

# COVID-19 ECHO update Nov 18 2020

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No disclosures

Opinions expressed only my own

# Agenda

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-New at-home test

-JAMA articles on

- 1) test avoidance
- 2) clinician experiences hitting limits in resources and patient care

-FDA resource testing overview, CDC meta-guidelines page

-North Dakota epidemic, is this what's in store?

-IHS trends

# Coronavirus (COVID-19) Update: FDA Authorizes First COVID-19 Test for Self-Testing at Home

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**For Immediate Release:** November 17, 2020

Today, the U.S. Food and Drug Administration issued an [emergency use authorization \(EUA\)](#) for the first COVID-19 diagnostic test for self-testing at home and that provides rapid results. The Lucira COVID-19 All-In-One Test Kit is a molecular (real-time loop mediated amplification reaction) single use test that is intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19.

**“The FDA continues to demonstrate its unprecedented speed in response to the pandemic. While COVID-19 diagnostic tests have been authorized for at-home collection, this is the first that can be fully self-administered and provide results at home. This new testing option is an important diagnostic advancement to address the pandemic and reduce the public burden of disease transmission,”** said FDA Commissioner Stephen M. Hahn, M.D. **“Today’s action underscores the FDA’s ongoing commitment to expand access to COVID-19 testing.”**

The Lucira COVID-19 All-In-One Test Kit test has been authorized for home use with self-collected nasal swab samples in individuals age 14 and older who are suspected of COVID-19 by their health care provider. It is also authorized for use in point-of-care (POC) settings (e.g., doctor’s offices, hospitals, urgent care centers and emergency rooms) for all

**Content current as of:**

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Infectious Disease

Coronavirus

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# The Lucira COVID-19 All-In-One Test Kit is the first FDA EUA authorized prescription at-home test for individuals 14 years and older.



1. Swab Your Nose



2. Stir Into Sample Vial



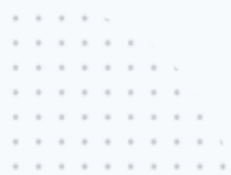
3. Get Results In 30 Minutes



4. Seek Treatment

Our clinical studies show 100% of users 14 and older were able to run our test.<sup>1</sup>

<sup>1</sup>Lucira Usability Clinical Study 07A-CLI-004/005 conducted Summer 2020 (n=352)



# Main points

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- self collected nasal swab
- by prescription only, for ages 14+
- results reported/linked
- wider availability Spring 2021



**New Online**

Views **22,524** | Citations **0** | Altmetric **92** | Comments **5**

**Medical News & Perspectives**

ONLINE FIRST

FREE

November 6, 2020

# First It Was Masks; Now Some Refuse Testing for SARS-CoV-2

Rita Rubin, MA

*JAMA*. Published online November 6, 2020. doi:10.1001/jama.2020.22003



COVID-19 Resource Center



Related  
Articles

## Main points

### **Moving from lack of test access to test avoidance**

- Knox County TN DoH: drop in tests but rise in hospitalizations, drop in University Screening participation from 68% to 45%
- NYC: parents avoiding testing children to ensure schools don't close

### **Reasons:**

- Fear of isolation, quarantine, loss of salary, sport, school
- Pandemic fatigue, exercising right to refuse

### **Discussion:**

- Importance of programs and messaging to recognize disincentives to testing

Original Investigation | Health Policy



November 6, 2020

# US Clinicians' Experiences and Perspectives on Resource Limitation and Patient Care During the COVID-19 Pandemic

Catherine R. Butler, MD, MA<sup>1,2</sup>; Susan P. Y. Wong, MD, MS<sup>1,2</sup>; Aaron G. Wightman, MD, MA<sup>3,4</sup>; [et al](#)

» [Author Affiliations](#) | [Article Information](#)

*JAMA Netw Open.* 2020;3(11):e2027315. doi:10.1001/jamanetworkopen.2020.27315



**COVID-19 Resource Center**

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2772567>



# Overview

- Semi-structured interviews

- Mostly attending physicians from large hospitals

- Discussed moving from contingency to crisis resource allocation situations, resource limitations, barriers to care

# Adapting to Resource Limitations

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- Expected and unexpected shortages could arise suddenly
- Frustration: shortages not acknowledged by leadership
- Struggled with acceptable practice vs. rationing
- Avoid situations where they would have to deny care, go to great lengths for alternative tx that might be unorthodox, nontraditional, and potentially harmful
- Sense of responsibility for poor outcomes



# Multiple Unprecedented Barriers to Care

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- Limiting physical interaction necessary but seen as detrimental to care
- Routine decisions among team could become tense (e.g. physical or remote exam)
- Conflicting goals of conserving resources, protecting oneself, and patient care
- Visitor restrictions complicate and disrupt engaging family members

# A Closer Look at COVID-19 Diagnostic Testing

This overview may be of interest to health care providers, test purchasers, and public health staff who want to know more about different types of tests.

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## For Health Professionals

[Coronavirus Disease 2019 \(COVID-19\) Resources for Health Professionals](#)

[Resources and Tools for Health Professionals](#)

[FDA-Health Professional Activities](#)

[Learning Activities](#)

[Stay Informed](#)

The FDA has been working around the clock to help increase the availability of critical medical products, including diagnostic tests, to fight the coronavirus disease 2019 (COVID-19) pandemic.

A patient and consumer [overview<sup>1</sup>](#) of COVID-19 testing has plain language information about both diagnostic and antibody testing for COVID-19. This companion resource takes a closer look at diagnostic testing for COVID-19 and may be of interest to health care providers, test purchasers, and other public health professionals.

## COVID-19 Diagnostic Tests

In certain types of emergencies, the FDA can issue an emergency use authorization, or EUA, to provide more timely access to critical medical products (including medicines and tests) that may help during the emergency when there are no adequate, approved, and available alternative options. The FDA has authorized for emergency use many [tests<sup>2</sup>](#) that can diagnose infection with the virus that causes COVID-19, [severe acute respiratory syndrome coronavirus 2](#) or [SARS-CoV-2](#).

## Emergency Use Authorization

The EUA process is different than FDA approval, clearance, or licensing because the EUA standard is more flexible than the full approval, clearance, or licensing standard. Under an EUA, the data must show that a product may be

**Content current as of:**  
11/16/2020

**Regulated Product(s)**  
Medical Devices  
Laboratory Tests

**Topic(s)**  
Outbreak  
CLIA (Clinical Laboratory Improvement Amendments)

**Health Topic(s)**  
Coronavirus



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# Clinical Questions about COVID-19: Questions and Answers

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html>

Updated Nov. 12, 2020

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What are you looking for?

## On This Page

[COVID-19 Risk](#)

[Infection Control](#)

[Transmission](#)

[Testing, Diagnosis, and Notification](#)

[Testing in Nursing Homes](#)

[Treatment and Management](#)

[Testing, Isolation, and Quarantine for Persons Who Have Recovered from Previous SARS-CoV-2 Infection](#)

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# Treatment and Management

## [Should post-exposure prophylaxis be used for people who may have been exposed to a person with COVID-19?](#) -

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There is currently no FDA-approved post-exposure prophylaxis for people who may have been exposed to COVID-19. For information about registered clinical trials of investigational therapeutics for pre- or post-exposure prophylaxis of SARS-CoV-2 infection, visit [ClinicalTrials.gov](https://clinicaltrials.gov) [↗](#).

For more information on movement restrictions, monitoring for symptoms, and evaluation after possible exposure to COVID-19, see [Interim US Guidance for Risk Assessment and Public Health Management of Persons with Potential Coronavirus Disease 2019 \(COVID-19\) Exposure in Travel-associated or Community Settings](#) and [Interim U.S Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease 2019 \(COVID-19\)](#).

The National Institutes of Health recently published guidelines on prophylaxis use for COVID-19 and testing and management of COVID-19 patients. For more information, please visit: [National Institutes of Health: Coronavirus Disease 2019 \(COVID-19\) Treatment Guidelines](#) [↗](#).

**How are COVID-19 patients treated?** +

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**Do patients with confirmed or suspected COVID-19 need to be admitted to the hospital?** +

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**When can patients with confirmed COVID-19 be discharged from the hospital?** +

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[Top of Page](#)

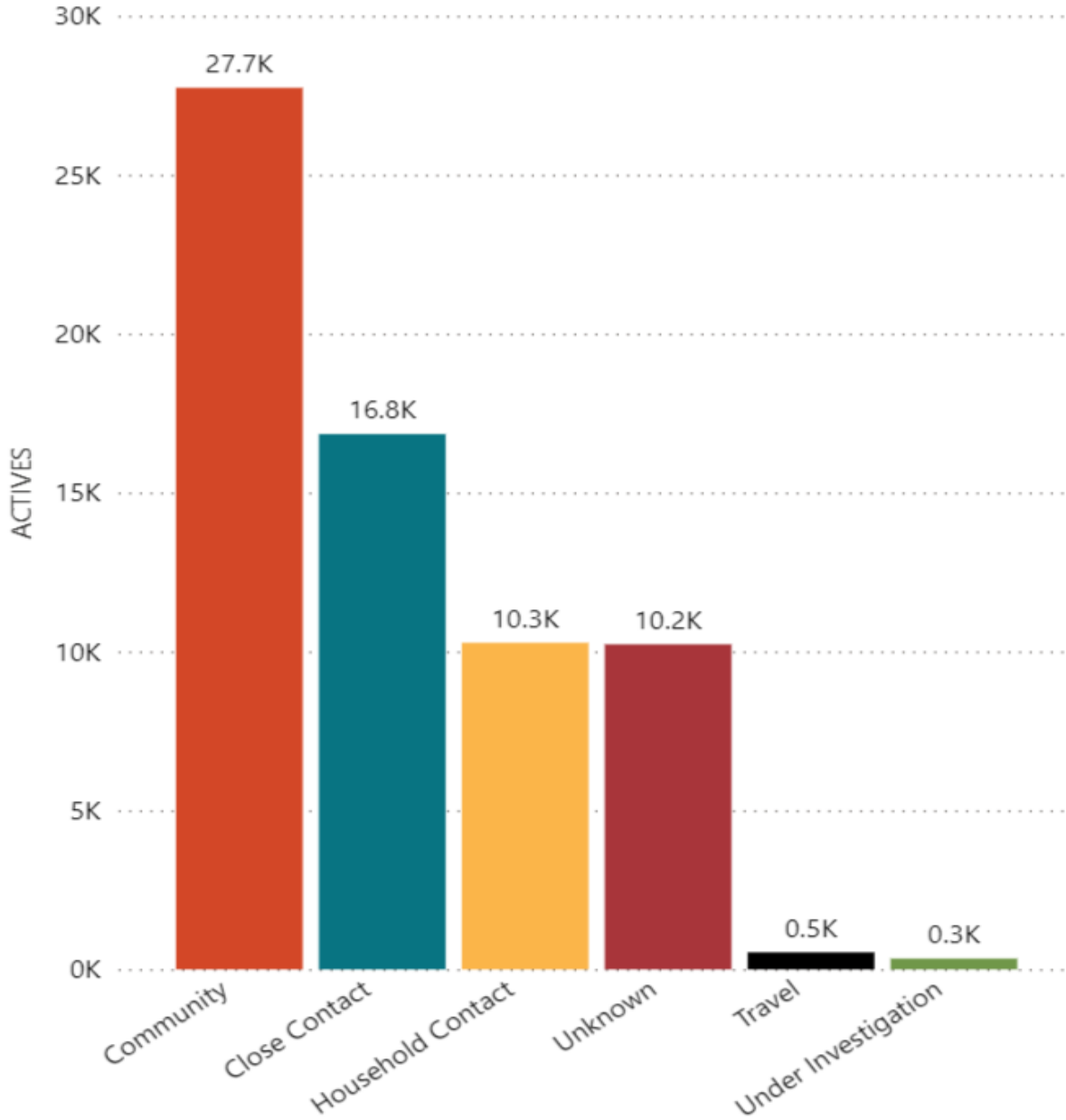
# Snapshot from North Dakota

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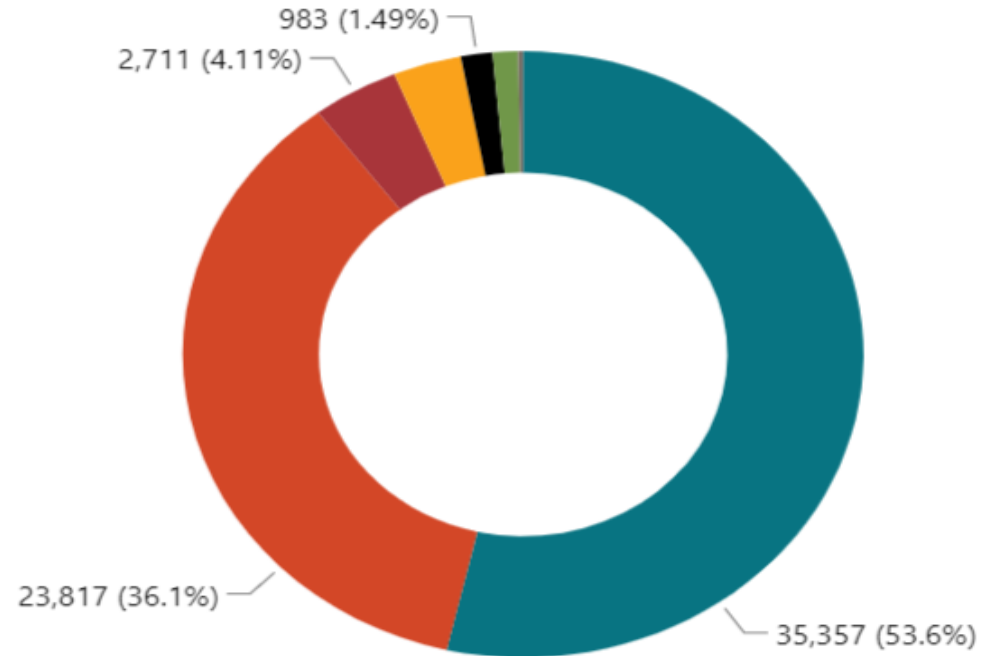
<https://doh.sd.gov/COVID/Calculator/default.aspx>

<https://www.health.nd.gov/diseases-conditions/coronavirus/north-dakota-coronavirus-cases>

### SPREADTYPE



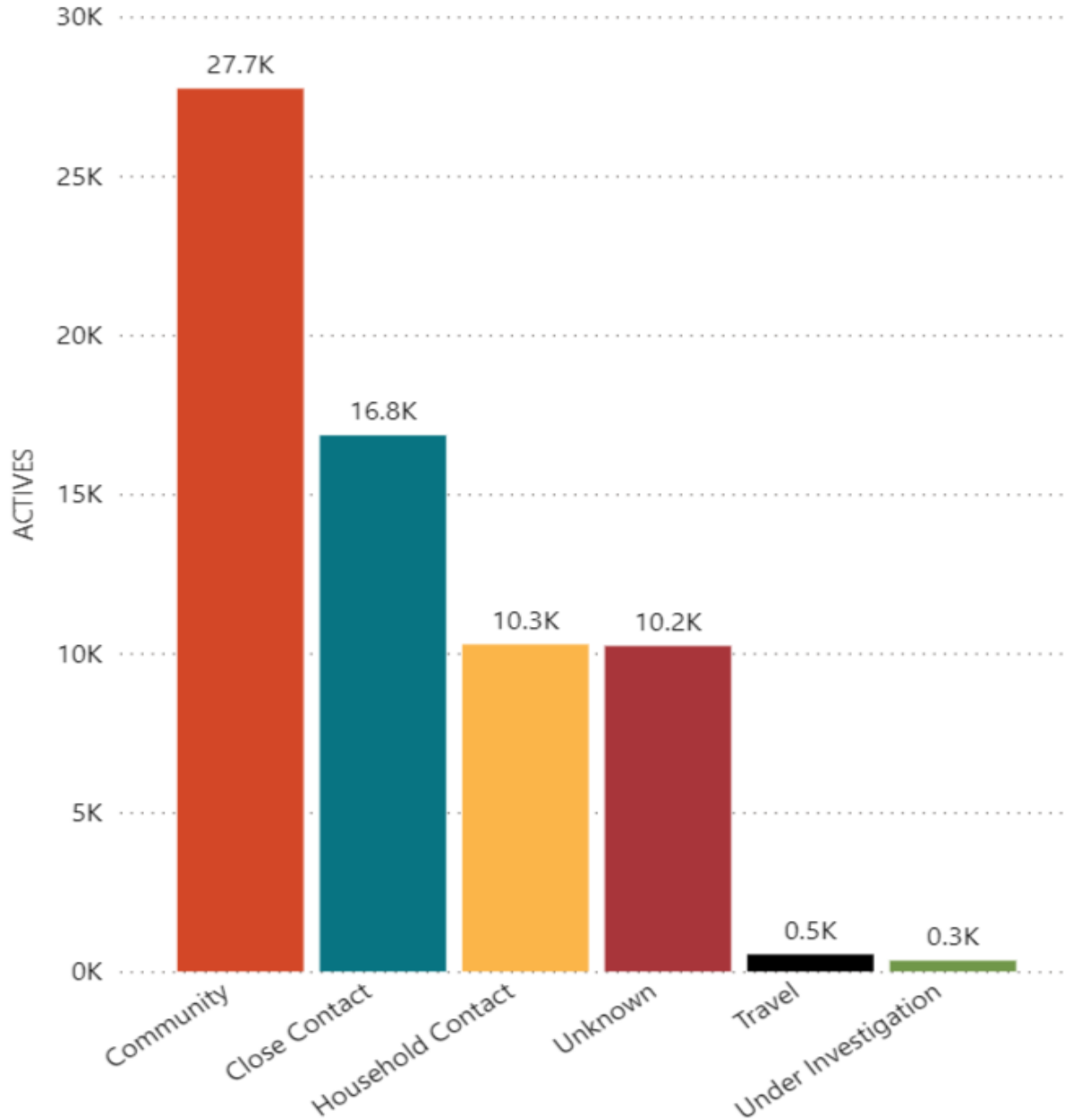
### RACE



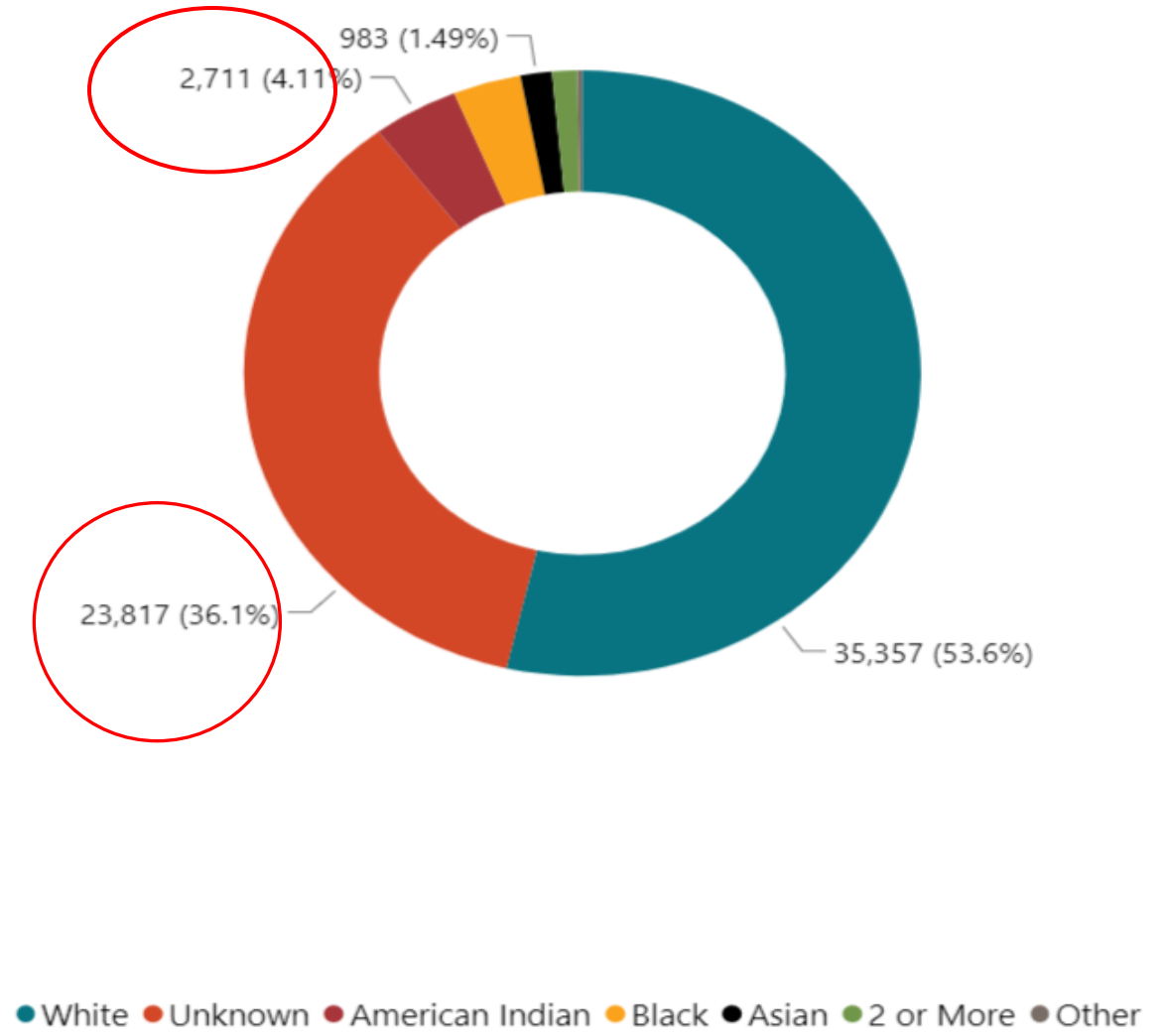
● White ● Unknown ● American Indian ● Black ● Asian ● 2 or More ● Other



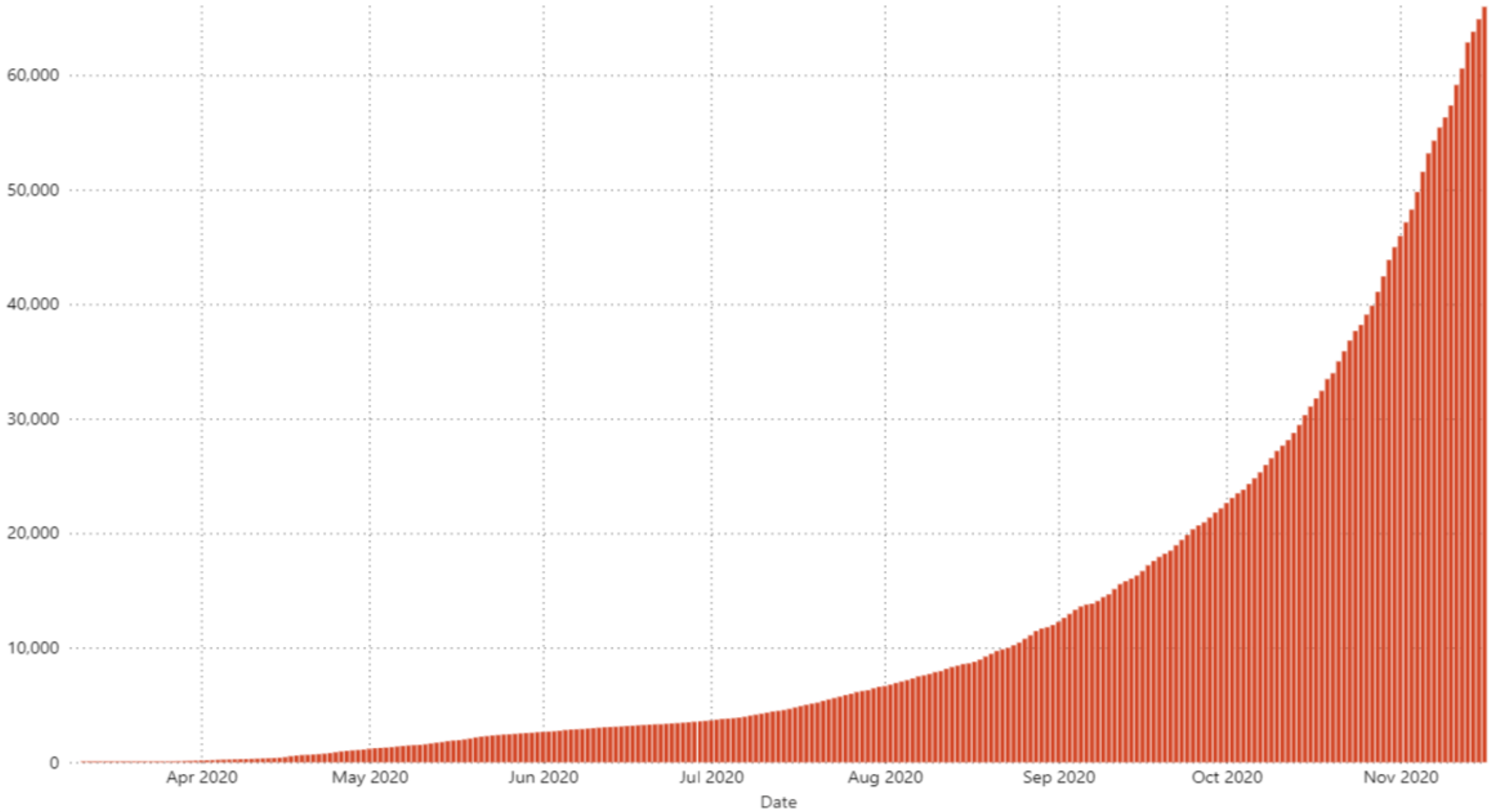
### SPREADTYPE



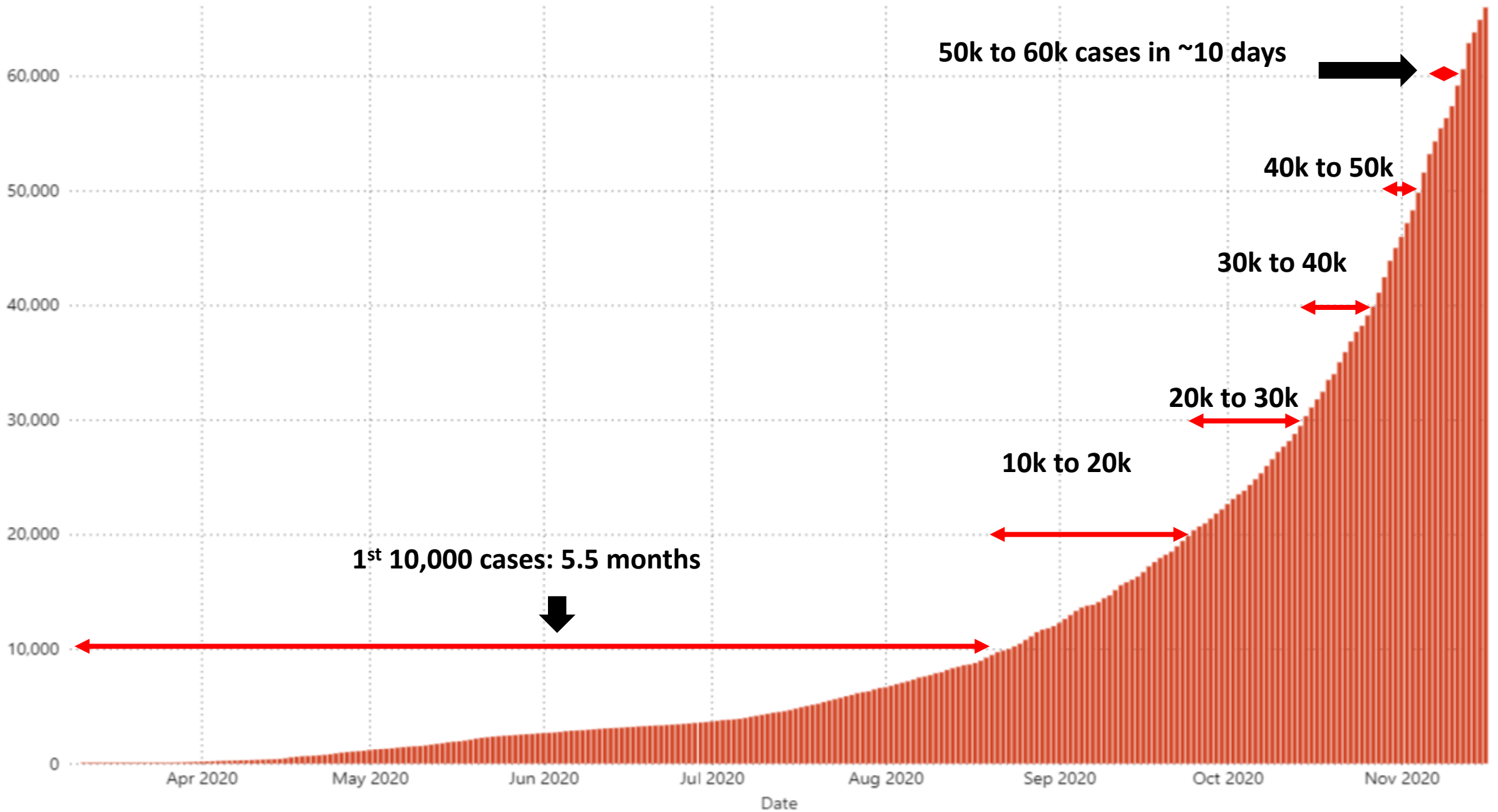
### RACE



# Cumulative Positives



# Cumulative Positives



**DAILY**

**CUMULATIVE**

POSITIVES

PREVIOUSLY TESTED NEG. BEFORE POS. TEST

POSITIVES

RECOVERED

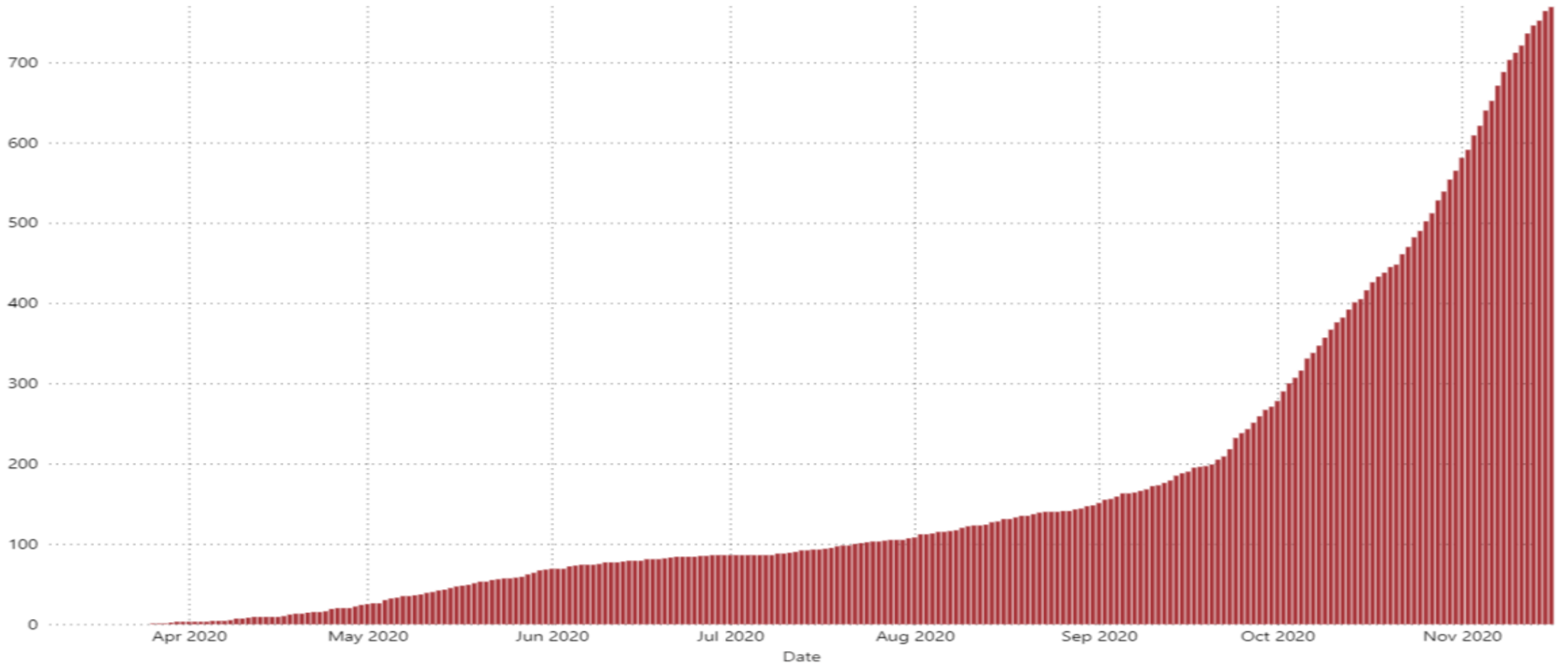
SERIAL TESTS

UNIQUE TESTS

14 DAY AVERAGE TOTAL PROCESSED TESTS

**DEATHS**

### Cumulative Deaths



# By age

- 10% cumulative cases 70+ y.o. (6,698/65,967)

-39% of current hospitalizations 70+ y.o. (157/399)

-83% cumulative deaths 70+ y.o. (642/769)

Of note approximately 1 in 1000 ND state residents have died of COVID-19 disease

## QUARANTINE AND ISOLATION CALCULATOR

### You have tested positive and have symptoms: Isolation Calculator

If you are symptomatic and have tested positive for COVID-19 then you must isolate for 10 days from the date your symptoms began. To stop or discontinue isolation, at least 10 days must have passed since your symptoms began **and** at least 24 hours have passed since your fever went away without the use of fever-reducing medications (such as Tylenol or Ibuprofen) **and** other symptoms have improved.

Enter the first day your symptoms began below.

### You have tested positive but have no symptoms: Isolation Calculator

If you are not symptomatic and have tested positive for COVID-19 then you must isolate for 10 days from the day you had your test done.

Enter your test date below.

### You have been identified as a close contact: Quarantine Calculator

If you have been in close contact with someone diagnosed with COVID-19 and are not having any symptoms

Enter the date of last contact with the person who tested positive below.

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If your symptoms have improved and 24 hours have elapsed without a fever without the use of medication, your last FULL day of isolation is: 11/29/2020.

### Your isolation ENDS on: 11/30/2020.

On this date, you may resume your usual activities but should still take precautions to reduce your risk (i.e. social distancing, frequent handwashing, and wearing a mask when social distancing isn't possible).



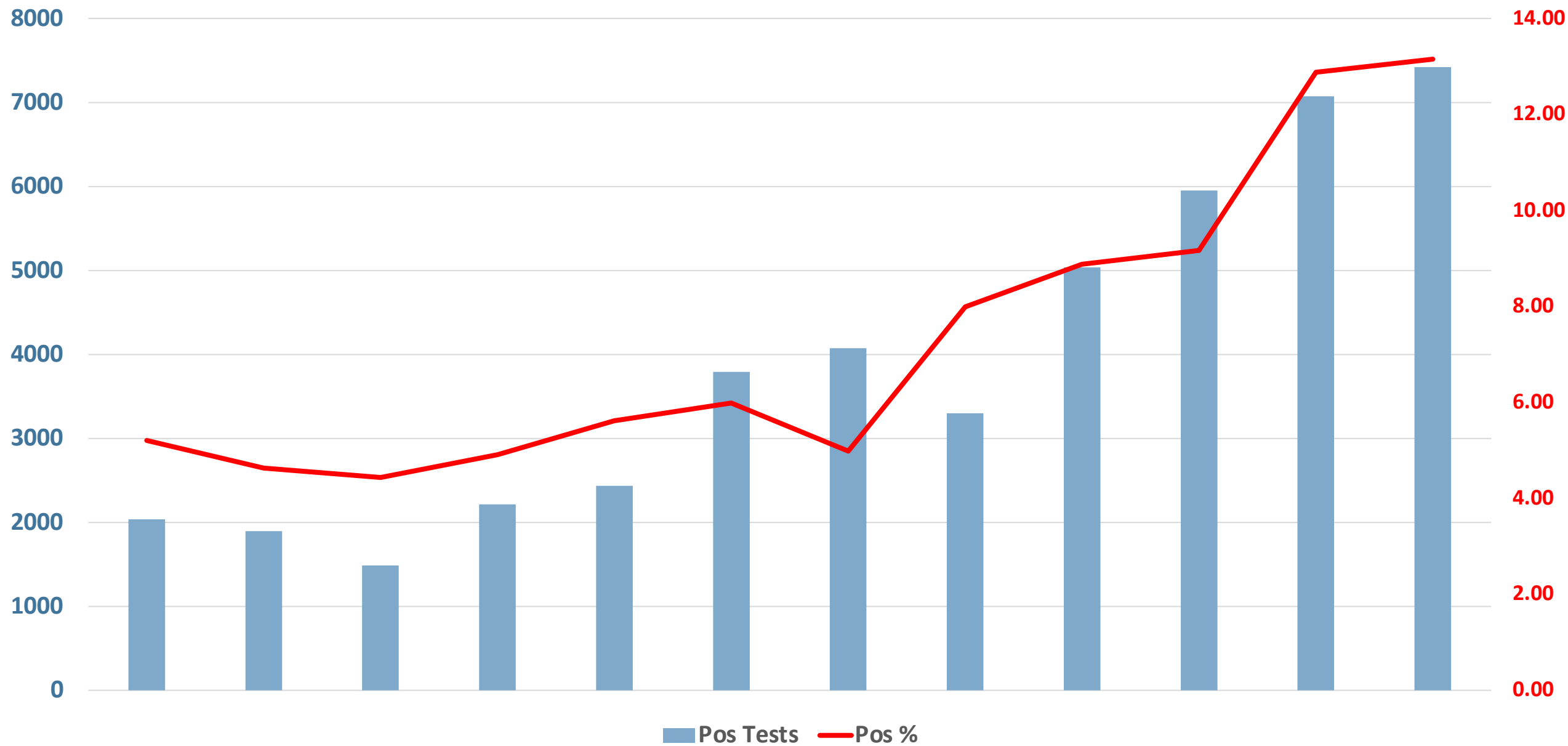


# IHS Dashboard Data update

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TRENDS LAST 2 WEEKS

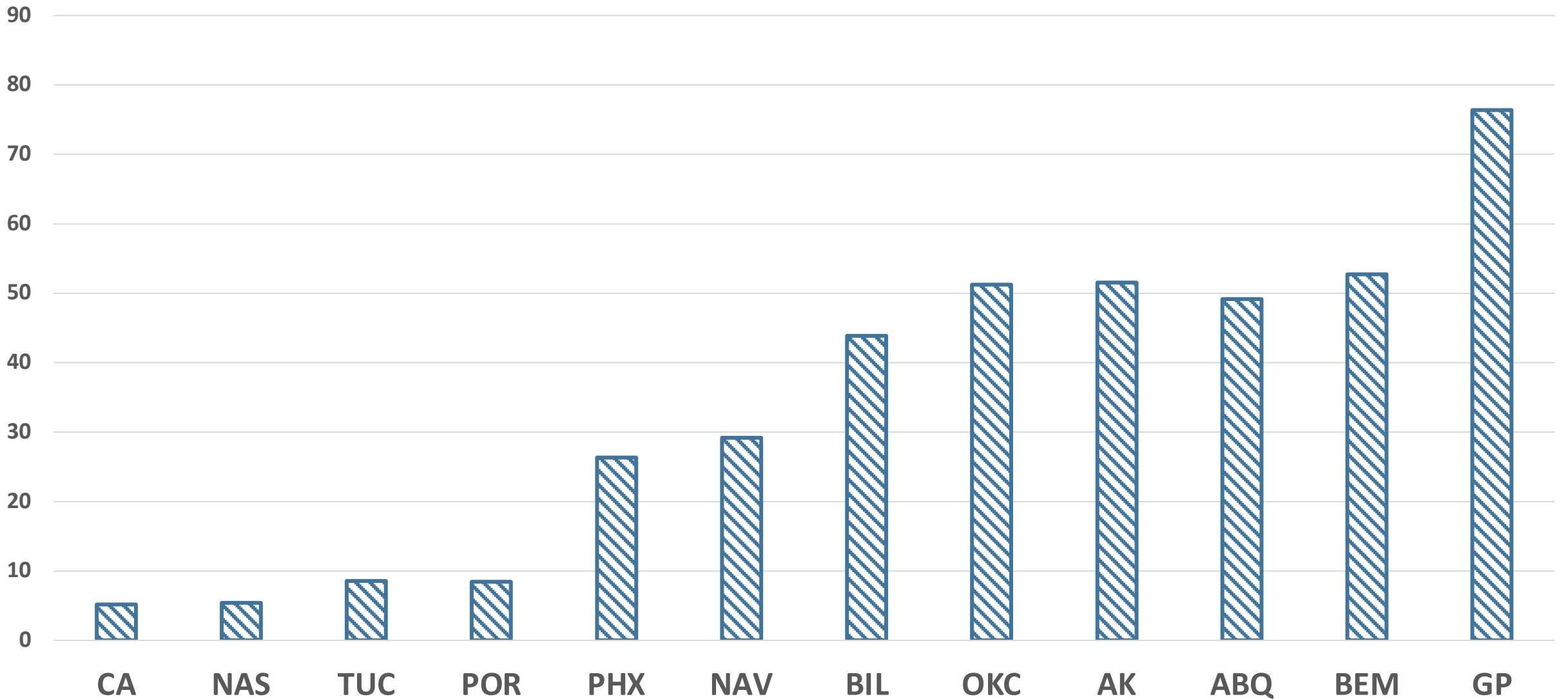
Positive tests, % Positive, IHS COVID Dashboard Aug 21-Nov 14, weekly



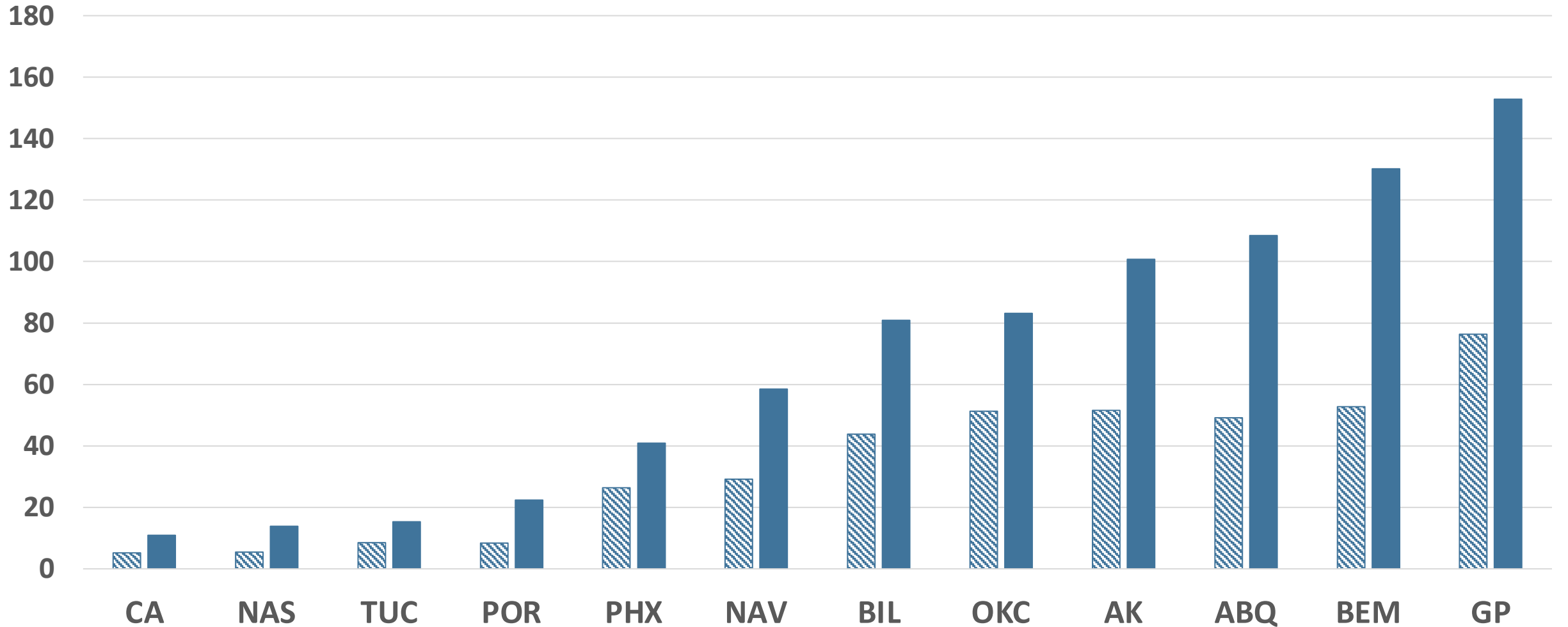


# Pos tests/10,000 User Pop, 11/1-11/7 2020

## IHS COVID Dashboard, by Area



Pos tests/10,000 User Pop,  
Nov 1 to Nov 7 (pattern) and Nov 8 to Nov 13 (solid)  
IHS COVID Dashboard, by Area



# Takeaways

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7 day rolling average positivity (positive tests/total tests) elevated

- >5% 11/12 Areas
- >10% in 7 Areas
- >15% in 4 Areas
- >20% in 1 Area
  
- All Areas trending upward in rates of positive tests per user pop, >2x in CA, NAS, POR, ABQ, BEM, GP

-Cumulative total of 88,765 + tests

Almost there

