Planning Your COVID-19 Testing Strategy

Testing Tips, Flips & Slips During COVID-19

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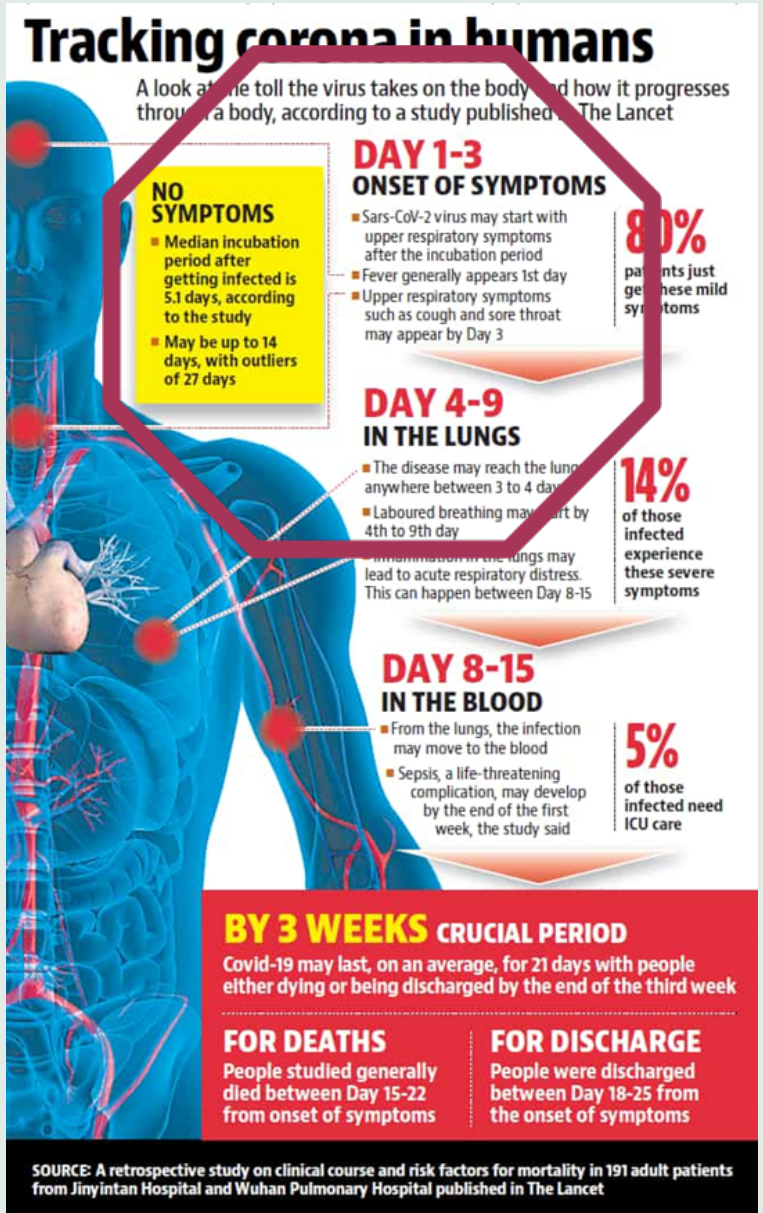
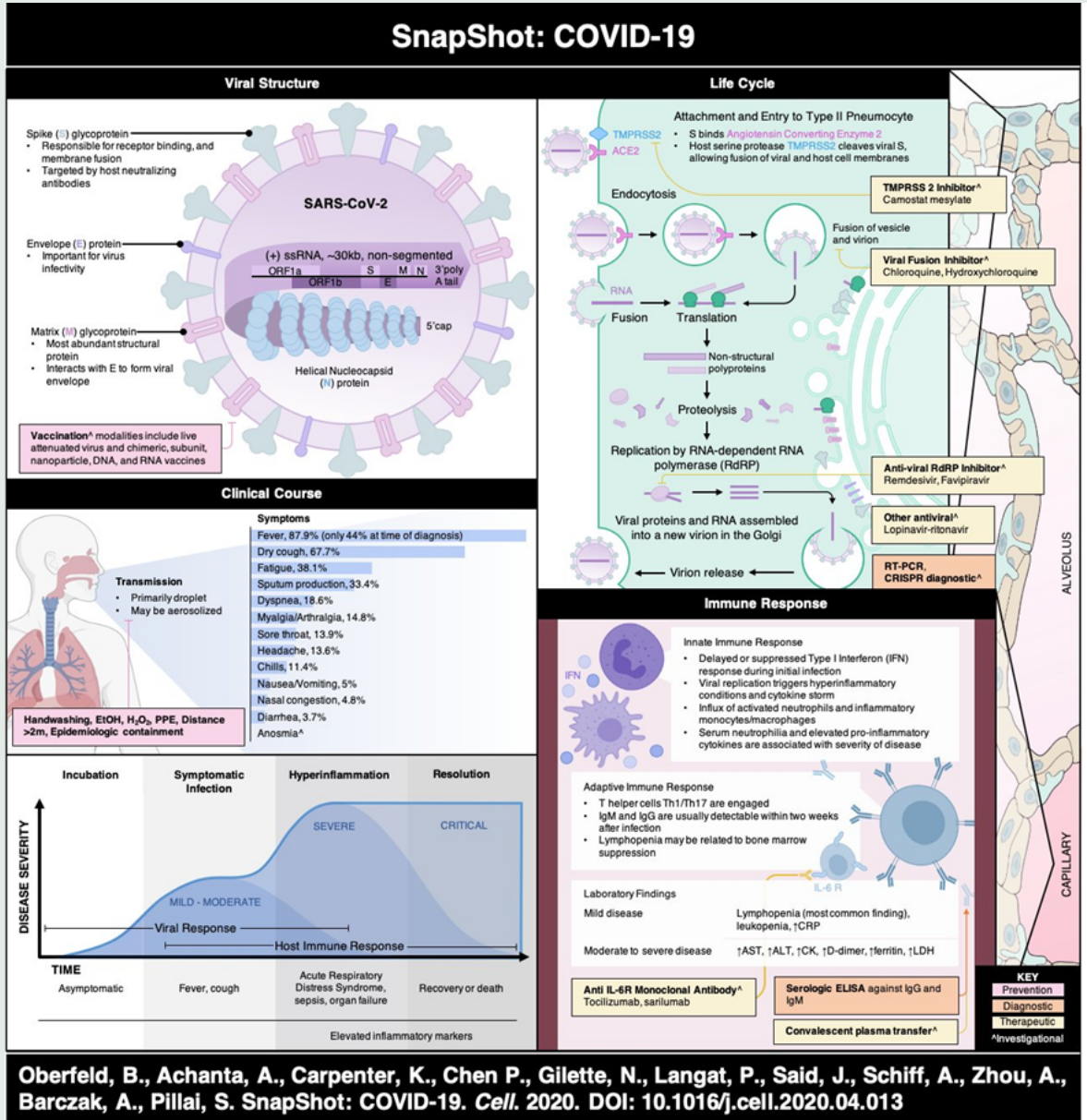
Beginning Of COVID-19 Testing Journey

- FDA restriction lifted 2/29/2020
- The immediately in effect guidance issued today describes the circumstances where the FDA does not intend to object to the use of these tests for clinical testing while the laboratories are pursuing an emergency use authorization (EUA) with the FDA. Importantly, this policy only applies to laboratories that are certified to perform high-complexity testing consistent with requirements under Clinical Laboratory Improvement Amendments.
- Important aspects of this guidance:
  - Laboratories developing the test must submit their data to the FDA **within 15 days** of validation for the EUA
  - Prior to this date all testing was performed by the CDC
  - Manufacturers began test development at this time, as well as some independent labs

Kinetics Of Progression Of COVID Infection





What Tests Are Available?

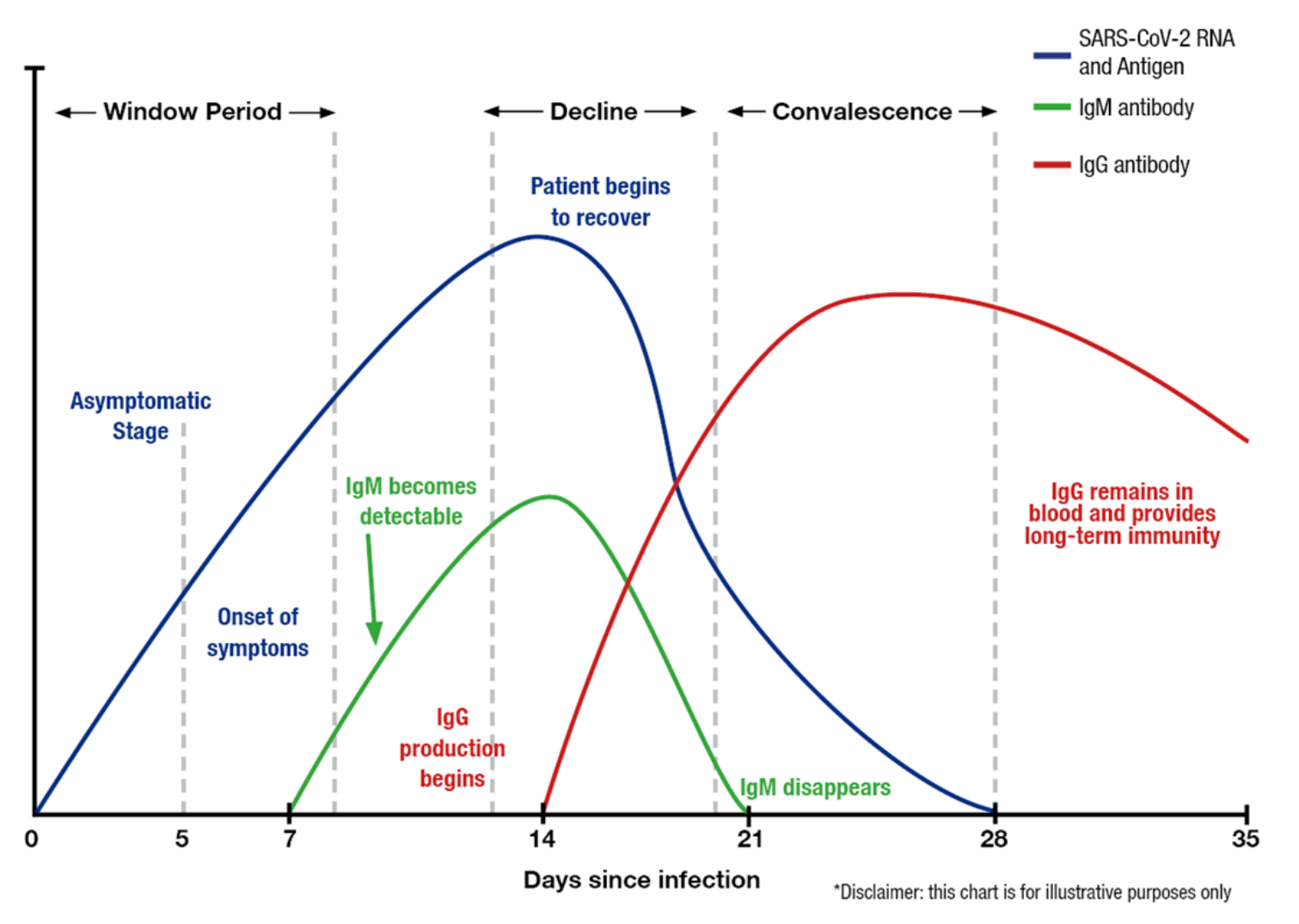
- Diagnosis
- High throughput
  - Roche-FDA EUA:
    - 6800 can handle 800 samples during an 8-hour shift
    - Specimen type: NP swab in viral transport media, universal transport media, 0.90% saline
    - Averages around 6 hours for report results in the most efficient of scenarios from the time the specimen is put on the instrument
  - Thermo Fisher-LDT:
    - Quant studio can handle 188 samples during an 8-hour shift with a standard set up**
    - Sensitive to as low as 20 copies/ml in our hands
    - Specimen type: NP swab in viral transport media, universal transport media, 0.90% sali

    - Averages around 6 hours for report results in the most efficient of scenarios from the time the specimen is put on the instrument
    - LDT allows adjustment of assay to account for new mutations

What Tests Are Available?

- Diagnosis
- Rapid TAT
  - Abbott ID NOW—results in 15 minutes
    - Specimen type: **dry nasal swab**
    - Sensitivity: hot topic
  - Cepheid—results in about 2 hours**
    - Specimen type: NP swab in viral transport media, universal transport media, 0.90% saline
  - BioFire—results in about 2 hours**
    - Specimen type: NP swab in viral transport media, universal transport media, 0.90% saline
    - Available now as part of the “Respiratory Panel”

Dynamics Of The Serologic Response



https://www.diazyme.com/covid-19-antibody-tests

What Tests Are Available?

- Serology-meaning and therefore utility of results still under investigation
  - Abbott-runs on the ARCHITECT
    - IgG
    - Performance optimized at 14 days post-infection
    - 99.6% specificity**; 100% sensitivity
    - Chemiluminescence (CMIA)
    - 2,000/day; reagent supply will support this (14,000/week)

Test Resource Considerations

- NP swabs
  - Saline
  - VTM
  - UTM

Waxing and waning supply of these various materials. Alternative specimen acquisition tool challenge = test validity

- Actual reagents for tests
  - Better scenario for antibody testing than for diagnostic testing
    - Roche-limiting our healthcare **system** to 5,264 tests/week
      - Regulated by the government
    - Thermo Fisher-reagent availability a little better
      - Currently allotting us tests ad-lib**
  - Abbott ID-NOW: 24/day
  - BioFire: Will learn this next week as test just now available
  - Cepheid: Will learn this next week, we are investigating bringing this instrument in

How Are We Managing Our Resources?

- Abbott ID-NOW:
  - L&D
  - 97% sensitivity
  - VERY SPECIFIC AND LIMITED USE BEYOND L&D, solid organ transplant cases that cannot wait for longer TAT
- Roche and Thermo Fisher
  - All other cases of “persons under investigation” not requiring rapid interpretation
  - **used to help get our OR’s up and running
    - Patients must be tested 48h in advance of surgery
    - Guides what level PPE required for surgery
  - Now that both instruments are running and providing 24/7 service, incorporating testing on all admits
- Abbott antibody testing
  - Part of pre-surgical work-up
- Guides decision tree regarding PPE utilized, in combination with diagnostic results
  - Establish if/when positives seroconvert
- Primarily obtained on inpatients
  - Return-to-work programs, employee monitoring, prevalence

Next Steps

- Community-based testing
  - Paired antibody/diagnosis?
  - Surveillance?
- Saliva as a specimen
  - Employee surveillance, schools, jails, population-based assessment of prevalence
- Data, data, data>publish, publish, publish
  - Meaning behind antibody testing
    - When paired with diagnosis (including quantitative viral load)
      - IgG response, duration
      - How much = “immune” and for how long?
      - Re-infection??
      - Asymptomatic carriers→Ab? Relevance?
- Why there was a precipitous drop in flu diagnoses…….???

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- Weekly Webcast Series: Plans and Strategies for Staffing,
- CANCER BUZZ Mini-Podcasts
- Evidence-Based Guidelines & Information
- Member Discussions & Resources on ACCCExchange

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