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COVID-19 Molecular Testing

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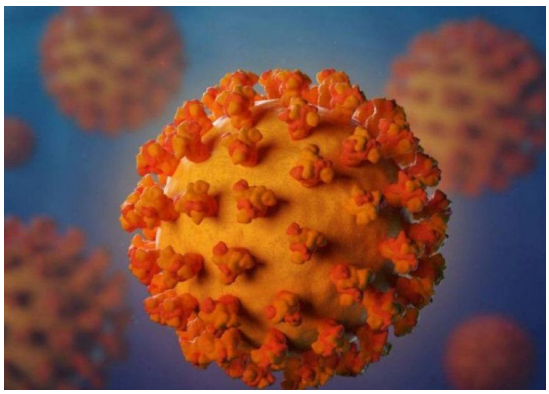
Disclosures

- Advisory Board Member for DiaSorin molecular

Coronaviruses: From the Common Cold to Global Contagion

Common human coronaviruses:

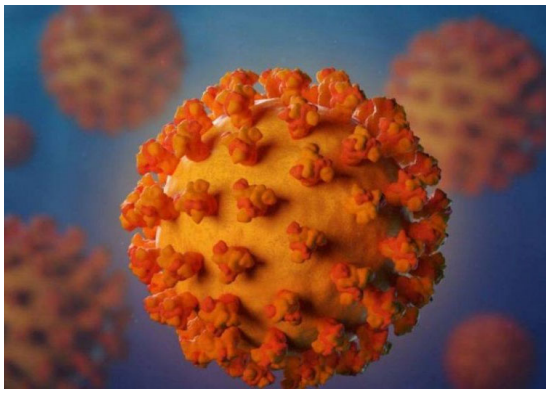
- HCoV-OC43
- HCoV-NL63
- HCoV-229E
- HCoV-HKU1



Coronaviruses: From the Common Cold to Global Contagion

Coronaviruses associated with severe disease:

- SARS (2002-2003)
  - ~8,422 cases (~10% CFR)
- MERS (2012)
  - ~2,500 cases (~35% CFR)
- SARS-CoV-2 (2019-2020)
  - ~3,200,000 cases
  - ~7% CFR



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Why do certain coronaviruses cause more severe disease?

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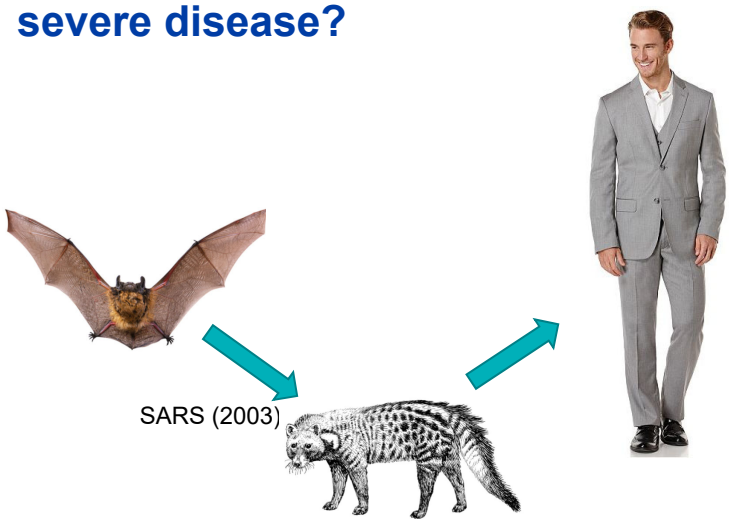

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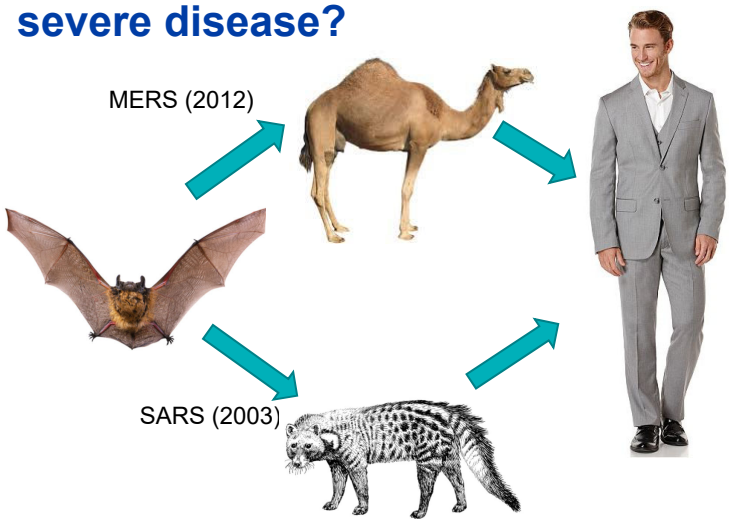

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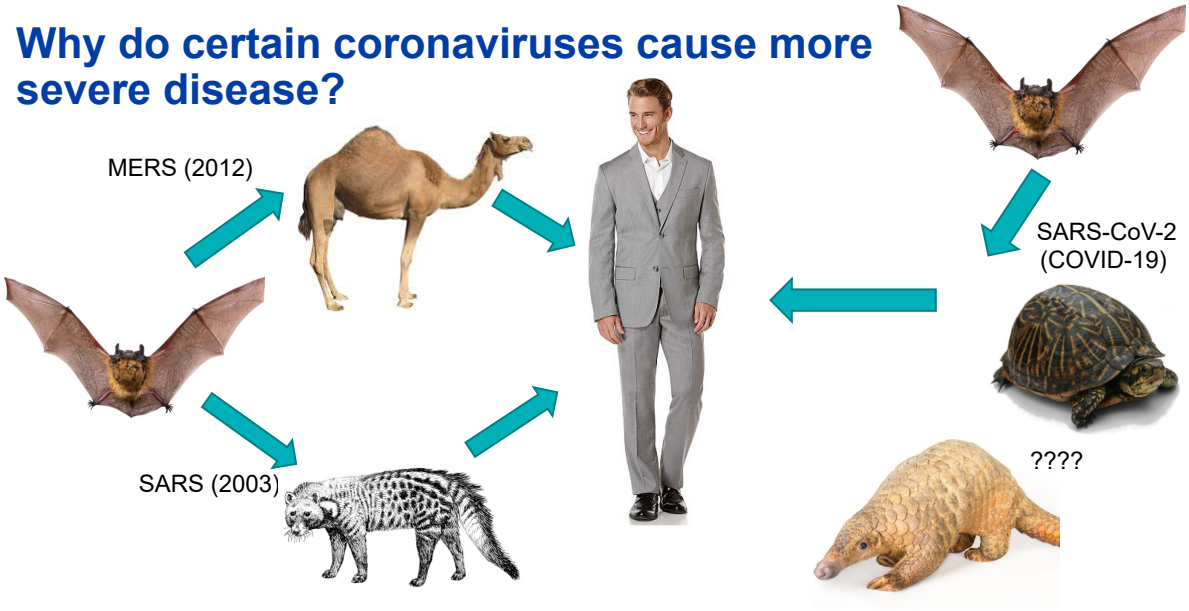

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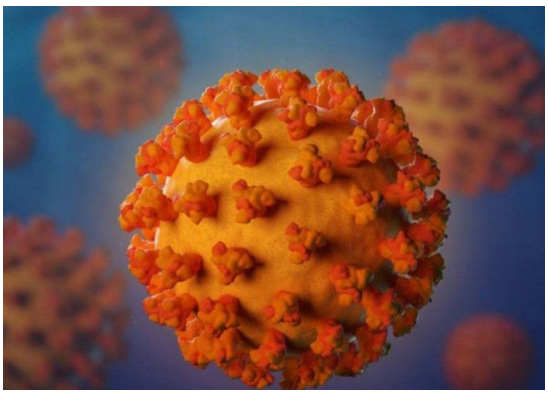
SARS-CoV-2 (COVID-19): Laboratory Testing

- Molecular (Real-time PCR)
  - Detects viral RNA in clinical samples
  - Diagnose active infection with SARS-CoV-2
- Serology
  - Detects antibodies (i.e., IgG) to SARS-CoV-2
  - Determines whether an individual has been exposed



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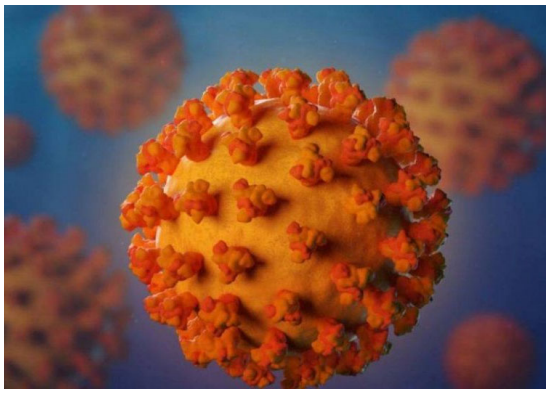
SARS-CoV-2 (COVID-19): Molecular Testing

Molecular (real-time PCR) tests have generally targeted a combination of the following genes:

- Nucleocapsid (N)
- Open reading frame 1ab (Orf1ab)
- Envelope (E)
- RNA dependent RNA polymerase (RdRp)



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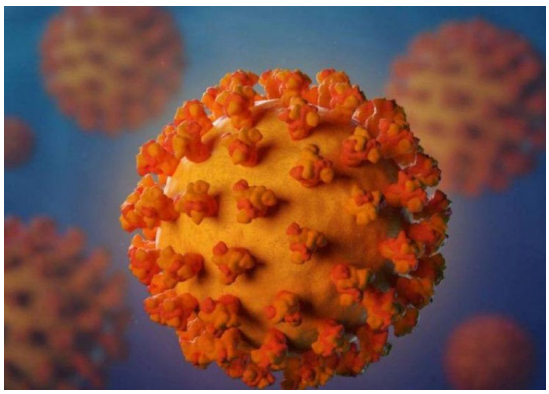
SARS-CoV-2 (COVID-19): Molecular Testing

Appropriate sample types:

- Nasopharyngeal swab (**preferred**)
- Oropharyngeal (throat) swab

If evidence of LRTI or later in disease:

- Sputum
- BAL fluid
- Tracheal secretions



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SARS-CoV-2 (COVID-19): Molecular Testing

When is SARS-CoV-2 shed at the highest amount?

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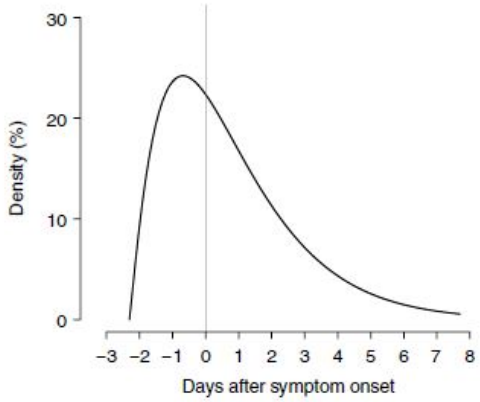
SARS-CoV-2 (COVID-19): Molecular Testing

When is SARS-CoV-2 shed at the highest amount?

- Peak viral shedding ~24 h **prior** to symptom onset
- Detection in upper airway (i.e., NP swab) likely drops after 3-5 days post onset



He X, Lau E, Wu P, et al: Temporal dynamics in viral shedding and transmissibility of COVID-19. Nat Med 15 Apr 2020

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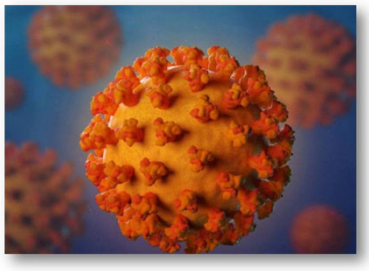

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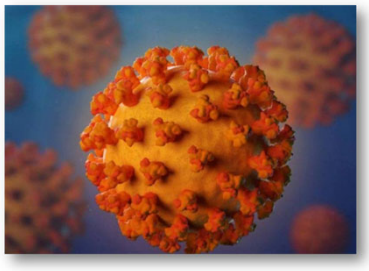
SARS-CoV-2 (COVID-19): Molecular Testing

What is the sensitivity of the COVID-19 PCR test?



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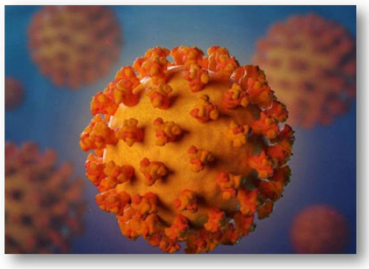
SARS-CoV-2 (COVID-19): Molecular Testing

What is the sensitivity of the COVID-19 PCR test?

Is it really only 60%?!



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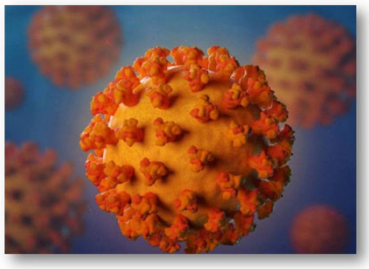
- At this point, laboratories know the analytical sensitivity of these tests



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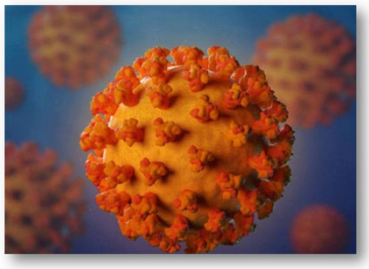
SARS-CoV-2 (COVID-19): Molecular Testing

What is the sensitivity of the COVID-19 PCR test?

Is it really only 60%?!

- At this point, laboratories know the analytical sensitivity of these tests
- The *clinical* sensitivity still needs to be defined
- Likely depends on several factors:
  - Timing of collection
  - Sample type
  - Quality of sample collected
  - Test



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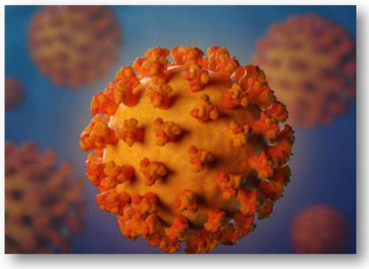
SARS-CoV-2 (COVID-19): Molecular Testing

- Study by Wang et al (JAMA 5 Mar 2020):
  - Assessed PCR detection among hospitalized patients
  - Detection rates in various clinical samples
    - BAL: 14 (93%) of 15 samples
    - Sputum: 75 (72%) of 104 samples
    - Nasal swabs: 5 (63%) of 8 samples
    - Throat swabs: 126 (32%) of 398 samples
    - Feces: 44 (29%) of 153 samples
    - Blood: 3 (1%) of 307 samples
    - Urine: 0 (0%) of 72



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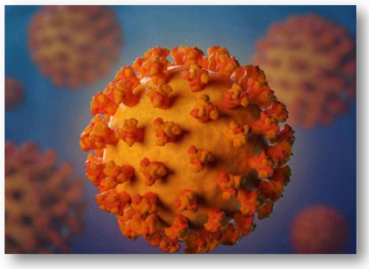
SARS-CoV-2 (COVID-19): Summary

- COVID-19 is caused by SARS-CoV-2
- Laboratory Testing for SARS-CoV-2:
  - Real-time PCR (acute diagnosis)
  - Serology (prior exposure)
- Sensitivity of PCR testing depends on:
  - Timing of disease when testing performed
  - Sample type collected
  - Quality of sample
  - Test performance characteristics



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Thank you!