Memorial Sloan Kettering Cancer Center

COVID-19 Diagnostics

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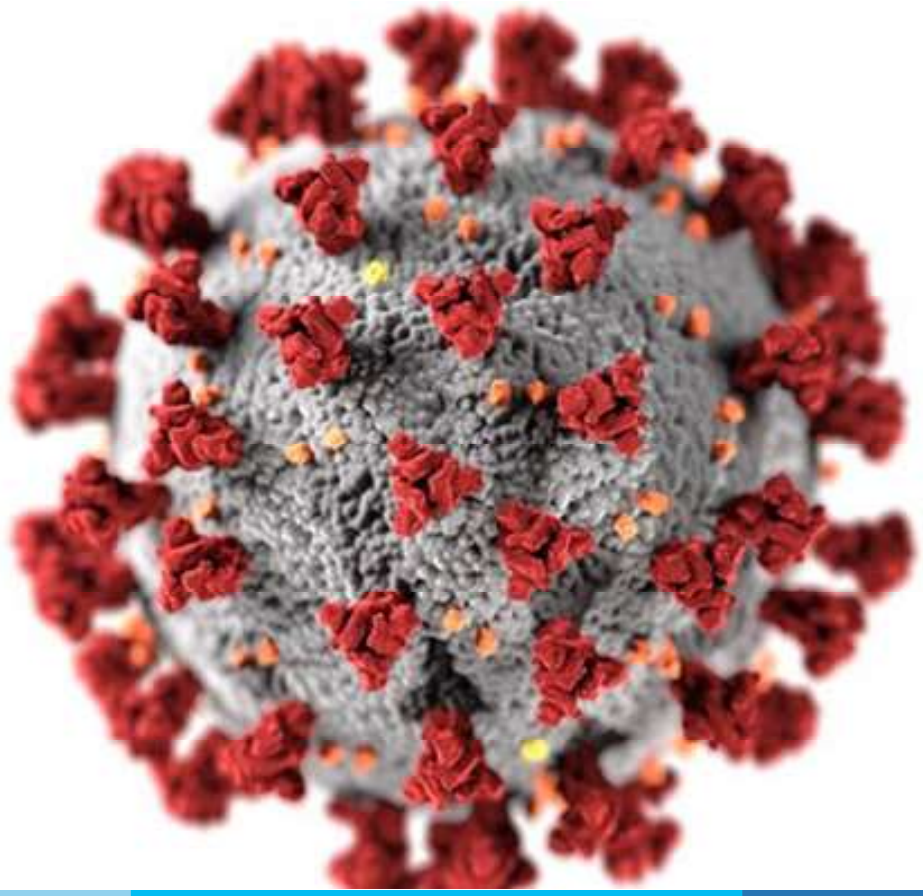
COVID-19: Coronavirus Disease 2019

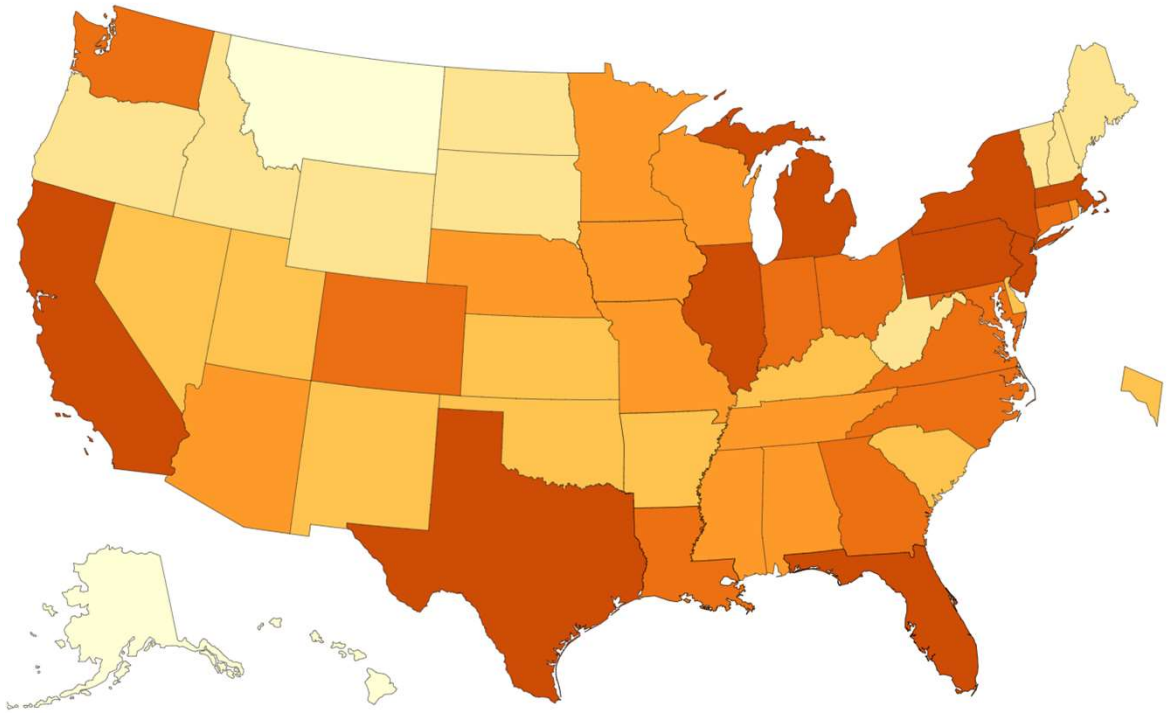
SARS-CoV-2
Highly contagious
Human-to-human spread by respiratory droplets

Incubation
2-14 days (median 5 days)

Disease spectrum
Asymptomatic to severe



US COVID-19 Cases, Deaths (as of May 26)



CASES
- 46,944 - 356,179
- 18,811 - 42,323
- 10,846 - 18,491
- 4,923 - 9,056
- 776 - 4,085
- 0 - 591

1,662,414
cases

98,261
deaths

SOURCE: CDC COVID Data Tracker

Symptoms of COVID-19

Clinical Assessment*

Cough, shortness of breath, fever, chills, headache, sore throat, muscle pain, loss of taste or smell

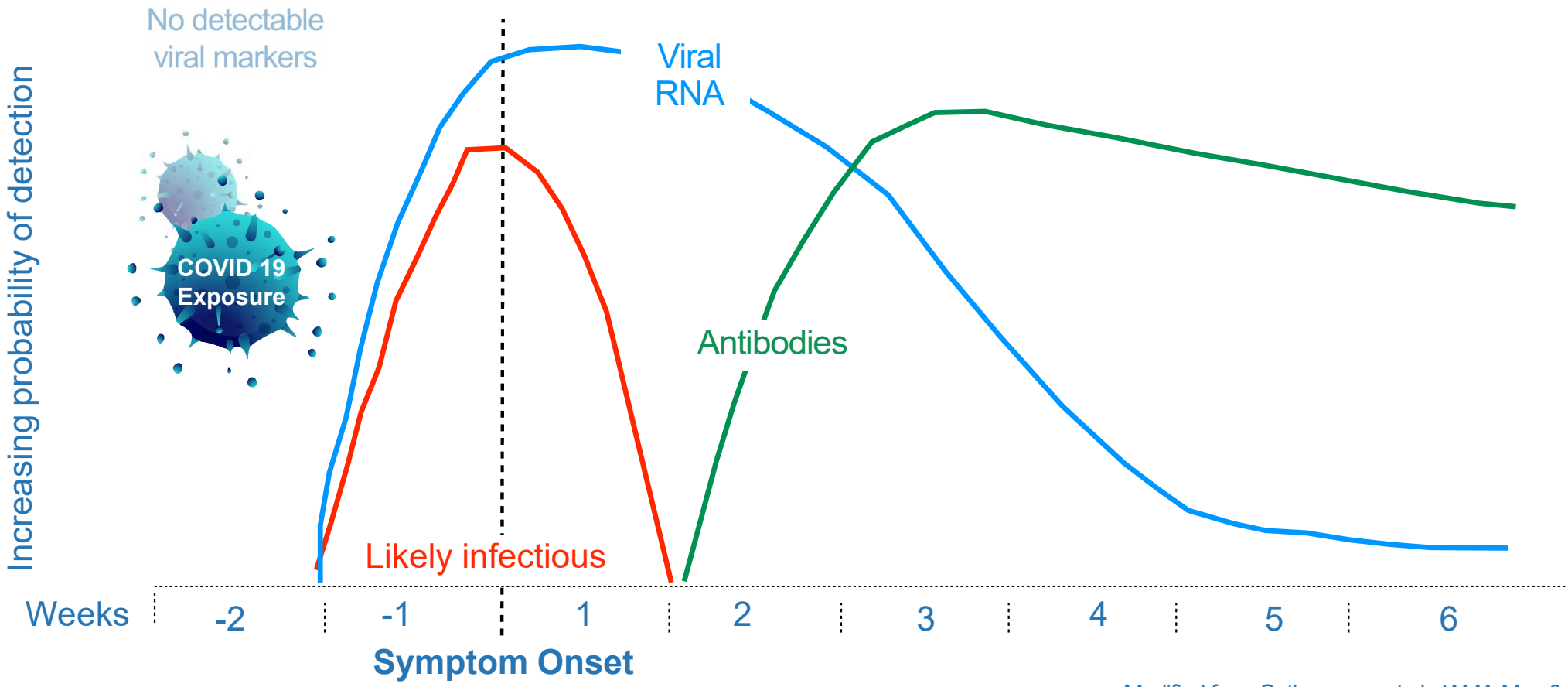
*Not all inclusive

Why Testing is Necessary

"Clinical assessment alone is not accurate in predicting COVID-19 diagnosis."

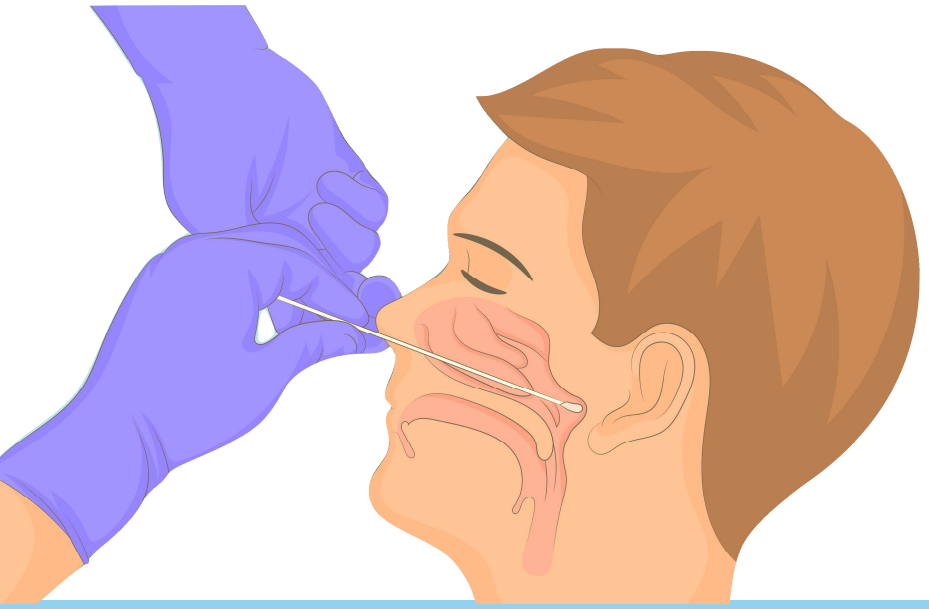
— Infectious Disease Society of America
Guidelines on the Diagnosis of COVID-19, May 2020

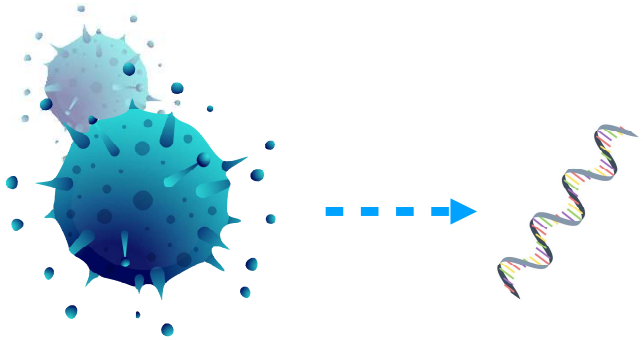
COVID-19 Progression: Viral markers



Modified from Sethuraman et al. JAMA May 6

COVID-19 Molecular Test: Its Purpose

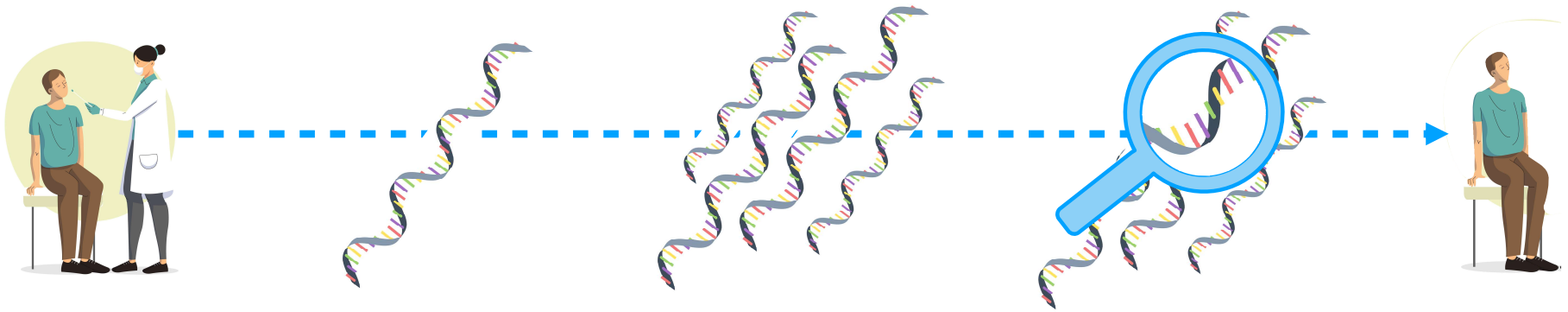




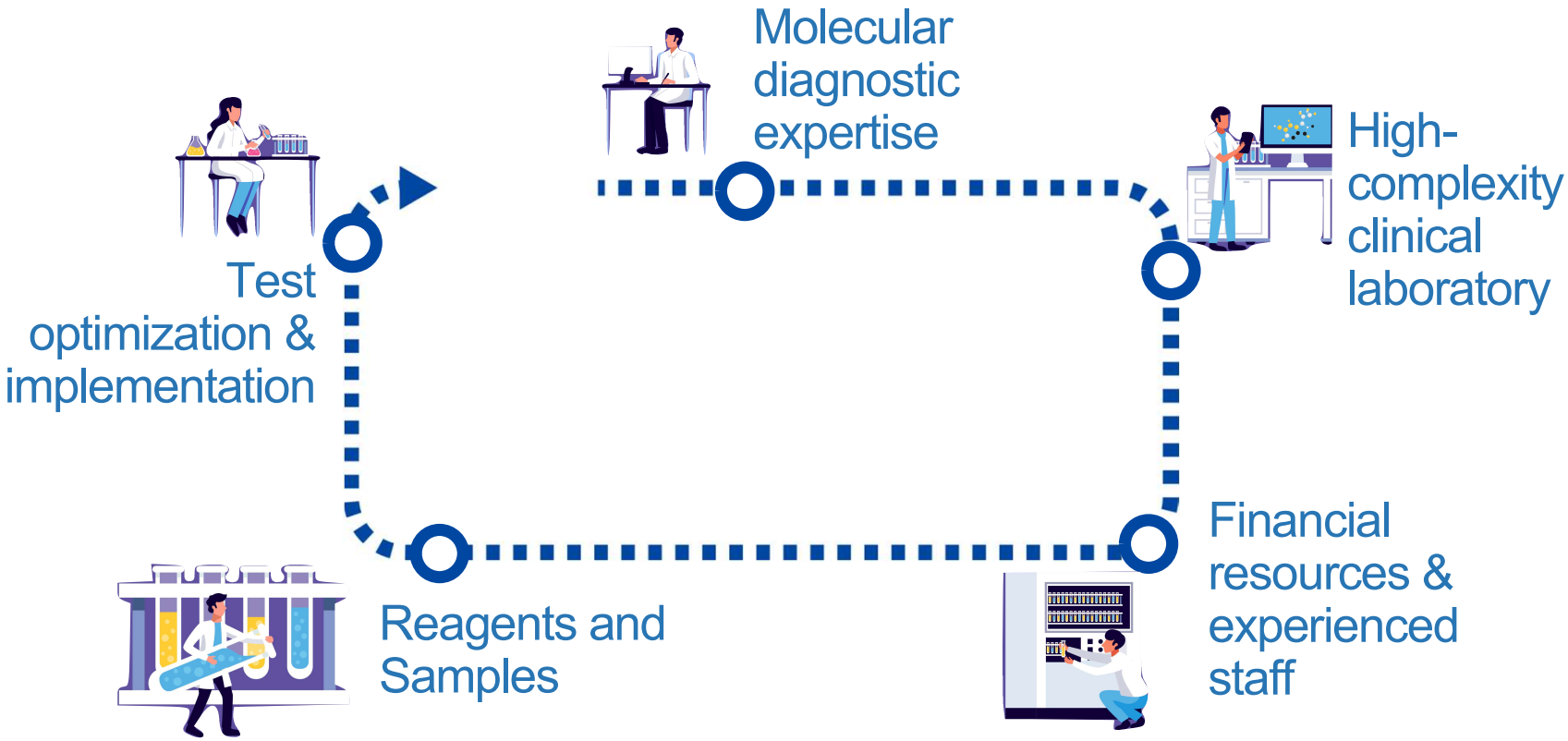
Diagnose acute infection by detecting viral RNA fragment

Virus may be viable or not viable

COVID-19 Molecular Test : From start-to-finish



Developing Molecular Test: A Complex Process



COVID-19 Molecular Tests: Performance

63 vendors and 28 laboratories with approved tests

Analytical Sensitivity

Ability to detect the virus

1,000-fold difference

Analytical Specificity

Ability to only detect the virus

99-100%

SOURCE: FDA COVID-19 EUA Information

Initial Negative Test? When and why repeat

Intermediate to high clinical suspicion	Repeat 24-48 hours
Low clinical suspicion	No re-testing

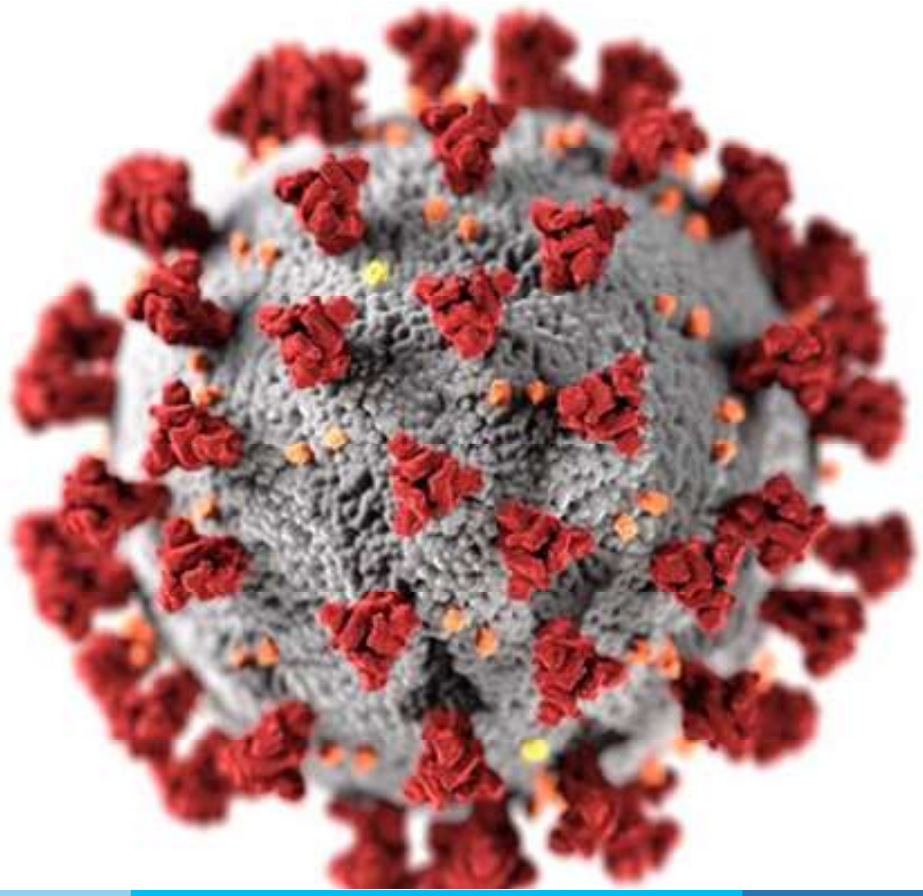
Infectious Disease Society of America Guidelines on the Diagnosis of COVID-19

COVID-19 Molecular Testing: Recap

Utility
Acute infection diagnosis through detection of viral RNA

Development
Requires significant expertise and investment

Interpretation
Clinical and laboratory guidance for optimal results interpretation



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QUESTIONS