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Reason for report:

INDUSTRY UPDATE

LIFE SCIENCE TOOLS AND DIAGNOSTICS

Update #3: The Current State of COVID-19 Testing in the U.S.

S&P 500 Health Care Index: **990.69**

Companies Highlighted:
ABT, HOLX, TECH, TMO

• **Bottom Line:** COVID-19 testing in the U.S. will surpass 1M cumulative tests any day now, highlighting the significant ramp up that went from no tests to 1M just within a month. Testing capacity should continue to increase, providing close to 10M tests cumulative capacity by end of April, in our view, but whether testing capacity would still be enough depends on the testing criteria, which currently include only in-patients and those who are symptomatic. Testing capacity is very likely to fall short if the criteria are broadened. Serology testing for COVID-19 is also gaining prominence as more reports of rapid serological tests are increasing but we see performance and scale-up (in millions) as key hurdles for success of these assays. KOLs point to serological testing holding potential to emerge as a part of COVID, and finally RVP (respiratory panel) testing algorithm longer-term.

• **COVID-19 testing in U.S. to reach 1M milestone soon but more ramp-up will be desired.** Testing should be reaching the cumulative 1M milestone in the U.S. any day now, highlighting the significant ramp in testing across mostly commercial labs in the last month. We continue to expect fully automated systems from Roche, Hologic (MP) and Abbott (MP) to handle the majority of the testing volume, followed by semi-automated and manual assays as reagent limitations are increasingly addressed. Still, we believe the criteria for testing are restricted to those who are in-patients or those with high fever and cough. Ultimately as COVID-19 cases rise in the rest of the country, a faster turn-around system is likely to be desired vs the current 3-6 days turn-around time from the reference labs.

• **The conversation is shifting to serological testing.** It appears that the conversation among both KOLs and investors is now shifting to the rapid serology testing or immuno-assay based approaches to broaden the testing to identify those exposed to SARS-CoV-2 and have antibodies to it vs those not exposed. This assay would provide views into penetration of the virus into the broader population while also providing another assay that could be used within the algorithm to test patients for COVID-19. Given that there is significant immunoassay capacity, such an assay could also be central lab or hospital lab assay. Our KOL discussions suggest that such a serological assay must exhibit high sensitivity in order to succeed as an screening assay. Both performance and scale-up are hurdles that we currently see for a serology assay for COVID-19.

• **KOL finally ramps capacity at his East Coast healthcare system.** We spoke to a pathologist KOL at a large East Coast healthcare system who was struggling to ramp capacity earlier. The lab is now performing 2,000 COVID-19 tests per day, mostly on HOLX Panther and a combination of semi-automated systems. He expects his institutions to now allocate semi-automated Genmark systems into each hospital for faster turn-around time while the central lab handles volume of 2x HOLX PantherFusion, and he expects to add another instrument to ramp up overall capacity.

Update #3: The Current State of COVID-19 Testing in the U.S.

COVID-19 testing in the U.S. will surpass 1M cumulative tests any day now, highlighting the significant ramp-up that rose from no tests to 1M just within a month. If testing was ramped up just 1 month before in February to these levels, the outcome would be much different today in both the number of cases and overall quarantine efforts across the U.S.

Testing capacity should continue to increase, providing close to 10M tests cumulatively by the end of April, but whether testing capacity would still be enough depends on the turn-around time, collection (swabs, etc.) limitations and overall strict criteria that only those who are symptomatic can be tested. If the testing criteria are broadened, the overall testing infrastructure would very likely be incapable of serving the broader patient population, which could be asymptomatic. Still, the ultimate line of defense continues to be significant volumes from large reference national labs using fully automated systems from Roche, HOLX and ABT.

We continue to investigate the current state of COVID-19 testing across the U.S. with an eye for total capacity, utilization, ramp-up of assays and ongoing feedback from KOLs. Testing volume is undoubtedly increasing (~100k/day now) and though inefficiencies of logistics, collections (swabs), turn-around time and rationing of tests are still very likely to continue in the near term, we remain optimistic that more capacity is coming online for in-patient and then symptomatic patients. Key drivers, in our view, have been significant broadening of the testing criteria at the FDA, announced scale-up of testing reagents and cartridges for fully automated systems and recent additions of point-of-care assays beyond the already EUA-approved assays from the national reference labs.

Increased testing capacity led to significant jump in cases last week

With a number of key FDA approvals in the past weeks for COVID-19 (SARS-CoV-2) assays, including those from Danaher's (DHR), Hologic (HOLX), Abbott (ABT), Genmark (GNMK), Quest (DGX), LabCorp (LH), Quidel (QDEL), Diasorin, Roche and TMO, the US saw an increasing number of both tests and positive cases daily. We believe this was largely anticipated following testing inefficiencies and problems when the COVID-19 outbreak first began, which we believe created a bolus of infected patients looking for testing that was not available yet. We expect that the majority of the daily/weekly testing capacity growth is being driven by fully automated systems that require less sample prep and offer a quicker time to result, from Roche, Hologic and Abbott. While testing volumes have expanded significantly over the past few weeks, from under 1k a day on March 10 to just under 100k tests performed on March 26, we anticipate that the daily volumes are likely approaching a plateau given the availability of a limited number of instruments on the market. We do see upside from additional instrument placements that come through in the coming weeks; however, the ability to ship, install and validate these instruments during the severe workflow disruptions remains to be seen.

The conversation is shifting to serological testing to address the growing testing demand and gain insights into the population exposure to SARS-Cov-2

It appears that both among the investment community and among the frontline lab directors overseeing COVID-19 testing (including the KOL who we spoke to), the conversation is now shifting to the hospitalization among confirmed patients and to a rapid serology testing or immuno-assay based approaches to broaden the testing to both identify those who have the disease and have built antibodies to it and those who have recovered from the disease to identify the number of people in the population that are exposed to SARS-Cov-2. As we discuss later in the note, the sensitivity of such assays remains a key factor at question as high sensitivity is desired in a screening assay, and though such assays hold promise in alleviating the current capacity constraints (as more immunoassays systems are available to run such assays), we have not seen announcements from major U.S. assay manufacturers on serological testing launches. We believe manufacturing scale will be required from any company that can provide a serological assay as likely millions would be needed.

Please see our earlier COVID-19 testing updates:

- The Current State of COVID-19 Testing in the U.S. (Link) Monday, March 16, 2020
- Update #2 The Current State of COVID-19 Testing in the U.S (Link) Monday, March 23, 2020

COVID-19 testing volumes continued to rise throughout the week as U.S. cases pass China and Italy; though testing per capita still lags

Testing bottlenecks continue to work towards resolution in our view, and we believe we may be nearing a saturation point in how many tests can actually be run in a day. As expected, the supply of tests is becoming less of an issue, and we expect that reference labs such as LabCorp, Quest and Opko are running near capacity. Since our last update, U.S. testing volumes have nearly tripled from ~254k on late March 22 to 735k on Sunday morning (3/29), with confirmed cases rising from ~32k to 118k over the same period. **The positivity rate (number of tests positive among total conducted) has surprisingly continued to inch higher to 16% (and to 34% in NY)**, a number that we continue to believe will likely decline as increasingly more testing is conducted in the longer-term, though to date has been impacted significantly by dense COVID-19 breakout hubs like New York City.

Despite ramping test capacity and having passed Italy in the number of cases, the U.S. remains well behind Italy and South Korea in testing per capita. We anticipate continued expansion in per capita testing in the U.S. ahead of other countries throughout the world, and believe that the U.S. will ultimately surpass Italy, though it remains to be seen if an immuno-assay will count as a unit of test volume further down the line.

Figure 1. Testing volumes per million people have ramped up significantly in the U.S. vs other countries

Testing Per Million Growth						
Country	Start Date	Start Total	20-Mar-20 Tests	Growth From Start	27-Mar-20 Tests	Growth W/W
US	8-Mar	5	314	**63x**	1,588	**5.1x**
Italy	8-Mar	826	3,499	**4x**	5,968	**1.7x**
Israel	8-Mar	401	1,247	**3x**	nm	**nm**
UK	8-Mar	347	960	**3x**	1,578	**1.6x**
Japan	4-Mar	66	118	**2x**	213	**1.8x**
South Korea	8-Mar	3,692	6,148	**2x**	7,348	**1.2x**

Source: Our World in Data, Business Insider, the COVID Tracking Project, Individual Country Ministry of Health Websites

The increase in test volumes has clearly correlated with the increase in total positive results, and we continue to believe that continued access to testing is a key factor in controlling the outbreak. Cumulative testing in the United States is likely to pass 750,000 by March 30, exceeding 2,300 tests per million, compared to 314 tests per million highlighted above on March 20, and up even more in the last two days. Cases in the U.S. have continued increasing as a result, and we expect any relative day-over-day slowdown in cases to be a positive sign for a slowdown of the transmission. Total cases of ~118k have increased significantly from just over ~30k one week ago, while day-over-day testing growth has been steady in the low-20% range, which has declined from highs above 50% growth, which we expect to continue declining further as the denominator grows.

The United States now has the most cases globally, though mortality rates remain significantly lower than other countries with sizeable outbreaks. While cases in the U.S. have recently surpassed Italy, and reported numbers from China, the mortality remains relatively low, below 2%. The below chart highlights the United States' relative position in cases and deaths compared to other countries, with mortality remaining well below many of the hardest hit European countries despite the late action and early hiccups in testing in the United States. We anticipate a declining number of daily cases will be a strong sign that the "peak" is nearing, however note that stabilization at current rates would still suggest ~20k new cases a day.

Figure 2. U.S. mortality rates remain relatively low despite significant ramp in cases

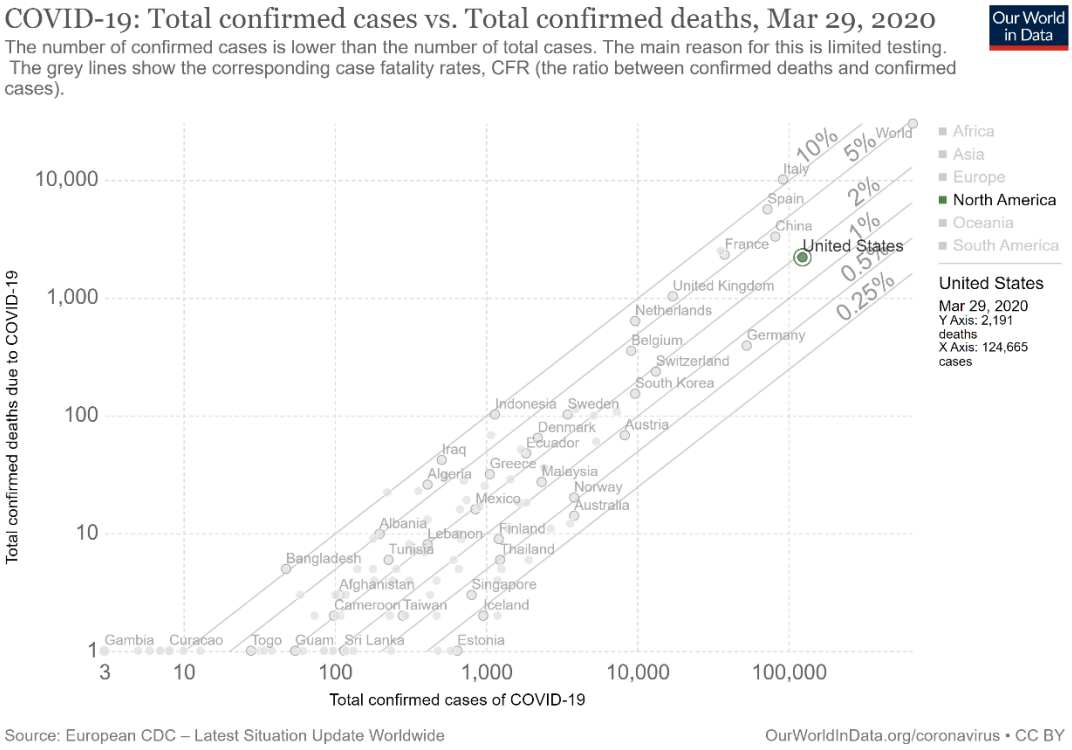
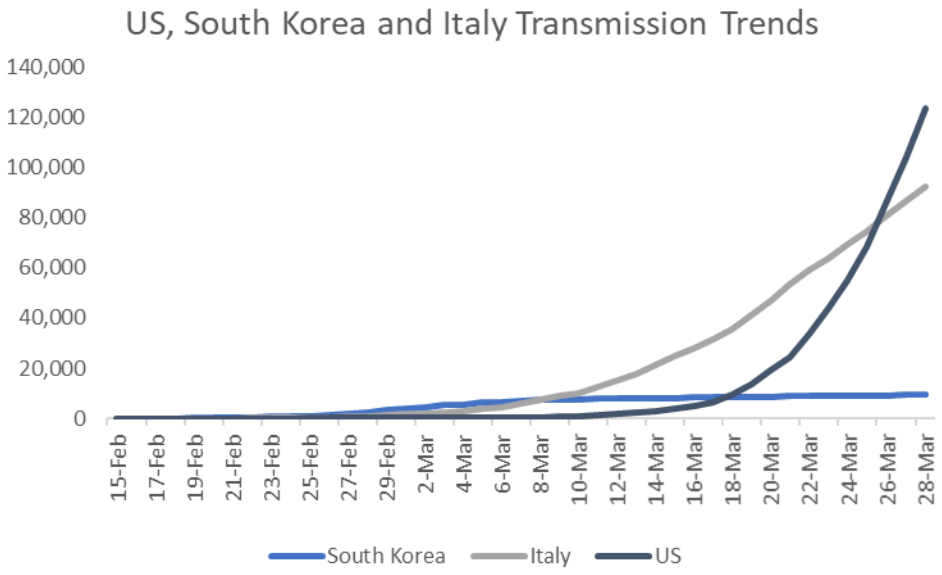


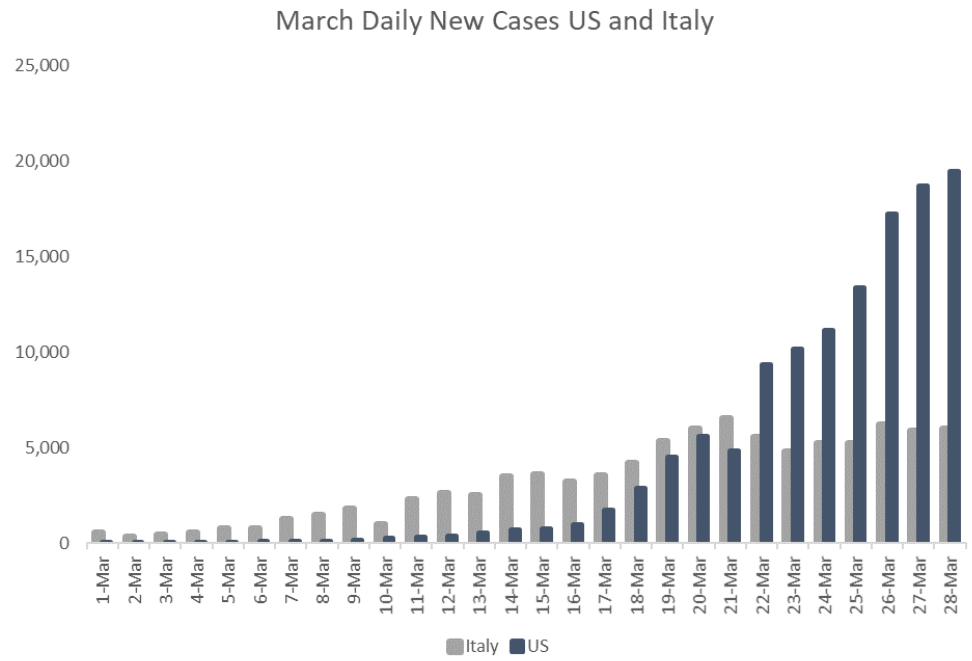
Figure 3. U.S. has surpassed Italy in number of cases, eye set on curve inflection



Source: https://www.worldometers.info/coronavirus/

When comparing daily new cases between Italy and the United States, we see a strong acceleration in the U.S. compared to a relative flattening in Italy. Throughout March, the daily cases in the United States have grown significantly, which we believe was relatively expected as more access to testing became available. In Italy, however, which we believe is ~10 days ahead of the United States in the outbreak, we can see relative stabilization in daily new cases beginning around March 21. While cases in the U.S. have recently surpassed Italy, the chart below suggests growth in daily new cases in the U.S. is still growing but holds potential to flatten as early signs indicate social distancing is working.

Figure 4. Italy vs. U.S. daily cases

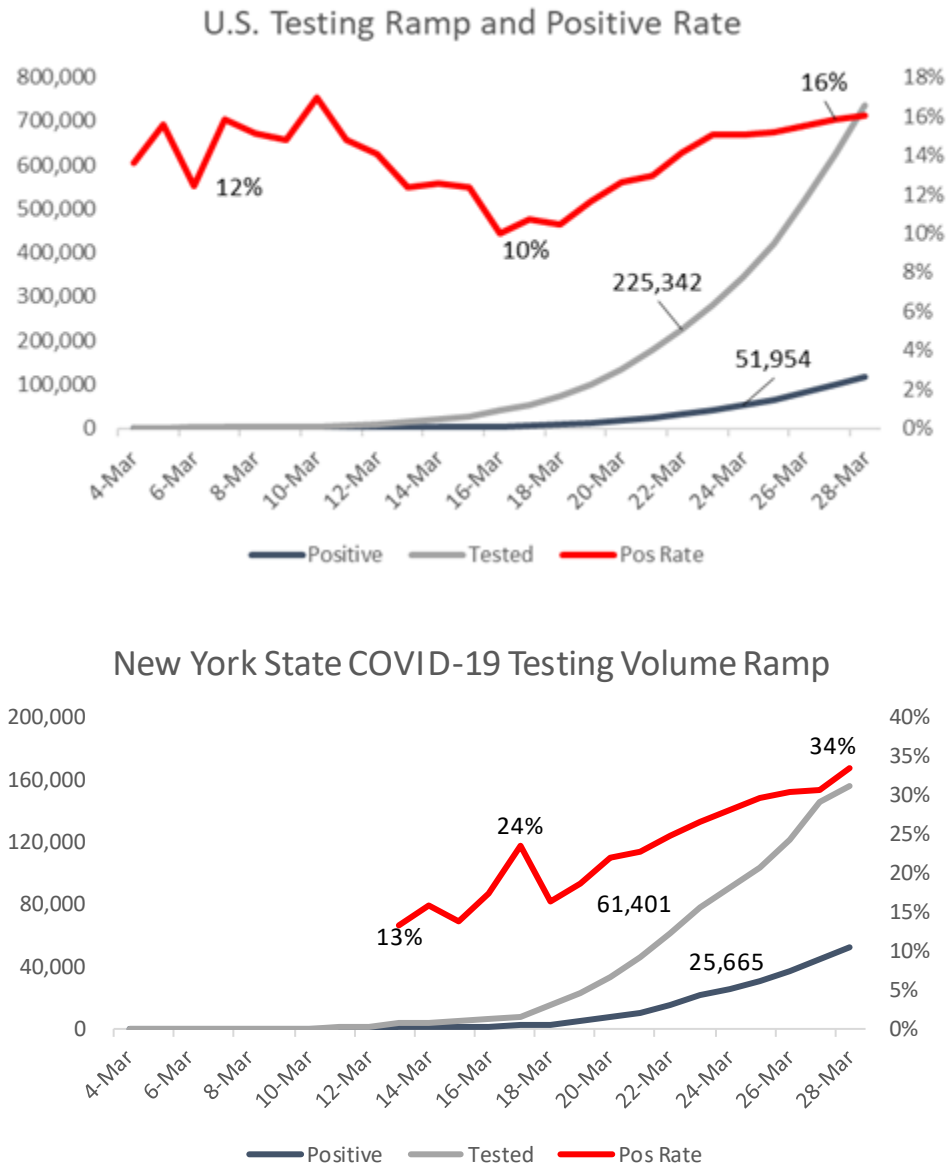


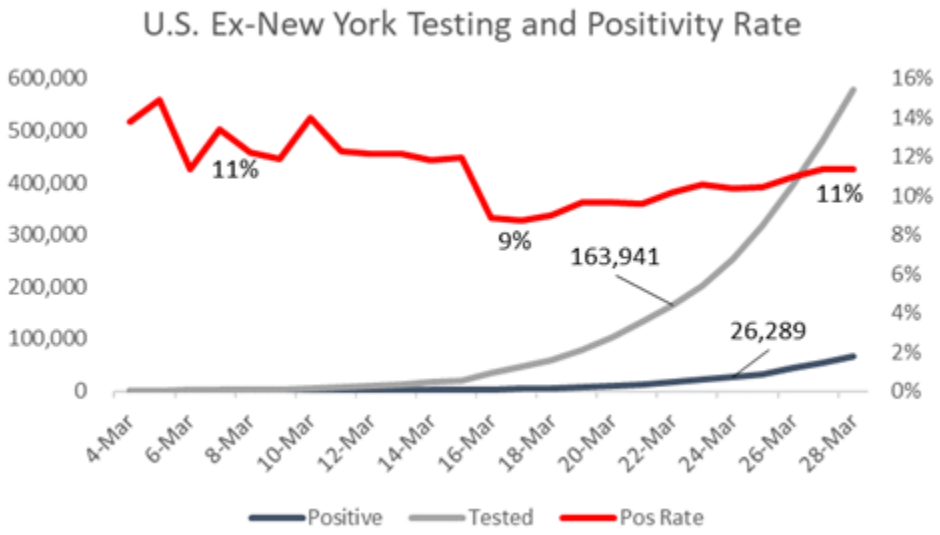
Source: https://www.worldometers.info/coronavirus/

New York State has been a key driver of higher than expected positivity rates

A key contributor to the growth in U.S. cases has been New York State. Given the dense population of the state, as well as New York City, COVID-19 has seen relatively quick spread resulting in swift social distancing measures being taken. While the U.S. as a whole is seeing mid-teens positivity rates, which we still believe to be high in the long term, New York's positivity rate has continued to climb, to highs above 30%. Excluding New York state cases and test volumes, we estimate the U.S. positive rate has been hovering around 10% for the last few weeks, a more realistic number that we expect to trend down over time. The ~52k cases in New York currently account for 44% of the total cases in the U.S. of ~118k, as of Sunday, March 29, 12:00 p.m. EST.

Figure 5. High positivity rates in U.S. driven by New York State





Source: The COVID Tracking Project

KOL highlights hospital capacity emerging as a larger concern and change in discharge criteria meant to reduce burden on testing

We also spoke to an East Coast lab director and pathologist KOL, who highlighted increasing capacity in his lab with 2 HOLX Fusion Panthers up and running and a third in the process of coming online, suggesting they are able to run 600-700 samples per instrument, yielding a total of ~2,000 sample per day between the PantherFusions and the semi-automated setup. The KOL highlighted the lab is also using the semi-automated Genmark (GNMK) instruments, however mentioned the company is still rationing their test kits significantly.

The KOL also highlighted that the individual hospitals in his large health system are now setting up GNMK instruments directly in the hospitals to expand internal testing capacity, and while tests are semi-automated with a few hours turn-around, having a system that could generate the result in 3-4 hours is valuable for high risk patients in hospital settings.

Discharge criteria changes as hospital capacity is an increasing concern for the KOL with a growing number of patients in hospital beds and ICU. As a result, the KOL highlighted that the health system is changing their criteria to discharge a patient in order to free up space. He highlighted that criteria have changed from 2 negative COVID-19 tests or 72-hours symptom-free for discharge -- they are now discharging patients based on oxygen saturation levels above 93%. This new criteria alleviate some of the testing demand at a time when tests are still being rationed to those who are sick and need a diagnosis.

Hospitalization rates likely to be a leading indicator of recovery

We expect focus to turn to hospitalization rate for the sickest COVID-19 patients in the coming weeks as hospitals begin to stretch capacity while handling a shortage of equipment in the hospital, including personal protective equipment for the doctors and nurses caring for the

patients. While data on hospitalization is more scarce, recent information from New York City, arguably the hardest hit area in the country, suggests rates approaching 40% on March 25 for those 75 years and older with steep drop-offs as the cohorts move younger. We believe hospitalization rates in key outbreak hubs throughout the country to be leading indicators on the progression of the outbreak and believe that slowing rates may signal a key inflection points.

Figure 6. New York City COVID-19 hospitalization rate as of 3/25

COVID-19 Cases in New York City By Age (03/25/2020)						
Age	Cases	Cases/10k	Hospitalized	Hosp. Rate	Deaths	Death Rate
0-17	446	2.6	28	6.3%	0	0.0%
18-44	8,880	26.4	629	7.1%	5	0.1%
45-64	6,786	33.0	1,061	15.6%	43	0.6%
65-74	2,226	31.8	550	24.7%	44	2.0%
75+	1,633	29.9	615	37.7%	100	6.1%

Source: NYC Department of Health and Mental Hygiene, Business Insider, SVB Leerink

Total hospitalization appears to be increasing as the outbreak continues spreading. New York State specifically, where the number of hospitalized patients started being reported on March 21, saw an initial decline as cases started climbing; however, the state saw a significant jump in rates late last week. The number of hospitalizations has been doubling much faster than initially expected in key hot spot areas according to recent reports. New York Governor Andrew Cuomo has suggested that the number of hospitalized patients was doubling every 2–3 days, while California's Secretary of the State's Health and Human Services suggested they are seeing numbers doubled every 3-4 days, faster than the 7-10 days they had initially expected.

Figure 7. New York State COVID-19 hospitalization rate as of 3/29

New York State					
	Positive Pts.	Hospitalized	Deaths	Hosp. Rate	Mort. Rate
21-Mar	10,356	1,603	44	15.5%	0.4%
22-Mar	15,168	1,974	114	13.0%	0.8%
23-Mar	20,875	2,635	114	12.6%	0.5%
24-Mar	25,665	3,234	210	12.6%	0.8%
25-Mar	30,811	3,805	285	12.3%	0.9%
26-Mar	37,258	6,844	385	18.4%	1.0%
27-Mar	44,635	8,526	519	19.1%	1.2%
28-Mar	52,318	10,054	728	19.2%	1.4%

Source: The COVID Tracking Project

For the country as a whole, hospitalization rates have increased dramatically over the past few days, even as cases continue to rise. With an increasing number of cases in the denominator, the significant spike in hospitalized patients in the country is becoming more of a

concern. While a majority of these patients are in New York State, we anticipate that over time the number of cases elsewhere in the country could continue to ramp, placing additional strain on hospital systems throughout the country. While the number of positive cases per day will likely be a key indicator of reaching peak, the hospitalization rate remains key in highlighting the ability to support continued hospitalizations throughout the country while aiding in the eventual recovery from the virus for individuals as well as a nation.

Figure 8. United States COVID-19 hospitalization rate as of 3/29

United States					
	Positive Pts.	Hospitalized	Deaths	Hosp. Rate	Mort. Rate
21-Mar	13,197	1,964	272	14.9%	2.1%
22-Mar	31,879	2,554	398	8.0%	1.2%
23-Mar	42,152	3,325	471	7.9%	1.1%
24-Mar	51,954	4,468	675	8.6%	1.3%
25-Mar	63,928	6,136	900	9.6%	1.4%
26-Mar	80,735	10,131	1,163	12.5%	1.4%
27-Mar	99,413	13,718	1,530	13.8%	1.5%
28-Mar	118,234	16,729	1,965	14.1%	1.7%

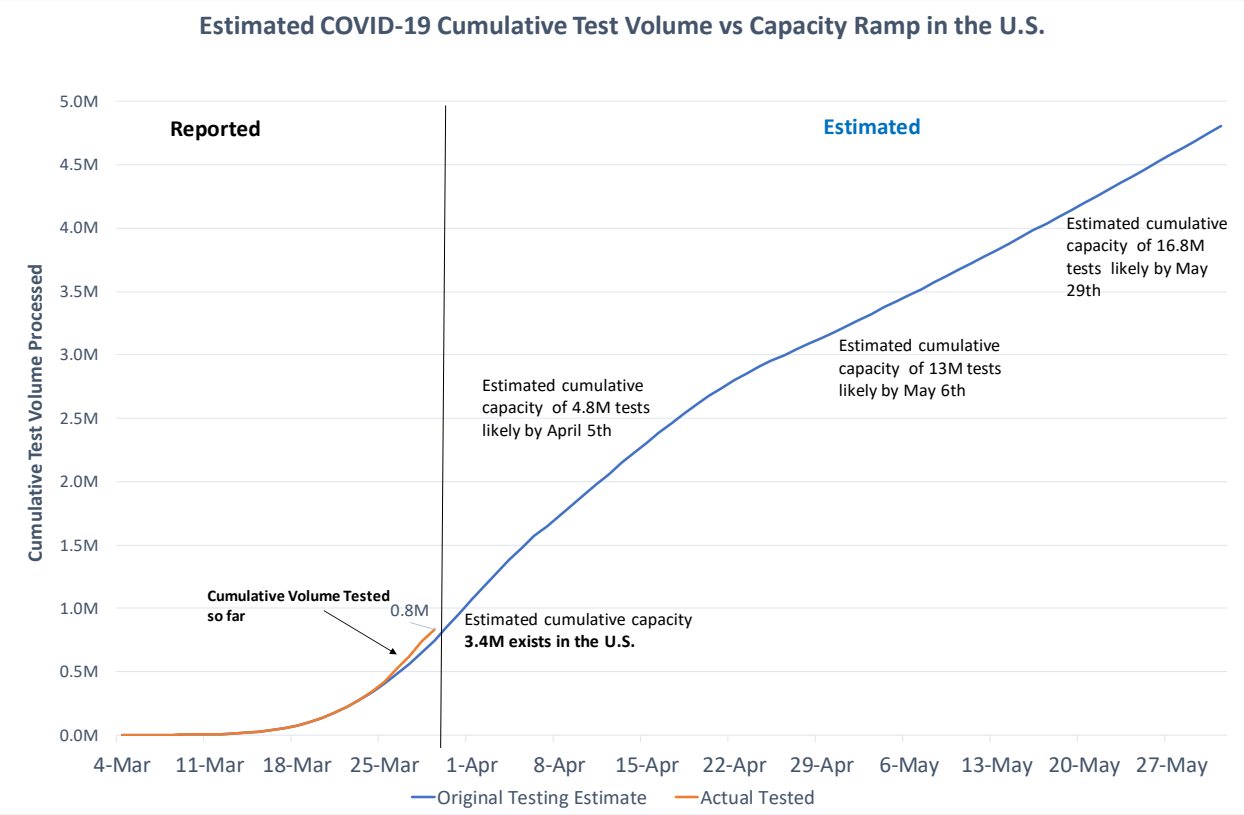
Source: The COVID Tracking Project

We expect the larger cities that had outbreaks occur earlier on in the United States have been rationed the lion's share of the medical supplies, putting follow-on outbreaks elsewhere in the country at risk. Louisiana is emerging as another key hot spot in the United States following Mardi-Gras in late February. Two weeks after their first case, Louisiana had nearly 3,000 cases as of March 27, which state officials highlighted as one of the fastest moving outbreaks globally. We anticipate that these more rural communities might be disadvantaged from fewer resources being available to them to control the outbreaks going on in their state, which suggests the outbreak may be gaining steam unnoticed in certain areas, creating a second wave of outbreak.

Testing capacity trend slightly higher vs our initial expectation

In our COVID-19 update last week, we attempted to model our expectations of the testing ramp under the assumption that testing capacity constraints were abating following a number of key approvals for Roche, HOLX and ABT. At the time, we assumed daily testing capacity would continue ramping from ~mid-40k on March 23 to over just over 100k a day by the end of March, with gradual stabilization and decline throughout the month of April. Over the past week, testing volumes have increased slightly faster than we modeled, adding around ~10k per day to start the week before jumping to ~100k+ tests per day on March 27. While this increase has happened faster than we modeled, we continue to believe that a plateau of daily testing adds is likely to occur in the near term; however, total testing volume will likely continue growing, though at a decelerating rate.

Figure 9. Actual Testing Volume Growth in the U.S. vs our Original Estimate



Source: The COVID Tracking Project (as of 3/29/2020 12pm EST), SVB Leerink Estimates

Focus shifting to a serological assay to identify the extent of spread within the population and to have a rapid assay that expands the testing criteria more broadly

With increasing testing capacity that more than covers the daily need for symptomatic patients, we believe investor focus will be turning towards an assay that identifies antibodies to SARS-CoC-2 high sensitivity. In our view, this so-called "go back to work" assay, needs to be scalable for the entire population, with quick turn-around times to limit backlog, and high sensitivity to ensure that currently infected or recovered but asymptomatic patients aren't continuing to spread the virus in the public. A serology-based screening assay is generally seeking highest sensitivity (thus low false negative rates) than lower specificity. Specificity is likely to be less of an issue, as a false positive would result in self-quarantine for a period of time, removing the person from the public anyway. A number of companies are already involved in manufacturing and commercializing a test like this; however, many are small, outside of US companies that would likely have problems scaling the assay in the United States in our view. Ultimately, we believe this will be a central lab test to support the required capacity, though

believe point-of-care testing may be an option down the road as companies continue to develop assays for COVID-19.

A serology test targets antibodies in plasma, which can be used to diagnose the virus or identify those who have been exposed and recovered without becoming significantly symptomatic. While this is a less accurate test vs the gold standard RT-PCR, we believe such an assay will be crucial in accurately identifying the total scope of the COVID-19 outbreak in the United States and the world. If manufactured and commercialized at scale, a test of this nature is likely to have a significant impact on the timing of return to normalcy as those who have been infected and recovered can test positive or be properly deemed "recovered" while others who have been infected can expect screening via this assay and to be followed up with RT-PCR if needed.

On March 16, the FDA issued a statement updating their COVID-19 guidelines, including for those developing a serological test. In their recommendation, the FDA recognized that serology tests are less complex than molecular tests and are only used to identify antibodies, limiting the diagnostic capabilities given the timeline of infection and antibody response. However, the FDA noted that they do not intend to object to distribution of serology tests for COVID-19 provided they are validated, have notified the FDA and have included warnings mentioning the tests have not been reviewed by the FDA and results are not to be used for diagnosis or exclusion. While we believe the focus among the public is shifting to serology type assays, further actions are likely needed from the administrative bodies to encourage development of and approve use for these assays. The CDC has also announced that they are developing a serological laboratory test to assist in determining the total U.S. COVID-19 exposure, and are looking for blood samples of patients at least 21 days after symptoms began.

A number of serological tests are already being publicized in the news, both within the U.S. and globally

SD Biosensor, a South Korean company represented in the U.S. as VelocityDx, recently agreed to a distribution agreement with Henry Schein for their serology assay. The SD Biosensor Standard Q IgM/IgG (immunoglobulin M/ Immunoglobulin G) test is one of the five being used in South Korea currently, where they are seeing a significant "trace, test and treat effort across the country", which likely has contributed to their muted outbreak compared to other countries around the world. This test is expected to be administered in a point-of-care setting with results in 15 minutes and no instrumentation requirements. Henry Schein has suggested that it expect hundreds of thousands of tests to be available by March 30, with a significant increase in availability throughout April. Despite the early efforts to bring a serological assay to market in the United States, the overall performance of the test is not enough to warrant a universal and robust serological assay with 81.8% sensitivity (high false negatives) and 96.6% specificity (low false positives). These careening assays require high sensitivity as the cost of sending a false negative patient back into the public poses a risk, whereas those that are false positive would simply stay home to recover.

Figure 10. SD Biosensor Standard Q IgM/IgG Rapid Test performance

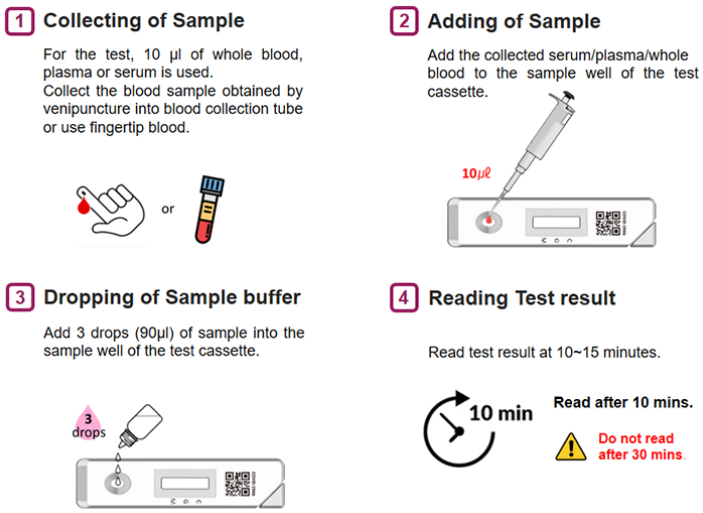
Combined positive test results are used to calculate total Duo test sensitivity				
		PCR		Total
		Positive	Negative	
STANDARD Q COVID-19 IgM+IgG	Positive	27	1	28
	Negative	6	29	35
Total		33	30	63
Sensitivity : 81.8%, Specificity : 96.6%				

Source: SD Biosensor

A team at the Icahn School of Medicine at Mount Sinai has developed a serological enzyme-linked immunosorbent assay (ELISA). This test is designed to measure antibody presence, or lack thereof in a patient's blood, even for those who came into contact with the virus months beforehand. The team hopes the assay will succeed in providing an accurate picture of the total infections across the country, those with new immunity that are able to care for current patients with significantly less risk, and identifying recovered patients that have high antibody levels to donate their blood to other severely impacted patients. Biotechne's Ella platform is being used also at Mount Sinai to develop a cytokine storm assay on the system.

Another South Korean company, Sugentech, has its own SGTi-flex COVID-19 IgM/IgG to identify antibodies in human whole blood, serum, or plasma. These kits, which detect the presence of antibodies, offer results to the naked eye in 10 minutes. Original expectations for Sugentech's COVID-19 serological test were for 300k tests to be exported per week, though these estimates were as of March 21 and have likely increased further as production capacity ramps.

Figure 11. Serological tests are easy to run and read



Source: Sugentech

Frequent COVID-19 Diagnostics Updates Continue

While updates this past week were less impactful on the overall testing capacity, we expect the focus in the near-term remains on speed and bringing the U.S. economy back online. We do, however, see incremental updates worth highlighting from QIAGEN, Bio-Techne, Quidel, Henry Schein and Abbott.

QIAGEN released QIAstat-Dx in the United States as the first COVID-19 focused syndromic test. This test is able to differentiate COVID-19 from up to 20 other respiratory infection in under an hour, which we believe holds potential moving forward. As we expect that investors and the public are looking for more access to testing, and quicker turn-around times, we believe a test that can differentiate between a number of other respiratory infections can play a role in the market provided it can be scaled. A patient may be tested for influenza and other respiratory infections prior to COVID-19, which to us suggests that one test that is able to centralize testing would be an encouraging development.

Bio-Techne (TECH) highlighted its intentions for its Ella Automated Immunoassay Platform to monitor immune response for COVID-19. The platform works by detecting Cytokine Release Syndrome (CRS) in patients and would likely be used to triage the most at-risk patients, as cytokines, or immune molecules, attack a patient's organs, which is a potentially fatal development in disease management.

Quidel announced on March 25 that its Lyra SARS-CoV-2 assay received an expanded EUA. The expanded EUA enables the assay to be used on three additional thermocyclers, including TMO's Applied Biosystems 7500, Roche's LightCycler 480 and QIAGEN's Rotor-Gene-Q. In our view, this expanded EUA suggests the industry's willingness to work together in an effort

to contain the spread of the virus, as different companies make their instruments available to run a number of assays.

Henry Schein (HSIC) announced the availability of an antibody-based rapid blood test for point-of-care administration. While Henry Schein is likely to only be providing logistics of the Standard Q COVID-19 IgM/IgG Rapid Test, we believe that efforts for fast turn-around, "go back to work" tests will continue and are likely to see adoption in the market given good performance. The aforementioned assay is manufactured by South Korean company SD Biosensor.

ABT launches a point-of-care molecular assay with rapid turn-around time. On March 26, U.S. Vice President Mike Pence suggested that Abbott Labs had submitted a point-of-care assay to the FDA**.** The following day, on March 27, ABT announced EUA and launch of its molecular point-of-care test that can detect positive results in as little as 5 minutes and negative results in 13 minutes. The test will run on the ID NOW platform, which is already widely available in a number of healthcare setting such as physician's offices, urgent care clinical and hospital emergency departments throughout the country. The tests are expected to be rolled out this week throughout the country, and between the ID NOW and m2000 platform assays, Abbott expects to deliver 1M tests. ID Now is expected to deliver 50k tests/day.

Figure 12. Updated Diagnostics Focused Timeline of COVID-19 in the United States

Date	Event	Tickers
27-Mar-20	Abbott announced EUA and launch of molecular point-of-care test to detect virus in as little as 5 minutes on ID Now platform.	ABT
26-Mar-20	Henry Schein announces availability of antibody based rapid blood test Standard Q COVID-19 IsM/IgG Rapid Test for point of care administration, manufactured by SD Biosensor	HSIC
	Vice President Mike Pence announces Abbott labs submitted point-of-care test to FDA	ABT
25-Mar-20	Quidel's Lyra SARS-CoV-2 Assay receives expanded EUA for use on three additional thermocyclers: Applied Biosystems 7500 (TMO), Roche LightCycler 480, and QIAGEN Rotor-Gene-Q	QDEL
	Bio-Techne highlights use of Ella Automated Immunoassay Platform to monitor immune response of COVID-19 by detecting Cytokine Release Syndrome to triage most at risk patients	TECH
24-Mar-20	QIAGEN releases QIAstat-Dx in U as first syndromic test for COVID-19 detection. Test can differentiate COVID-19 from 20 other resp. infection in one hour.	QGEN
	Perkin Elmer receives EUA for RT-PCR test for immediate testing in CLIA labs. Test marketed as IVD device and available in 30 countries worldwide	PKI
20-Mar-20	Danaher's Cepheid receives EUA, has 5,000 US point of care instruments, 23,000 worldwide.	DHR
19-Mar-20	LabCorp announces expectation to perform 20k tests/day by Friday March 20, ahead of initial 10k/day by end of week and 20k/day by end of month. 3-4 day TAT	LH
	GenMark receives EUA for ePlex SARS-CoV-2 test with 2 hour testing TAT.	GNMK
18-Mar-20	Abbott announces EUA for m2000 based assay, immediately shipping 150k tests with plan to ramp to 1M/week by end of March	ABT
17-Mar-20	QIAGEN announces intentions to ramp RNA extraction ktis to support 10M+ tests/month by the end of June 2020 and 20M+ test/month by the end of 2020	QGEN
16-Mar-20	Thermo Fisher suggests current 1.5M tests available to ship, with quick ramp to 2M per week, and 5M per week by April.	TMO
	Roche announces 400k kits began shipping 03/13 for completion this week with 3.5 hr TAT once started. Plans to ship additional 400k/week moving forward.	ROG-CH
	FDA issues EUA for Hologic's Panther Fusion Assay and LabCorp's RT-PCR test	HOLX, LH
	FDA loosens EUA restrictions, allow all states the authority to approve tests developed in their state, and enables comm. Manufacturers to distribute prior to EUA	
15-Mar-20	Alphabet (Google) launches Verily site to triage patients in the Bay Area with expectations to expand over time.	
13-Mar-20	**FDA gives flexibility to NY State Dept. of Health to authorize certain labs to begin testing after validation and notification in lieu of EUA**	
	Roche cobas COVID-19 test receives FDA EUA in markets accepting CE-mark, for use in cobas 6800/8800	ROG-CH
	OPKO BioReference Laboratories to partner with NY State Dept. of Health for drive through testing, expects 5k add'l tests at satellite locations next week	OPKO
	Luminex announces four independent labs have validated LDTs using ARIES System, enabling immediate COVID-19 menu additions	LMNX
	Pres. Trump declares National Emergency, increased access to and funding for testing, and new website tool for "drive by" testing recommendations	
	Thermo Fisher receives EUA from FDA, for SARS-CoV-2 test optimized for TMO's Applied BioSystems 7500 Fast Dx RT-PCR instrument	TMO
12-Mar-20	Eurofins announces two labs in US now offer COVID-19 testing through RT-PCR. Planss for TEM-PCR Viral Panels next week	ERF-FR
	Bio-Rad launches standard with synthetic COVID-19 RNA transcripts and human genomic DNA, allowing labs to test a molecular assay's entire process	BIO
11-Mar-20	GNMK announces submission of EUA for ePlex RUO assay	GNMK
	Politico highlights potential shortage of RNA extraction kits	
10-Mar-20	**Viracor Eurofins Launches test with same day results (12-18 hours) targeting March 13 start**	**ERF-FR**
	FDA Commissioner Stephen Han suggest 4M additional tests to be shipped by end of next week	
9-Mar-20	CDC confirms testing available in all 50 states with 78 state and local public health labs, with 75k distributed kits	
8-Mar-20	CDC has run 1,700 tests compared to 200,000 in South Korea	
5-Mar-20	**Quest Diagnostics launches COVID-19 testing service to start testing March 9, 2020**	**DGX**
	LabCorp makes test available for ordering by physicians or authorized healthcare providers	**LH**
4-Mar-20	**Luminex announces promising early results on NxTAG CoV Expanded Panel and successful validation from two European reference labs using single-target test on ARIES System**	**LMNX**
3-Mar-20	**FDA lifts restriction, enabling high-complexity CLIA labs to run internally validated tests prior to EUA**	
2-Mar-20	**GenMark Diagnostics announces global shipments of ePlex RUO test kits**	**GNMK**
29-Feb-20	U reports first death, announces new travel restrictions for areas in Italy and South Korea	
25-Feb-20	Only 12 labs in 5 states in Us have ability to test for COVID-19	
Feb-20	Cases continue to spread globally, hubs include South Korea, Iran, Italy	
	Initial rollout of tests in US from CDC produce inconclusive results with faulty reagent	
	Initial testing in US restricted to severly symptomatic patients that were in China or had contact with lab-confirmed patient	

Source: Company reports, CDC, FDA, New York Times, Politico

Disclosures Appendix

Analyst Certification

I, Puneet Souda, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Distribution of Ratings/Investment Banking Services (IB) as of 12/31/19

Rating	Count	Percent	IB Serv./Past 12 Mos. Count	IB Serv./Past 12 Mos. Percent
BUY [OP]	153	73.9	59	38.6
HOLD [MP]	53	25.6	4	7.5
SELL [UP]	1	0.5	0	0.0

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.

The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

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