

Reinfection

Serological tests

Forecasting: What may happen if stay-at-home orders were to be lifted

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Q: What serology tests are being offered under the policy outlined in Section IV.D of the Policy for Diagnostic Tests for Coronavirus Disease-2019? (Updated 4/20)



A: As stated in Section IV.D of the FDA's *Policy for Diagnostic Tests for Coronavirus Disease-2019*, the FDA does not intend to object to the development and distribution by commercial manufacturers, or development and use by laboratories, of serology tests to identify antibodies to SARS-CoV-2, where the test has been validated, notification is provided to FDA, and information along the lines of the following is included in the test reports:

- **This test has not been reviewed by the FDA.**
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

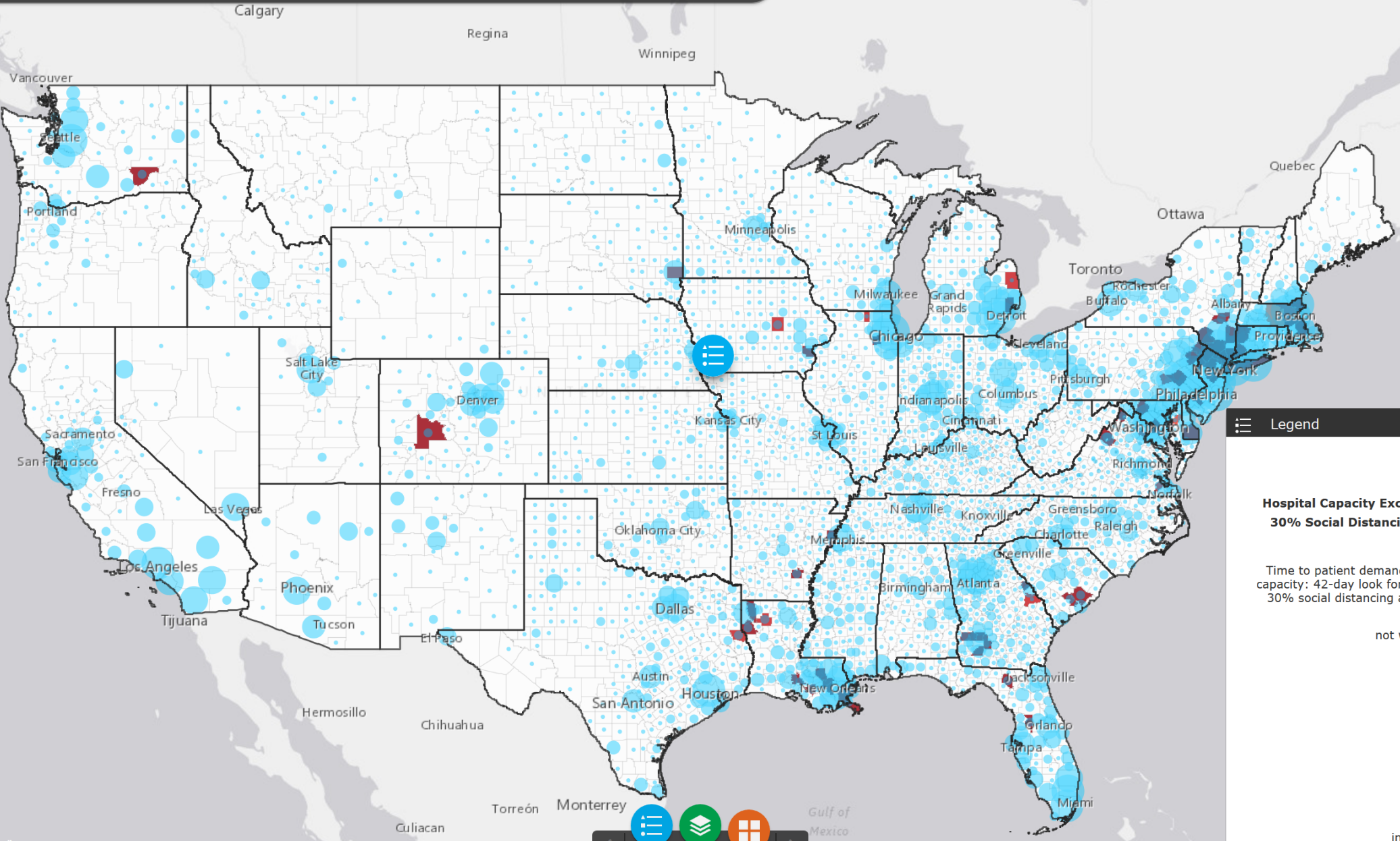
To help ensure the above information is provided in the test report, as described in the guidance, commercial manufacturers could include this information in their Instructions for Use (IFU) or other labeling provided to laboratories.

This policy does not apply to at home testing.

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Legend

1 - 50

**Hospital Capacity Exceeded in 42-days:
30% Social Distancing, Medium Surge
Response**

Time to patient demand exceeding hospital capacity: 42-day look forward from 4/19/20, 30% social distancing and a medium surge response

- not within 42-days
- 36 to 42-days
- 29 to 35-days
- 22 to 28-days
- 15 to 21-days
- 8 to 14-days
- 1 to 7-days
- insufficient data

400km
300mi



Government-mandated social distancing ⓘ

Mass gathering restrictions
👤 March 11, 2020

Initial business closure
🏢 March 16, 2020

Educational facilities closed
🎓 March 13, 2020

Non-essential services closed
📺 March 25, 2020

Stay at home order
🏠 March 23, 2020

Travel severely limited
✈️ Not implemented

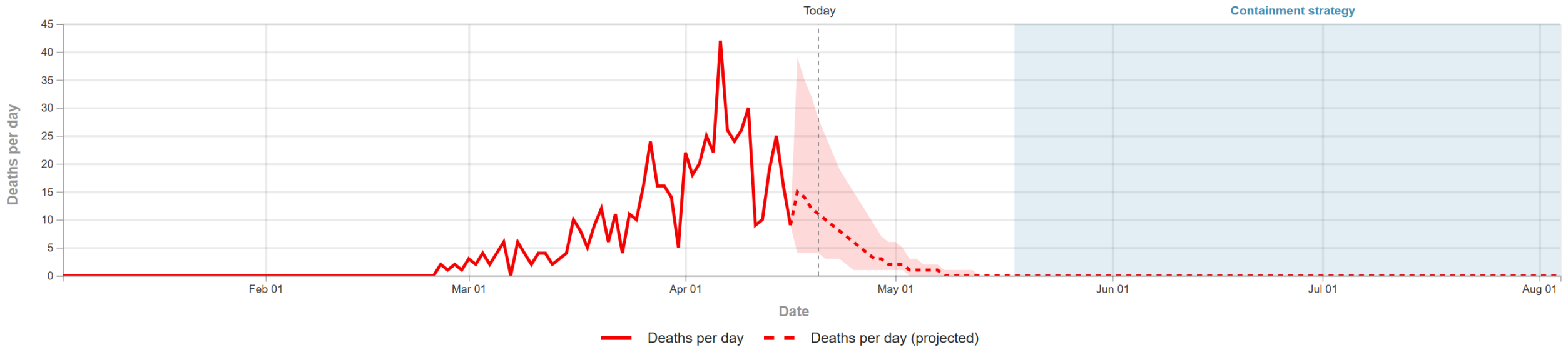
Deaths per day ⓘ

14 days
since projected peak in daily deaths

42 COVID-19 deaths
projected on April 6, 2020

Containment strategy ⓘ

After May 18, 2020, relaxing social distancing may be possible with containment strategies that include testing, contact tracing, isolation, and limiting gathering size.



All deaths specific to COVID-19 patients.

Shaded area indicates uncertainty ⓘ



Government-mandated social distancing ⓘ

Mass gathering restrictions

March 12, 2020

Initial business closure

March 16, 2020

Educational facilities closed

March 18, 2020

Non-essential services closed

March 22, 2020

Stay at home order

March 22, 2020

Travel severely limited

Not implemented

Deaths per day ⓘ

4 days

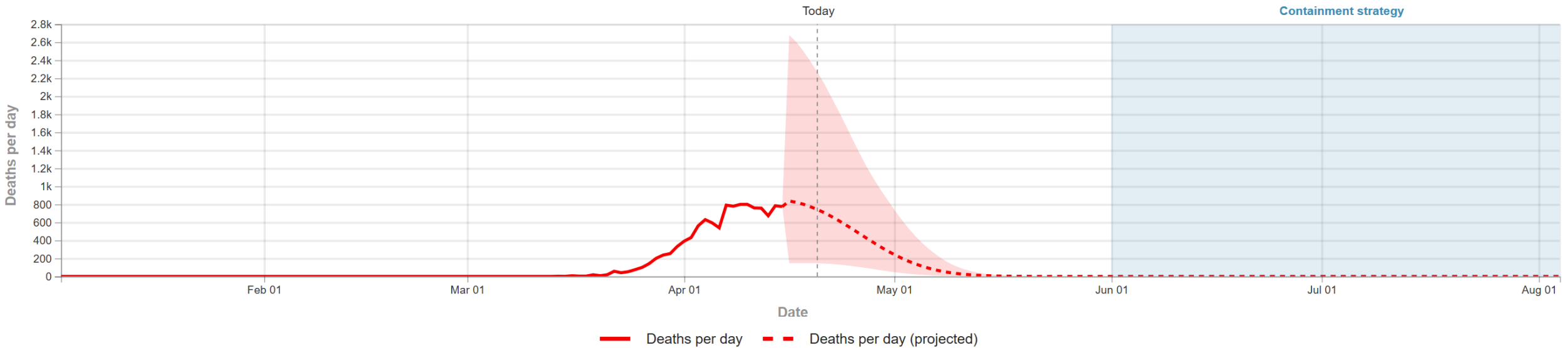
since projected peak in daily deaths

837 COVID-19 deaths

projected on April 16, 2020

Containment strategy ⓘ

After June 1, 2020, relaxing social distancing may be possible with containment strategies that include testing, contact tracing, isolation, and limiting gathering size.



All deaths specific to COVID-19 patients.

Shaded area indicates uncertainty ⓘ



Mass gathering restrictions

March 24, 2020

Initial business closure

March 25, 2020

Educational facilities closed

March 17, 2020

Non-essential services closed

April 1, 2020

Stay at home order

Not implemented

Travel severely limited

Not implemented

Deaths per day

0 days

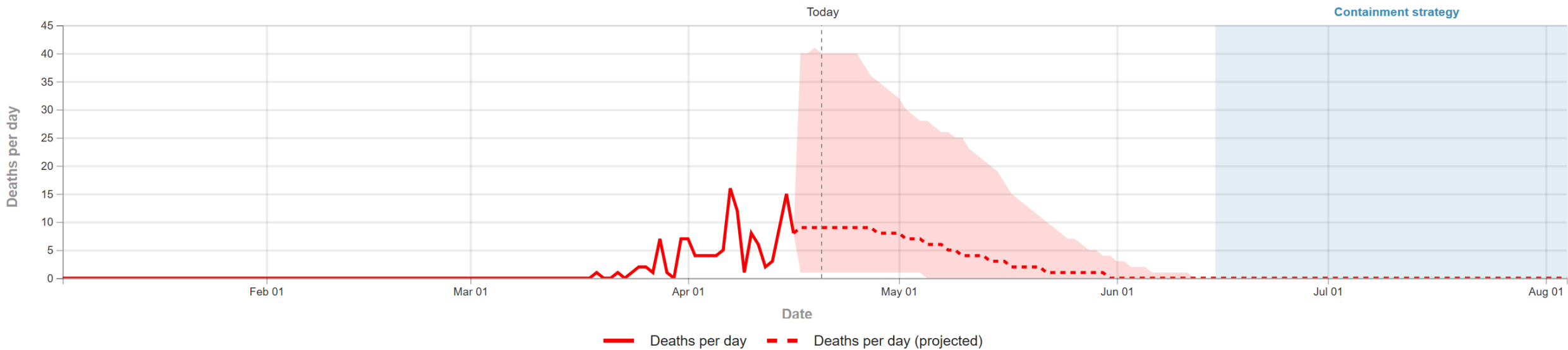
until projected peak in daily deaths

9 COVID-19 deaths

projected on April 20, 2020

Containment strategy

After June 15, 2020, relaxing social distancing may be possible with containment strategies that include testing, contact tracing, isolation, and limiting gathering size.



All deaths specific to COVID-19 patients.

Shaded area indicates uncertainty

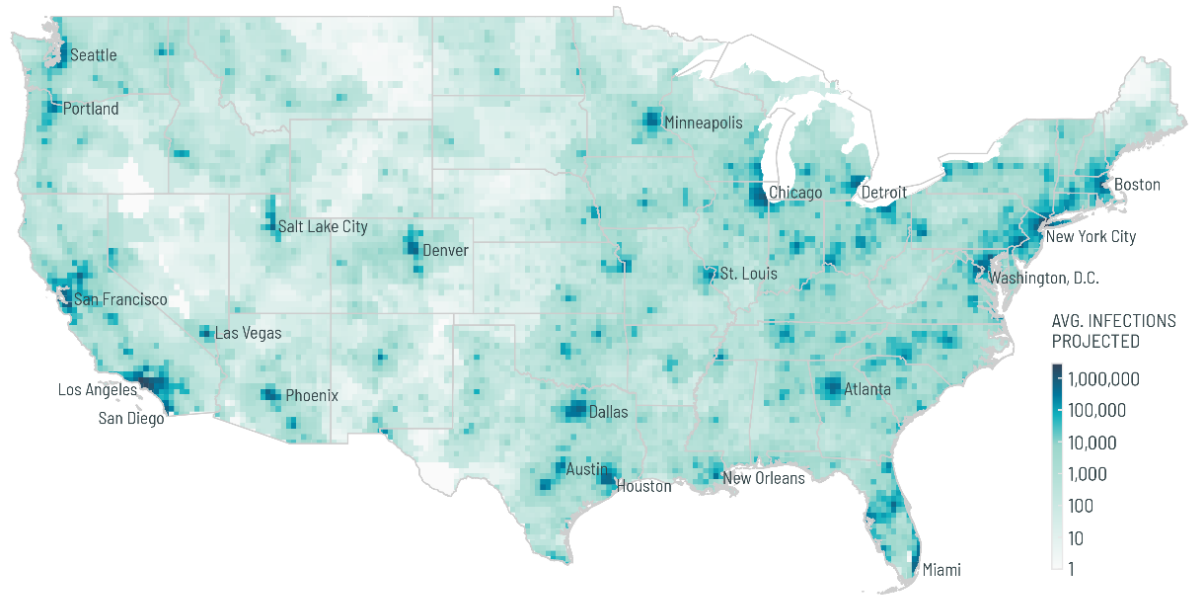
MODELING COVID-19 IN THE UNITED STATES

Projections updated on:
April 4, 2020

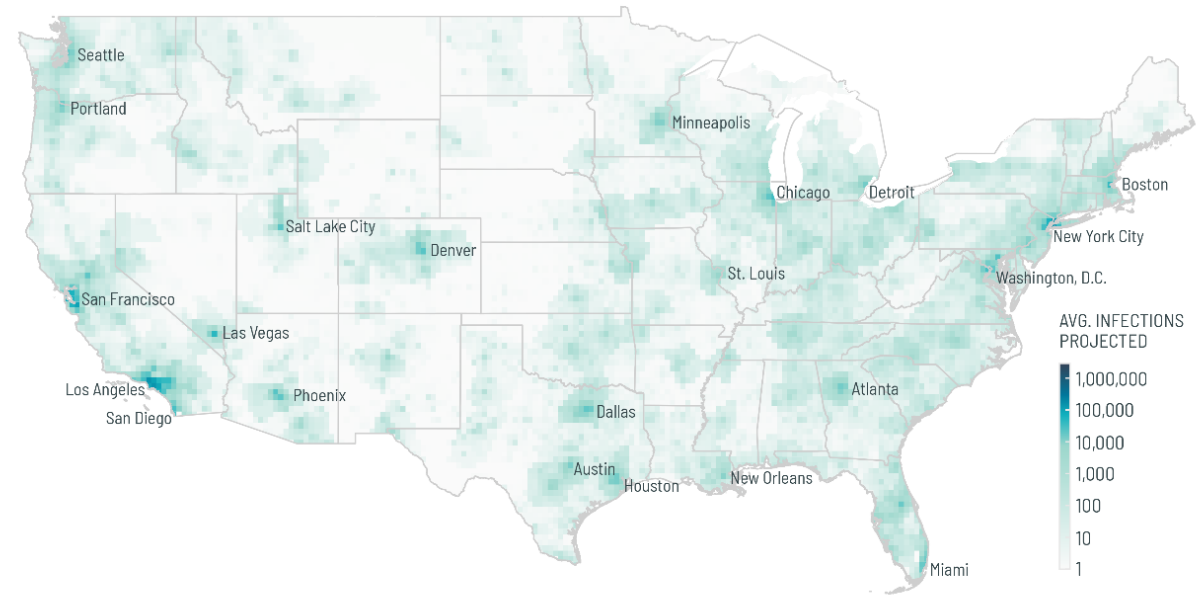
The social distancing projections assume that "stay-at-home" orders and mitigation policies are extended for the entire period of time considered here.

PROJECTIONS FOR:
May 1, 2020 ▼

UNMITIGATED PROJECTIONS



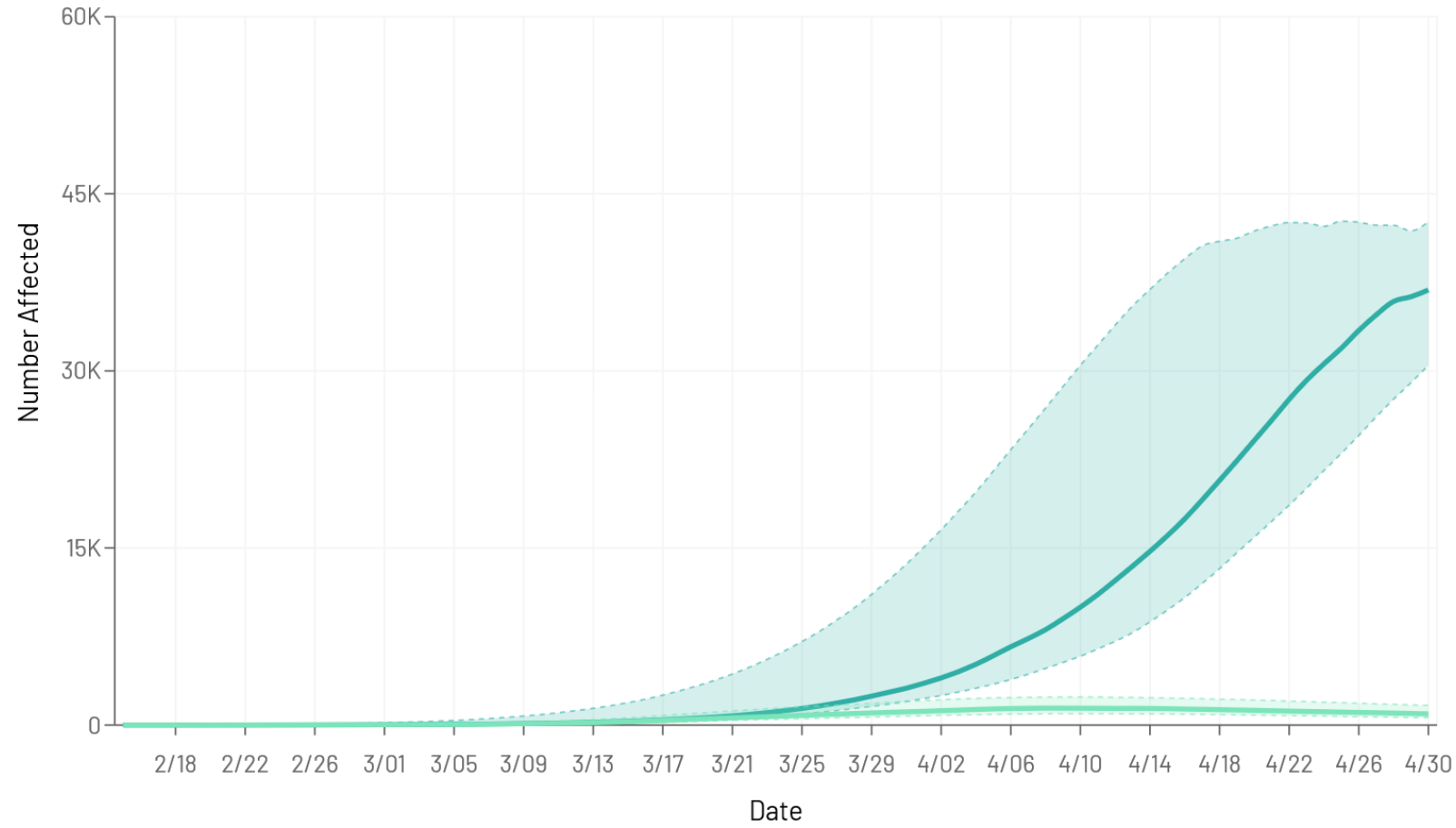
SOCIAL DISTANCING PROJECTIONS



SET LOCATION:

USA

INFECTION AND DEATH PROJECTIONS FOR USA



Metric

- Total Infections per 10,000
- New Deaths

Scenario

- Mitigated
- Unmitigated

Scale

- Linear
- Logarithmic

—○— New Deaths, Unmitigated (Median) —○— New Deaths, Mitigated (Median)