

Consumer and Investment Management Division

# Re-Opening of the Economy and Managing Risks of Additional Waves (Eleventh in a Series)

April 30, 2020

# **Investment Strategy Group**

Taking Stock of COVID-19

# Roadmap to Re-Opening

## Role of Serological Testing

## Luciana Borio, Vice President, In-Q-Tel

- Former Director for Medical and Biodefense Preparedness Policy, National Security Council
- Former Acting Chief Scientist of the Food and Drug Administration
- Adjunct Assistant Professor of Medicine at Johns Hopkins University

# Mark McClellan, Director, Duke-Margolis Center for Health Policy at Duke University

- Former Administrator of the Centers for Medicare & Medicaid Services
- Former Commissioner of the Food and Drug Administration
- Former member of the President's Council of Economic Advisers

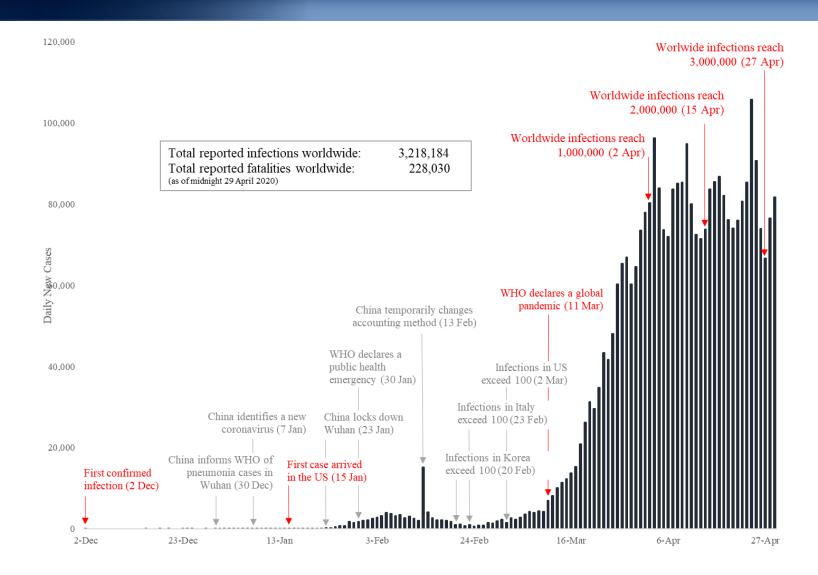
# **Florian Krammer,** Professor of Vaccinology, Icahn School of Medicine at Mount Sinai

- First in the nation to develop a COVID-19 antibody test
- Previously focused on the design of a universal influenza vaccine
- Principal Investigator of the Sinai-Emory Multi-Institutional Collaborative Influenza Vaccine Innovation Center that aims to develop improved seasonal and universal influenza vaccines

Source: Investment Strategy Group

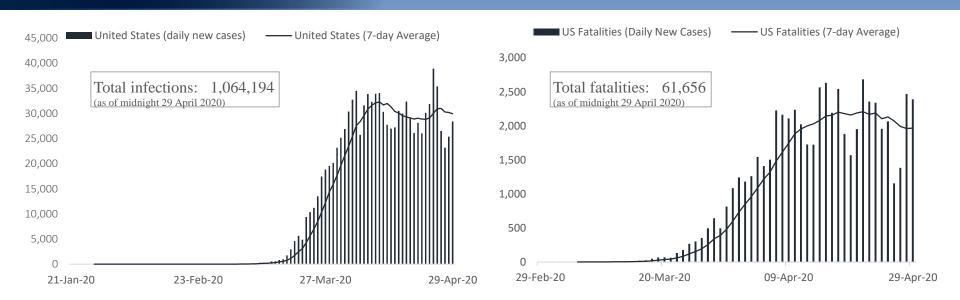


## SARS-CoV-2 Pandemic Timeline



<sup>\*</sup> As of April 29, 2020

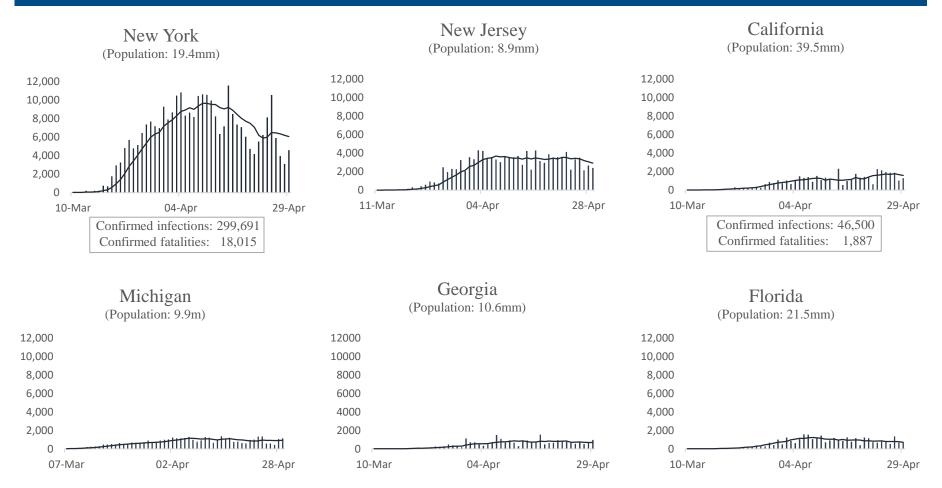
## COVID-19 Infections and Fatalities in the United States



• While the number of new daily infections and fatalities remains high in the United States, the outbreak appears to have plateaued and may now be on a downward trajectory.



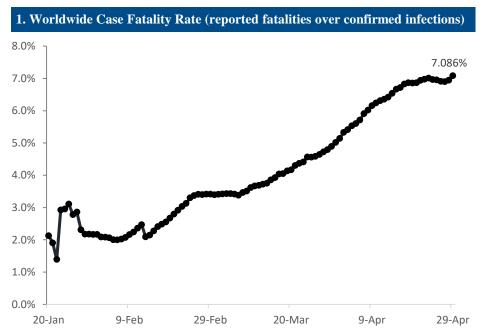
#### 1. Infections in Select US States (Daily New Cases and 7 Day Moving Average)



<sup>\*</sup> As of April 29, 2020 Source: Investment Strategy Group, The COVID Tracking Project







#### 2. Fatalities in Settings with Robust or Anti-Body Testing

	N	Tested	Infected	Fatalities	CFR
USS Theodore Roosevelt	4,845	All	940	1	0.11%
USS Kidd	380	239	64	0	0%
Gangelt (Germany)*	12,446				0.37%
Iceland	364,134	46,377	1,792	10	0.56%
Charles de Gaulle (ship)	1,800	All	1,081	0	0%
New York State**	19.4mm	3,000	417		0.5%

<sup>\*</sup>For Gangelt, CFR was derived based on cluster study of 1,000 inhabitants.

- The case fatality rate, based on confirmed infections and fatalities, has been increasing steadily since mid-February.
- However, in locations with robust or near universal testing, and now with anti-body testing, the case fatality rate is significantly lower.

<sup>\*\*</sup>For New York state, CFR was derived based on results of a Phase I anti-body testing announced by Governor Cuomo on 23 April.

# Reproduction Number (R0) – How Have Control Measures Impacted the Spread of the Virus





1. Reproduction Number (R0) (in the early days of the outbreak)					
S	SARS	MERS	SARS-CoV-2	H1N1	Seasonal Flu
R0 (reproduction number)* 2	2 - 4	<1**	2 - 4	1.33	0.9 to 2.1

<sup>\*</sup>An epidemiologic metric used to describe how many persons, on average, can each infected person spread the virus to

2.	Est	ima	tes (	of th	ie R	epro	duc	tion	Num	ber (	(R0	)

	R0
Without controls	2.2 - 3.28
New York State	0.8
Seattle area*	0.75
Germany**	1
France	0.6
Wuhan	0.32
Italy	0.8

<sup>\*</sup> The data for the Seattle area is from King, Snohomish, and Pierce Counties

Note: These are most recent estimates available, except for Without Controls and Wuhan, which are from March.

 Social distancing and other control measures have reduced the reproduction number even in localities with some of the worst outbreaks.

<sup>\*\*</sup>Overall, the reproduction number (R0) of MERS-CoV was <1, with significant heterogeneity in specific contexts.

<sup>\*\*</sup>Germany had managed to reduce R0 to 0.7 earlier this month.



# Therapies and Vaccines: Recent Developments

### 1. Potential Therapies

Product	Developer	Anticipated Next Steps
Remdesivir	Gilead	FDA's Emergency Authorization Use
Favilavir	Fujifilm	Phase 2 trial in US started April 2020
Chloroquine or hydroxychloroquine		RECOVERY trial results expected by June 2020
Lenzilumab	Humanigen, Inc.	Phase 3 recruitment expected
REGN3048-3051, Antibodies from mice	Regeneron	Phase 1 expected to start June 2020

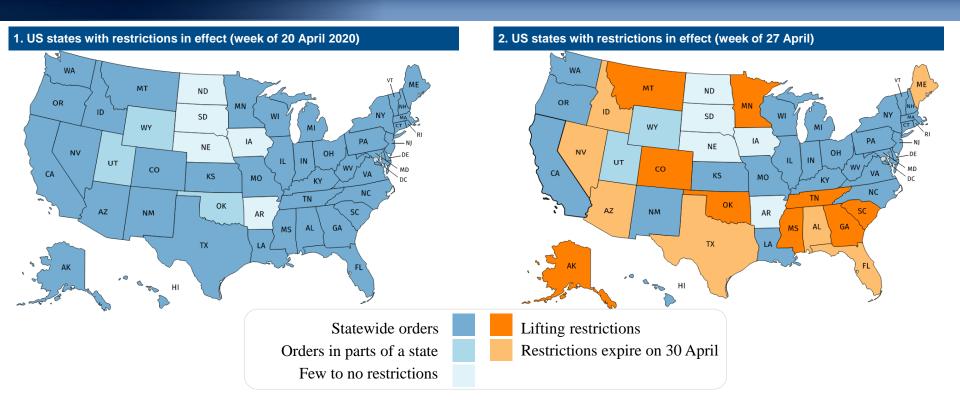
#### 2. Potential Vaccines

Product	Developer	Anticipated Next Steps
mRNA	Moderna	Phase 1 started March 2020, study ends June 2021; Phase 2 to start Q2 2020; Phase 3 to start fall 2020
Non-replicating viral vector; Ad26 (alone or with MVA boost)	Johnson&Johnson	FIH study starts in Sep 2020; First batches available in Q1 2021
Non-replicating viral vector; ChAdOx1	Jenner Institute, Oxford University	Phase 1/2 began April 2020
BCG Vaccine	Texas A&M University	Recruiting volunteers

# Some US States Are Moving to Lift Restrictions



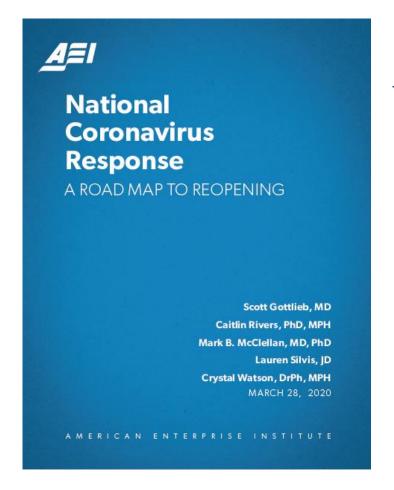




- During the height of the pandemic from March to mid-April, the majority of US states imposed some level of temporary restrictions on socio-economic activities.
- Some governors are now moving to lift elements of these restrictions and more are expected to modify theirs as they approach the expiration date on their orders.



# A Roadmap to Reopening





This report provides a road map for navigating through the current COVID-19 pandemic in the United States. It outlines specific directions for adapting our public-health strategy as we limit the epidemic spread of COVID-19 and are able to transition to new tools and approaches to prevent further spread of the disease. We outline the steps that can be taken as epidemic transmission is brought under control in different regions. These steps can transition to tools and approaches that target those with infection rather than mitigation tactics that target entire populations in regions where transmission is widespread and not controlled. We suggest measurable milestones for identifying when we can make these transitions and start reopening America for businesses and families.

# White House Guidelines to Reopening





## Gating Criteria

## Symptoms

- Downward trajectory of influenza-like illnesses reported within 14 days
- Downward trajectory of COVIDlike syndromic cases reported within 14 days

#### Cases

- Downward trajectory of documented cases within 14 days
- Downward trajectory of positive tests as a % of total tests within a 14-day period (flat or increasing volume of tests)

## Hospitals

- Treat all patients without crisis care
- Robust testing program in place for at-risk healthcare workers, including antibody testing

### Phase 1

+ no rebound

### Phase 2

+ no rebound

### Phase 3

#### Individuals

- Vulnerable individuals should continue to shelter in place.
- When in public, maximize physical distance from others.
- Avoid socializing in groups of 10+.
- Minimize non-essential travel

## Employers

- Encourage telework
- Return to work in phases
- Close common areas
- Minimize non-essential travel
- Consider special accommodation for vulnerable individuals

## Specific Employers

- Schools that are currently closed should remain closed
- Visits to senior living facilities should be prohibited
- Large venues can operate under strict distancing protocols
- Resume elective surgeries
- Bars should remain closed

## • Individuals

- Vulnerable individuals should continue to shelter in place.
- When in public, maximize physical distance from others.
- Avoid social settings of 50+
- Non-essential travel can resume

## Employers

- Encourage telework
- Close common areas
- Non-essential travel can resume
- Consider special accommodation for vulnerable individuals

## Specific Employers

- Schools can re-open
- Visits to senior living facilities should be prohibited
- Large venues can operate under moderate distancing protocols
- Resume elective surgeries
- Bars may operate with reduced standing room occupancy

#### Individuals

- Vulnerable individuals can resume public interactions.
- Low-risk populations should minimize time spent in crowds

## Employers

• Resume unrestricted staffing

## Specific Employers

- Visits to senior living facilities can resume
- Large venues can operate under limited distancing protocols
- Bars may operate with increased standing room occupancy



#### American Enterprise Institute National Coronavirus Response: A Roadmap to Reopening<sup>1</sup>

# Phase 1

## **Slow the Spread**

- · Maintain physical distancing
- Increase testing capacity, build data sharing infrastructure
- Ensure functioning of health care system
- Increase supply of PPE

- · Implement surveillance systems
- Scale contact tracing, isolation and quarantine
- Encourage public to wear masks

# Phase 2

## **State by State Re-opening**

- Implement case-based interventions
- Begin to relax physical distancing measures
- Special care for vulnerable populations
- Accelerate development of therapeutics
- Identify those who are immune

# Phase 3

## **Establish Immune Protection; Lift Physical Distancing**

- Mass vaccination or therapeutic distribution when supply is abundant
- · Global vaccine scale-up and vaccination
- Serological surveys to determine population immunity

## Triggers to Move to Next Phase

- Sustained reduction in cases for 14 days
- Safe hospital care without crisis standards
- Able to test all people with symptoms
- Active monitoring of confirmed cases and their contacts



Once a vaccine has been developed, has been tested for safety and efficacy, and receives FDA emergency use authorization, states can move to Phase III



# Phase 4

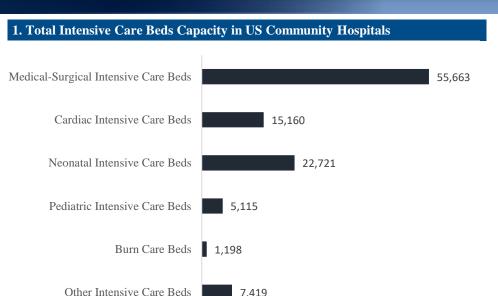
## **Rebuild Readiness for Next Pandemic**

- Develop vaccines for novel viruses in months, not years
- Modernize & fortify the health care system
- Establish a national infectious disease forecasting center
- Move to coordinated governance system

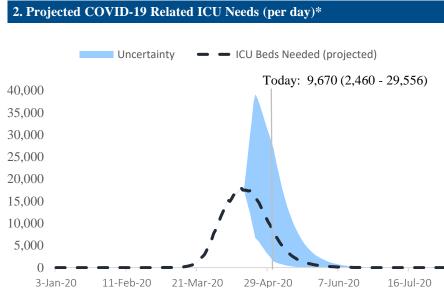
# ICUs Appear to Have Withstood the High Demands of this Wave of the Outbreak

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Note: Intensive care bed counts as reported to the American Hospital Associations. Total intensive care beds are not summed because the care provided is specialized.



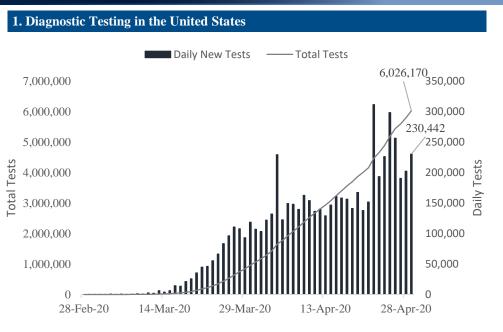
\*Based on modeling done by the Institute for Health Metrics and Evaluation

• The expansion of ICU capacity in places like New York and California and efforts by doctors, nurses, and other healthcare professionals avoided overwhelming the healthcare system during the peak of this wave of the outbreak.



3,815,000

# Diagnostic Testing – Key to Re-opening the Economy





2. Current and Recommend Diagnostic Testing Levels (per week)

\*Note: Rockefeller Foundation's recommendation above is the minimum. The recommended maximum is 30,000,000 tests per week.

Harvard Global Health Institute

- After initial struggles, diagnostic testing for COVID-19 in the United States has improved considerably.
- As more states move to lift their restrictions and businesses prepare to re-start their activities, demand for both diagnostic and anti-body testing is likely to increase further.



# Contact Tracing Through Apps

- CDC deems contact tracing a key strategy for preventing further spread of COVID-19.
- However, contact tracing is a labor-intensive process.
  - During the high of the outbreak in Wuhan, Chinese authorities dispatched more than 1,800 teams, with a minimum of 5 people per team to trace tens of thousands of contacts a day.
  - In the US, the CDC has indicated that a substantial expansion of public health fieldworkers will be needed to undertake contact tracing. Independent assessments have suggested that some 300,000 fieldworkers may be needed in order to effectively conduct contact tracing.
- A number of countries are turning to smartphone apps to help with contact tracing.
- In the US, Apple and Google are expected to release by mid-May a mobile software tool that will let iPhones and Android devices talk to each other and enable future digital contact tracing.

#### 1. Select Contact Tracing Apps And Developers Around the World







Australia

Norway

China







Czechia

Israel

Iceland







North Macedonia

Singapore

Austria



Google



# Mount Sinai Laboratory's COVID-19 Antibody Test

#### 1. COVID-19 ELISA IgG Antibody Test

- On March 17, a team led by virologist Florian Krammer, PhD, at Mount Sinai, managed to develop the first in the nation serological enzyme-linked immunosorbent assay (ELISA) test
- There are three main advantages to this test:
  - Providing an accurate picture of how many people have been infected;
  - Identifying people with new immunity to SARS-CoV-2 who could care for COVID-19 patients at zero or minimal risk; and
  - Identifying newly recovered patients with high antibody levels who can donate their antibody-rich blood, known as convalescent plasma, to potentially save patients with severe COVID-19.
- On April 15, the US Food and Drug Administration authorized the emergency use of Mount Sinai's test.







#### 1. List of FDA Authorized Serological Test (as of 27 April)

Date of EUA	Manufacturer	Technology
4/1/2020	Cellex Inc.	Serology IgM and IgG
4/14/2020	Ortho Clinical Diagnostics, Inc.	Serology Total Antibody
4/14/2020	Chembio Diagnostic System, Inc	Serology IgM and IgG
4/15/2020	Mount Sinai Laboratory	Serology IgG
4/24/2020	Autobio Diagnostics Co. Ltd.	Serology IgM and IgG
4/24/2020	DiaSorin Inc.	Serology IgG only
4/24/2020	Ortho-Clinical Diagnostics, Inc.	Serology IgG only
4/26/2020	Abbott Laboratories Inc.	Serology IgG only

• Anti-body tests are proliferating in the United States and internationally, but their quality is uneven.

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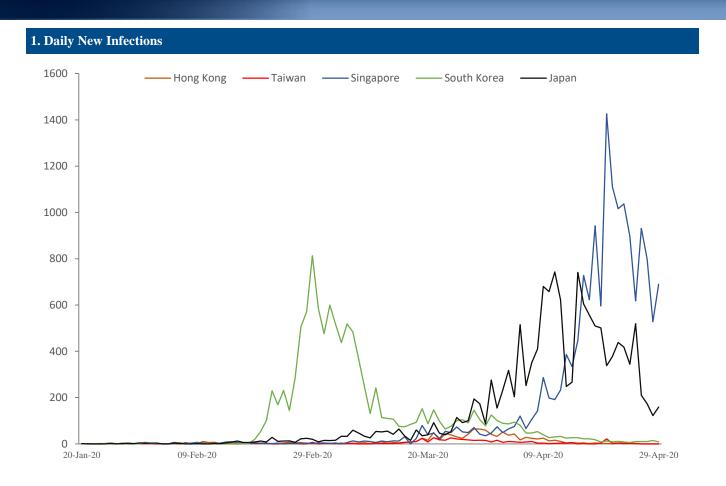


# Testing the results of anti-body tests

1. Specificity in blood donor plasma specimens collected before July 2018					
	Total N	<b>Positive</b>	%	95% CI	
<b>Lateral Flow Assays (LFAs)</b>					
BioMedomics (US)	107	14	86.92%	79.02-92.66	
Bioperfectus (China)	104	5	95.19%	89.1498.42	
DecomBio (China)	107	11	89.72%	82.35-94.76	
DeepBlue (China)	108	17	84.26%	76.00-90.55	
Innovita (China)	108	4	96.30%	90.79-98.98	
Premier Biotech (US)	108	3	97.22%	92.10-99.42	
Sure Biotech (US/HK)	108	0	100.00%	96.64-100.00	
UCP (US)	107	2	98.13%	93.41-99.77	
VivaChek (US)	99	5	94.95%	88.61-98.34	
Wondfo Biotech (China)	106	1	99.06%	94.86-99.98	
<b>Enzyme-linked immunosorbe</b>	nt assays (I	ELISAs)			
Epitope	108	11	89.81%	82.51-94.80	
Krammer Lab, Mount Sinai	108	1	99.07%	94.95-99.98	

- A recent analysis of 10 rapid tests that deliver a yes-no signal for antibodies (LFAs) and two tests using a lab technique known as ELISA demonstrated specificity greater than >99% only for two LFAs (Sure Biotech, Wondfo) and one ELISA (Krammer Lab, Mount Sinai Hospital)
- False positives can become dangerous when making policy and personal decisions about who can go back to work.

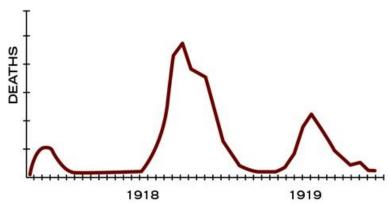
# A Second Wave or a Temporary Breakdown in Strategy?



• After successfully containing the initial outbreak in January and February, Japan and Singapore have recently experienced an increase in the new number of infections.



#### 1. The 1918 Flu Pandemic (H1N1 Virus) - "Spanish Flu"

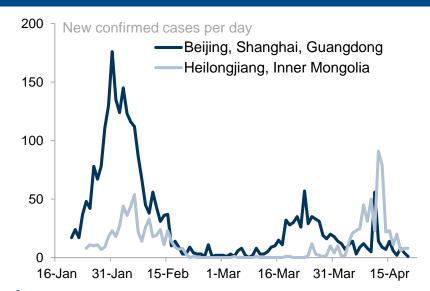


Note: There were 3 different waves of illness during the pandemic, starting in March 1918 and subsiding by summer of 1919. Pandemic peaked in the U.S. during the second wave, in the fall of 1918. This highly fatal second wave was responsible for most of the U.S. deaths attributed to the pandemic.

There's a possibility that the assault of the virus on our nation next winter will actually be even more difficult than the one we just went through... We're going to have the flu epidemic and the coronavirus epidemic at the same time.

CDC Director Robert Redfield Interview with The Washington Post 21 April 2020

#### 2. China: Some Restrictions Re-Imposed Due to Imported Cases



[A second round of the coronavirus] is inevitable... If by that time we have put into place all of the countermeasures that you need to address this, we should do reasonably well. If we don't do that successfully, we could be in for a bad fall and a bad winter.

> NIAD Director Anthony Fauci Interview with CNN 29 April 2020





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Period	Gross Return	Net Return	Differential
1 year	6.17%	4.61%	1.56%
2 years	12.72%	9.43%	3.29%
10 years	81.94%	56.89%	25.05%

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