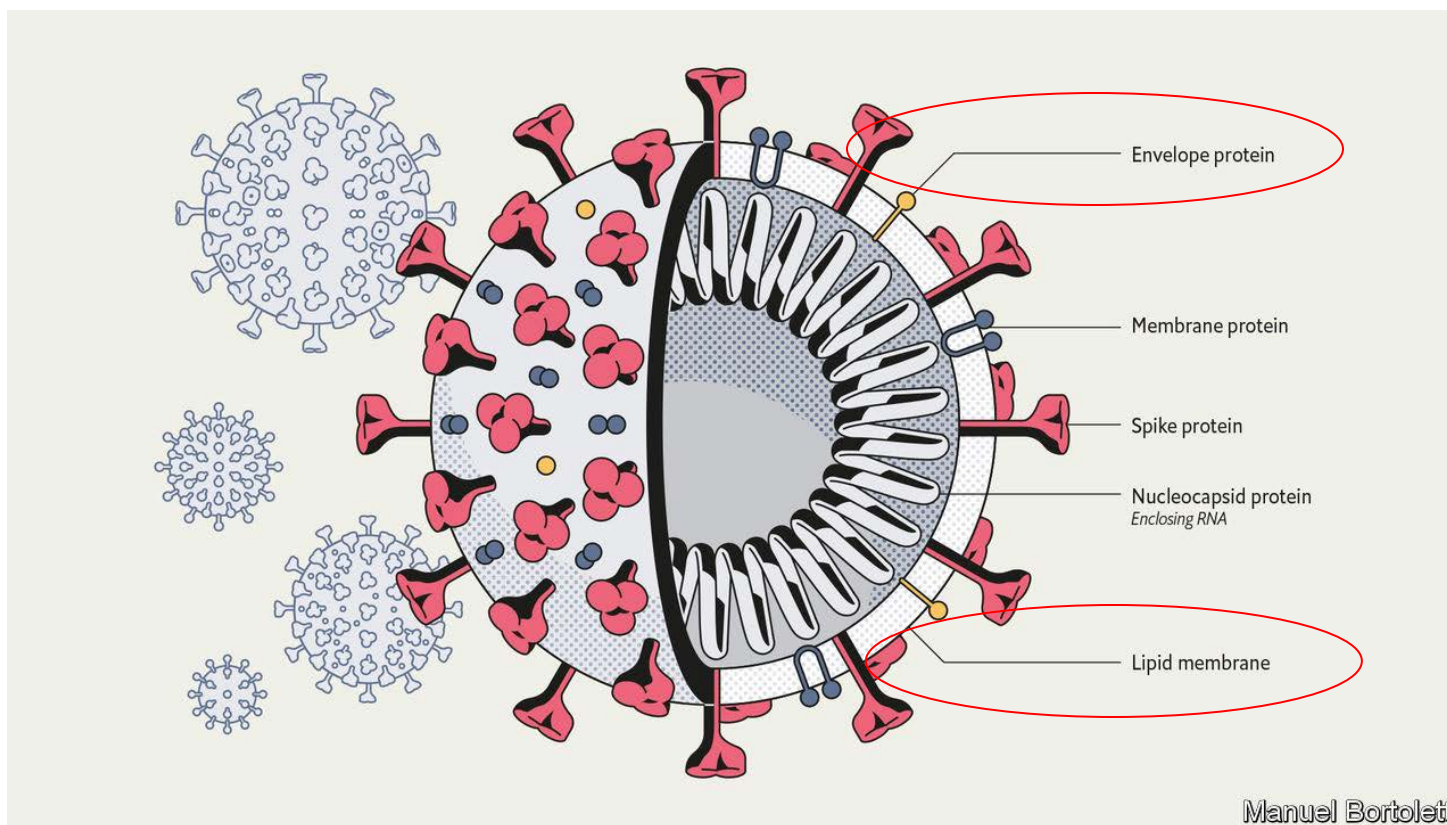


- Many determine if current or past infection with any coronavirus
- Some can determine if COVID19 specifically
- Tests whole blood, serum, or plasma
- Over 50 companies offering tests; most in China
- All Emergency Use Authorizations (EUAs); FDA does not clear
- Follow-up testing needs to be done to rule out infection; swab diagnostic

Treatment

- 21 companies with drugs for treatment
- Body's own immune system over-reacts to virus and damages its own cells; "cytokine storm"
 - Cells to battle causing system inflammation
- Most promising: remdesivir (former Ebola drug; 2013/4)
 - Disrupts viral RNA replication at the enzyme level
- Anti-malaria: efficacy not proven (chloroquine, hydroxychloroquine; 1940s)
 - Creates a toxic cellular environment to prevent replication
- Plasma; convalescent plasma from those who are well.

SARS-CoV-2: Enveloped RNA

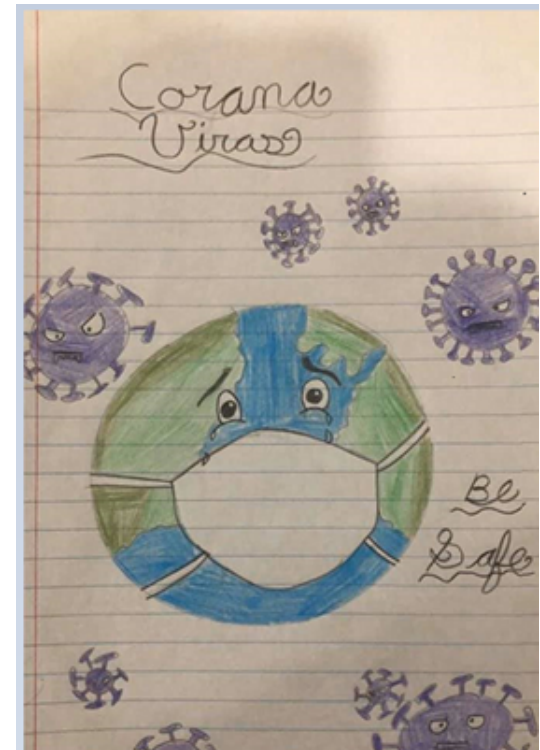


Vaccine

- 12 companies working on vaccine
- \$1B for Vaccine R&D, testing
 - Gov't Biomedical Advanced Research & Development Authority
- Moderna first clinical trials with NIAID (RNA)
- Inovio in phase 1 clinical trials (DNA)

Immunity

- Because the outbreak is only a few months old, there are no data on long-term immune response
- While other coronaviruses demonstrate evidence of reinfection, this usually does not happen for many months or years



Outcomes with Patients on Ventilators

- When lungs can't effectively exchange oxygen with the bloodstream
- Ventilator mechanically exchanges O₂
- COVID19 high levels of pressure and O₂ because lungs are so inflamed
- Ventilator causes damage
- No effective cure for COVID19 pneumonia
- If extreme, ECMO is done delivering O₂ straight into blood
 - Extracorporeal membrane oxygenation; life supporting while lungs heal
- Recovery: 33 out of 98 in UK; 3 out of 22 in Wuhan, China

FDA Industry Hotline: Coronavirus COVID-19 Diagnostic Tests and Shortages

For Industry Questions: COVID-19 Diagnostic Tests, and COVID-19 device shortages,
including all Personal Protective Equipment for masks and respirators

- Contact our toll-free line 24 hours a day: 1-888-INFO-FDA,
choose option *

Or Email:

- Shortages: deviceshortages@fda.hhs.gov
- Diagnostic Tests: COVID19DX@FDA.HHS.GOV