

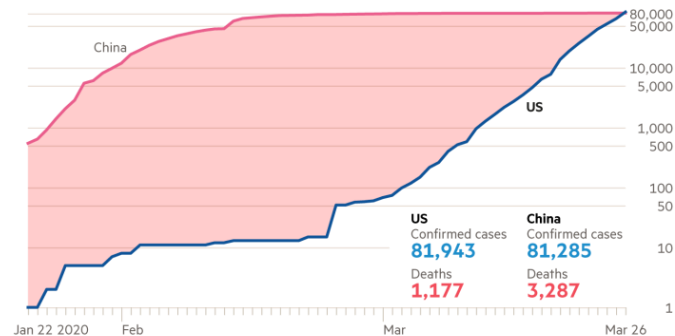
## A Rapid Covid-19 IgM/IgG Serological Test for Point-of-Care

# U.S. Covid-19 Cases Now Surpass China

– Covid-19 cases in U.S. could be worse than Italy if we do nothing to change the course

## US Covid-19 cases now surpass China

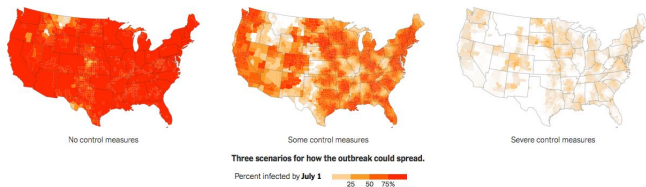
Cumulative number of cases as of 8.46pm Mar 26 GMT



Sources: FT analysis of Johns Hopkins University, CSSE; Worldometers  
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## Coronavirus Could Overwhelm U.S. Without Urgent Action, Estimates Say

By James Glanz, Lauren Leatherby, Matthew Bloch, Mitch Smith, Larry Buchanan, Jin Wu and Nicholas Bogel-Burroughs March 20, 2020



BREAKING | 20 views | Mar 27, 2020, 01:24pm EDT

## New York Now Has Almost Half Of All Coronavirus Cases In The U.S.



Sergei Klebnikov Forbes Staff

Markets

I cover breaking news, with a focus on money and markets.



Another 7,377 cases were reported overnight, Cuomo said. EDUARDO MUNOZ ALVAREZ/GETTY IMAGES

**Topline:** New York Governor Andrew Cuomo said in a press conference on Friday that the number of reported coronavirus cases in the state has risen to nearly 45,000 people, and though the rate of infection is still doubling, it is doing so at a slower pace.

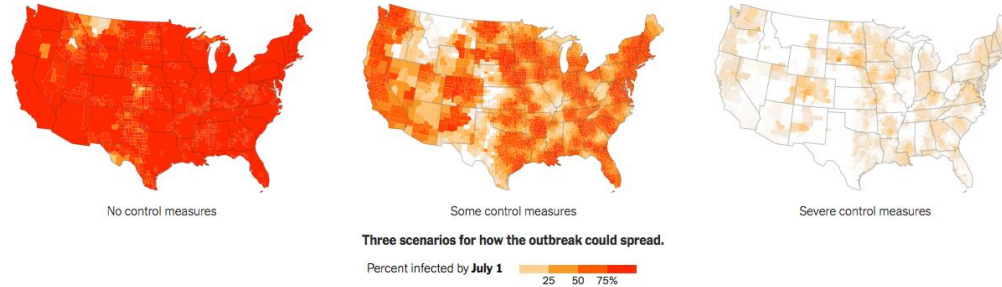
## Critical Needs – Test, Test, Test

– More than 60% of all infected cases are transmitted from asymptomatic carriers

**nature**  
International weekly journal of science

### Coronavirus Could Overwhelm U.S. Without Urgent Action, Estimates Say

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Nicholas Bogel-Burroughs March 20, 2020



– Based on Nature report, more than 60% of all infected cases are transmitted from asymptomatic carriers (<https://www.nature.com/articles/d41586-020-00822-x>).

– A rapid, affordable test at the point-of-care test is essential to control the virus and alleviate current testing bottleneck.

# Our Response – A UNITE TEST

– A Rapid Covid-19 Serological IgG/IgM Test

**U**ndercovers anti-covid19 IgM and IgG antibodies

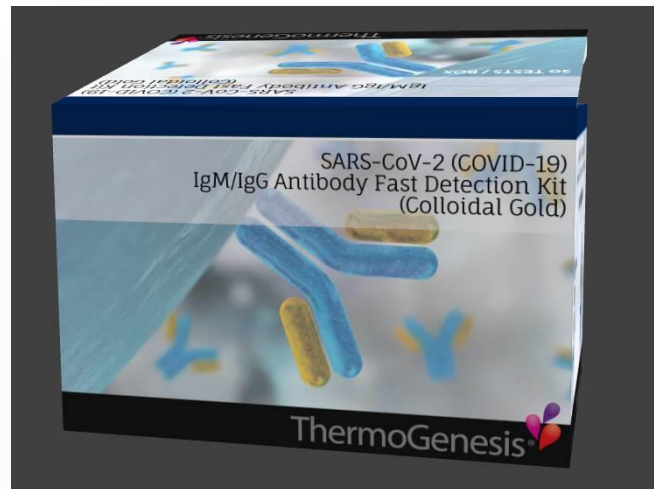
**N**eeds only a single drop of blood

**I**n less than 10 minutes

**T**ested at the point-of-care

**E**xpected cost less than \$30

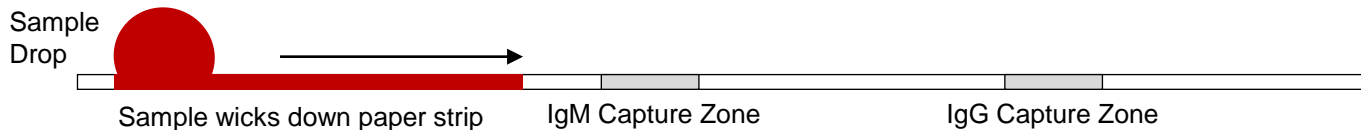
- *Simple: no lab equipment required.*
- *Easy: fingertip blood sample (same as home glucose test)*
- *Fast results: less than 10 minutes to result*



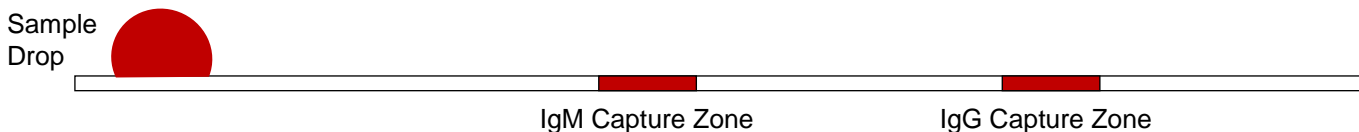
## How It Works

In immunochromatography for serological (antibody) testing, a small blood sample is mixed with reagents containing purified viral protein labeled with a dye.

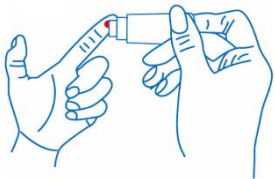
Applied to a paper strip, the sample wicks along the length of the strip, carrying along the antibodies (if present) and dyed viral protein they bind to.



Separate capture zones for IgM and IgG antibodies yield visible red stripes of anti-virus IgM and/or IgG antibodies if present in the sample.



# Performing the Test and Interpreting the Results



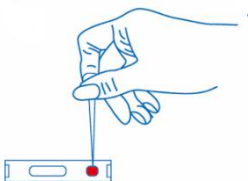
## Collect

Using the included lancet, 1 drop of fingertip blood is collected.



## Mix

The specimen is mixed with the included reagent.

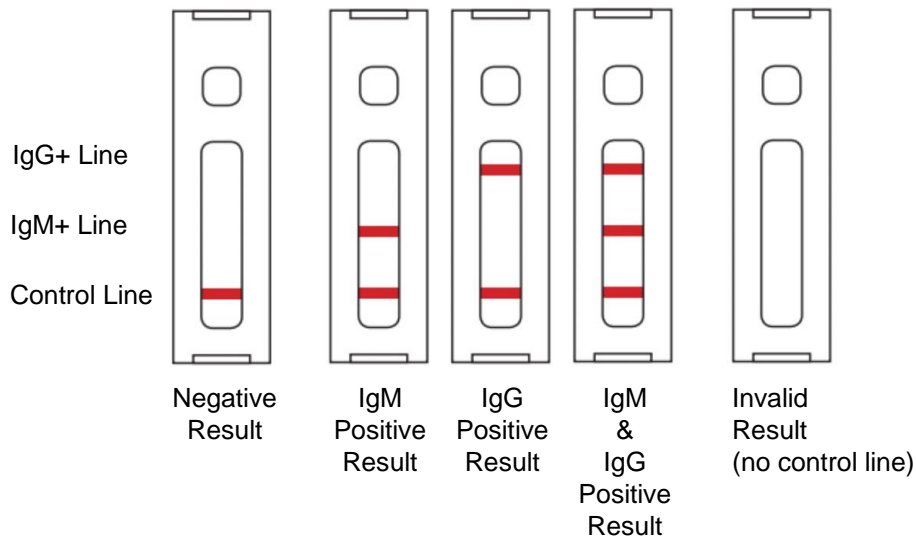


## Load

Five drops of the blood/reagent mixture are added to the included test cartridge.

## Results

Three minutes later, the result is read by eye.

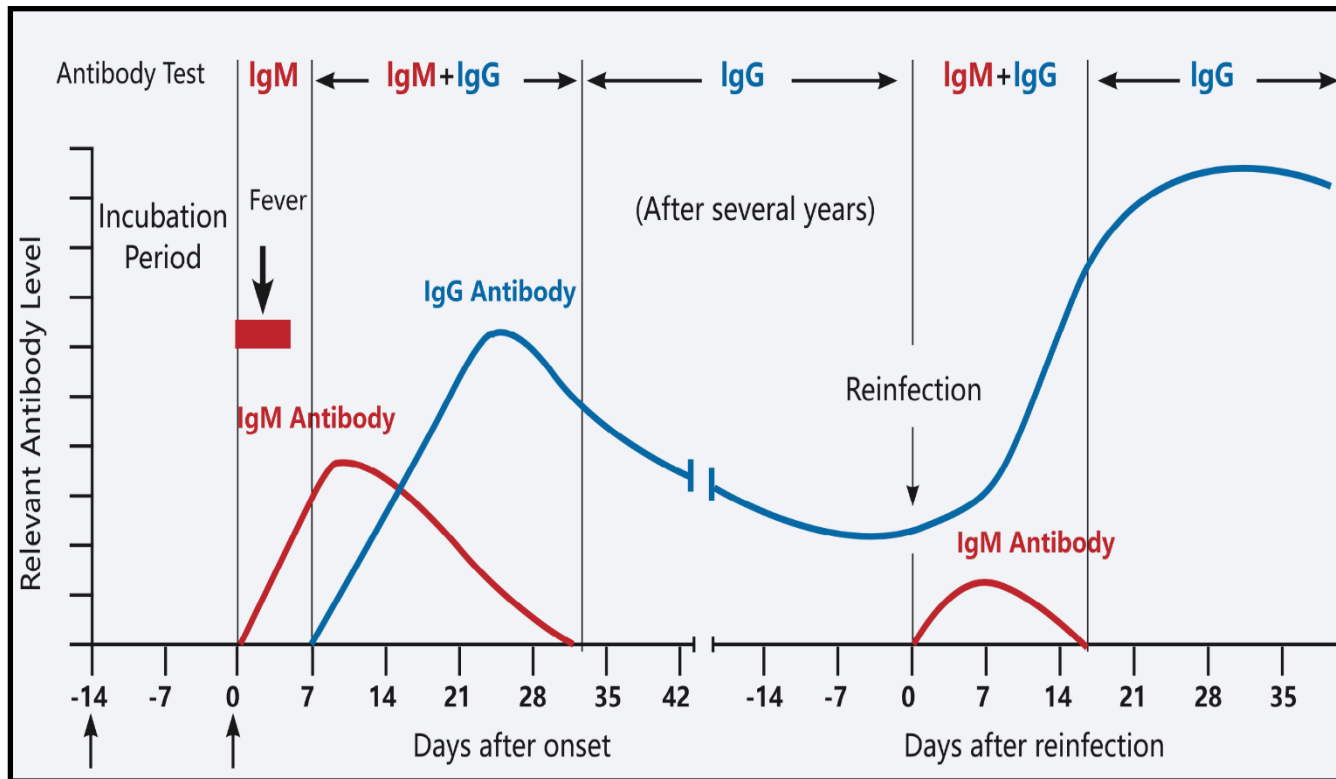




# Detecting anti-Covid19 Ab Response, Not the Virus *Per Se*

Timeline of COVID-19 Infection and Patient's Immune Response

- Human immune system mounts an IgM and IgG antibody response in patients infected with coronavirus
- IgM and IgG antibodies can be detected in Covid-19 infected patients 0-7 days earlier than clinical signs and symptoms appear.
- ThermoGenesis Covid-19 IgM/IgG Detection Kit is administered similar to a home diabetic glucose test & can be read within 10 minutes.
- If detected in asymptomatic person, it may also mean the person has recovered from mild infection and have developed protective immunity.



# Triage of Individuals Based on Test Results

## ***Symptomatic Individuals:***

- **Positive result (+):** indicates that there is an ongoing COVID-19 infection.
- **Negative result (-):** indicates that either not a COVID-19 case or still in early phase of viral infection
  - ➔ Retest with PCR method can rule out viral infection.

## ***Asymptomatic Individuals:***

- **Positive result (+):** indicates the person may either in early infection stage or may have recovered
  - ➔ Retest in 14 days, if no symptom has developed, that means the person has recovered.
- **Negative result (-):** healthy.

## ***Note:***

- All serological tests have false positives and false negatives. In addition, a small number of patients may never develop antibody response to the virus, therefore could be negative even with an ongoing viral infection.



## Validated Performance

Clinical studies conducted by Jiangsu Superbio Biomedical (Nanjing) Co., Ltd. (using PCR-positive and -negative patient blood samples) indicate high reliability:

**111 of 112** PCR-NEGATIVE PATIENTS TESTED NEGATIVE (99.1% Negative Coincidence Rate)

**14 of 14** PCR-POSITIVE PATIENTS TESTED POSITIVE (100% Positive Coincidence Rate)

In additional studies, no cross-reactivity (false positives) was observed in PCR-negative patients known to be positive for Influenza A, Influenza B, Adenovirus, Mycoplasma pneumonia, or Respiratory syncytial virus infections.

## With a COVID-19 Vaccine At Least a Year Away, Rapid Testing is the Immediate Critical Unmet Need

- Conventional PCR-based testing requires sophisticated central laboratory technology, imposing days or weeks of delay from specimen collection to reported result.
- Serological (antibody) tests employing immunochromatography (IC) are the 'gold standard' for truly rapid serological testing.
- **2012:** FDA approved first IC test for HIV, stating:  
*“This test is targeted to people who would not otherwise be tested. There's a large group of people who are infected, and don't know it [...] FDA predicts that the availability of the OraQuick HIV test will contribute measurably to public health.”*

### ***Immunochromatography (Serological Test):***

- *Mature, robust, rapid technology requiring no special equipment;*
- *Ideal for point-of-care and community testing.*

# Ensure Future Benefit of Immunotherapies to Everyone in Needs

**For more information:**

For ImmuneCyte, visit:

[www.immunecyte.com](http://www.immunecyte.com)