NEUBERGER BERMAN

Neuberger Berman Equity Research Team

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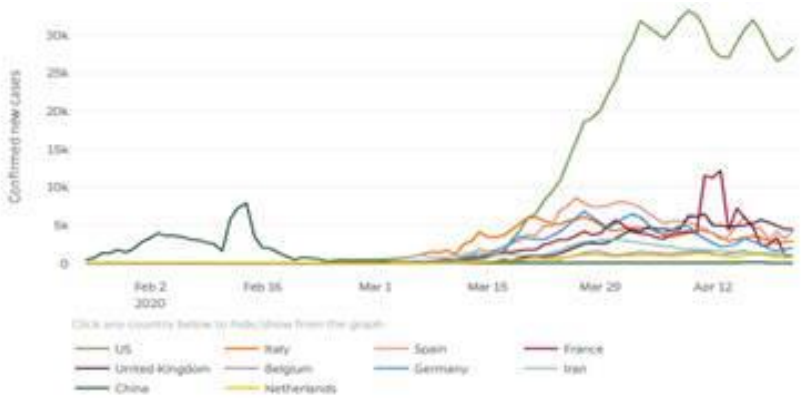
Where Are We in the Pandemic?

Our current thoughts on the spread of SARS-CoV2, variables that could affect a "second wave" and whether we are prepared for next year's flu season, should the coronavirus linger.

With new information about the SARS-CoV2 virus (that causes the COVID-19 disease) emerging on a weekly basis, new testing methodologies across both molecular and serological modalities on a daily basis and "leaked" data on treatments as well as updates on vaccine manufacturing, we wanted to summarize our current thoughts on how things stand in relation to the spread of the disease.

Where are we in the pandemic? As of Friday morning, there were ~2.8mm confirmed COVID-19 cases worldwide, ~872,000 in the United States and ~272,000 in New York State, the epicenter of the U.S. with a case fatality rate of ~5.7%. That's lower than for most countries in EU, in line with that of China and only modestly above Germany's rate of ~3.5%. Based on this data, the curve is flattening across most of Europe and stabilizing in the U.S., although we note that there are ~10 "hot spot" states that we are keeping our eye on. Hence, we do not dismiss the risk of rolling clusters in various cities as southern states including Georgia, Florida and South Carolina attempt to "open up." Regarding Europe, most of the Big 5 countries are flattening if not declining, except for the U.K. where the case count is highly volatile and additions are bouncing between 4,500 and 4,800 per day with a testing positivity rate of ~33%.

Confirmed Cases by Country



Source: John Hopkins University, https://coronavirus.jhu.edu/data/cumulative-cases

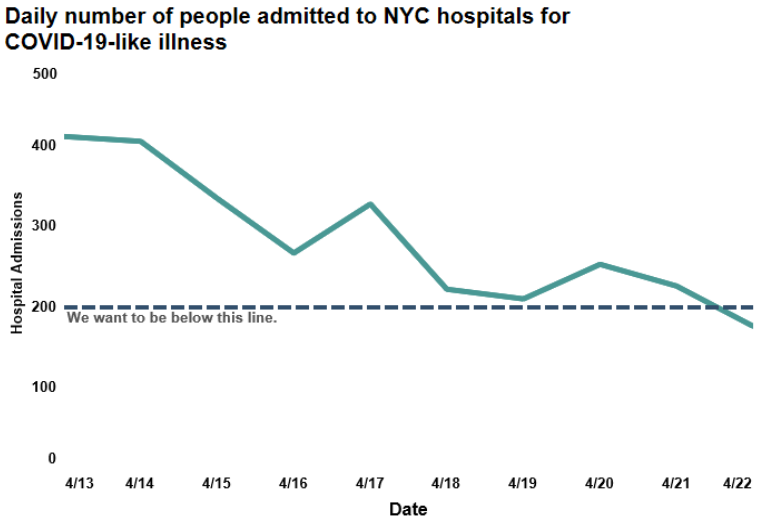
Risk of resurgence, the so-called second wave: We are carefully tracking cases in Singapore given a recent cluster in migrant worker housing with cases increasing from ~600 – 700 per day last week to ~1,000 (as of April 24) for a total of 11,178 cases or a doubling every six days versus the U.S. rate of more than 15 days. Japan, Taiwan and, to a lesser extent, China are experiencing a slow increase of new COVID-19 cases, however, at least for China, the majority of cases appear to be in returning citizens and not from within the country. To this end, emergency measures have been re-implemented, however the trends offer a cautionary note as to how this virus lingers. Additionally, many have asked if COVID-19 will mirror the Spanish flu of 1918 and 1919 with respect to several peaks across ~10 month timeframe from April 1918 to February 1919. While one can never say never, we remind all that back then there were limited supportive care treatments, the health care system was in its infancy with regard to capacity and advances, and soldiers were returning from war, which likely contributed to waves of spread.

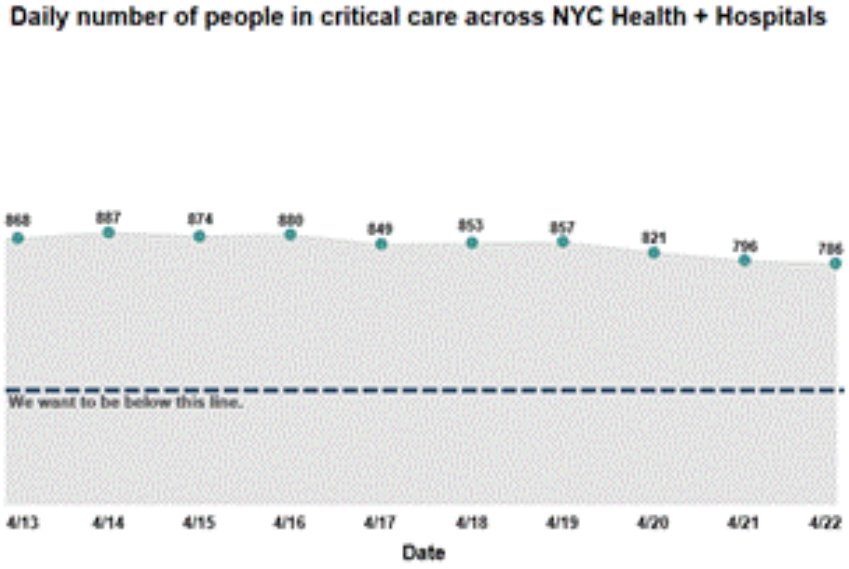
What about seasonality? We refer you to elegant work done by our Chief Data Scientist Michael Reece and his team in this regard (https://www.nb.com/en/us/investing-in-volatile-markets). Suffice it to say, we are in complete agreement that the odds of SARS-CoV2 completely going away in the summer a la influenza is quite low, although we recognize recent published studies regarding direct sunlight's impact on killing the virus: Hotter outdoor surfaces could lead to lower resident time (or half-life) of the virus, and perhaps somewhat slower transmission from surfaces.

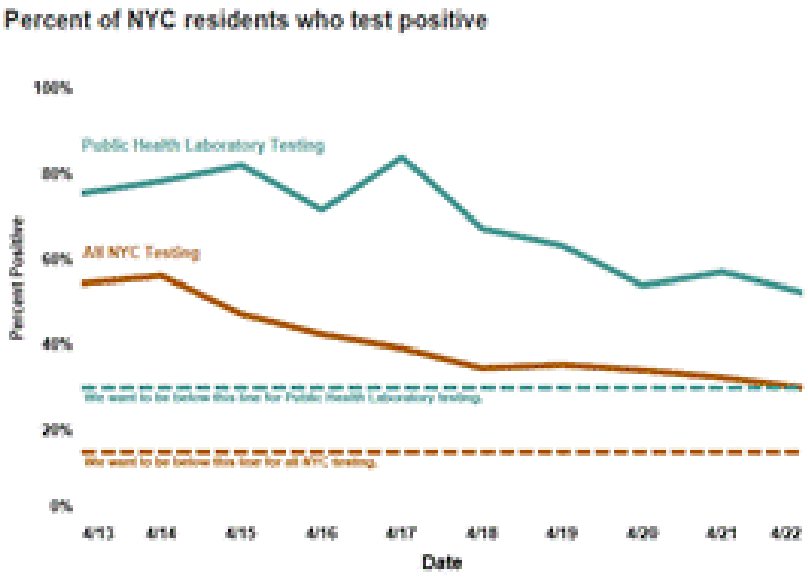
Are we there yet? When can we "reopen" society? With parts of Europe moving toward easing/reopening and several U.S. states on a similar track, we are naturally being asked when it will be safe to reopen without risk of a backslide into self-quarantine. To provide some perspective, we have included the Trump administration's slide deck on guidelines to open the U.S. We have also been tracking New York State and New York City's COVID-19 statistics and offer the following on milestones to reopen NYC as per Mayor DeBlasio's taskforce. (Note that we believe ultimate authority probably lies with Governor Cuomo.)

Three Milestones to Reopen NYC

Daily new hospitalizations for COVID-19 illness needs to be below 200 admissions per day for 10 consecutive days, lower ICU occupancy of at or less than 375 patients in the ICU for 10 consecutive days, and with testing, we need to have less than a 15% COVID-19 positivity rate across all of NYC and hold steady or go lower for 10 consecutive days, respectively. Recent status is shown in the displays below.







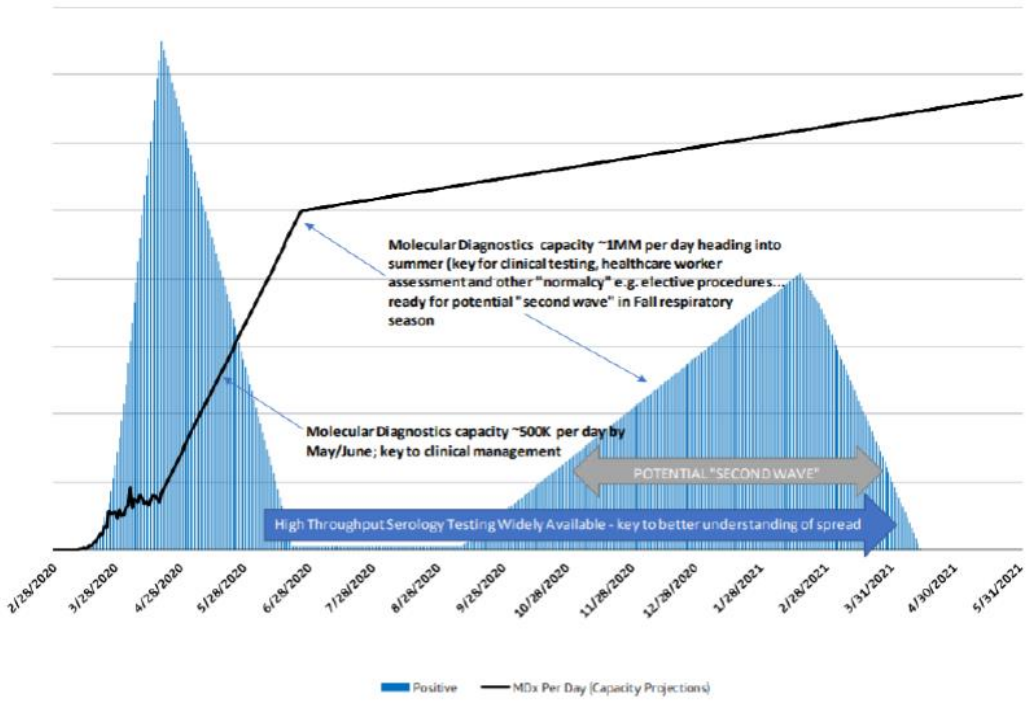
Source: nyc.gov.

So once we reach these milestones how do we know it's safe? To be fair, these benchmarks simply attempt to ensure that the health care system would be able to handle the second wave, and really don't address who could go back to work and who has immunity. While, again, I defer to our data science team for detailed analysis regarding herd immunity and assessment of the plethora of sero-survey studies (https://www.nb.com/en/us/investing-in-volatile-markets), we thought it might be helpful to frame testing capacity both on the molecular front, which is the type of test used to identify the presence of SARS-CoV2 with a nasal and/or throat swab and possibly saliva as the source material, and serology testing to detect antibodies to the virus once someone is infected, which uses blood.

How many molecular tests to detect the virus are needed going forward? Regarding the need for more molecular testing, we agree with a note out of the Cowen Life Sciences team that capacity to run these RT-PCR tests to detect the virus is ample and expanding by the day. Reagents, swabs and transfer media are what could be rate-limiting factors, but recent news suggests this is improving.

- Currently, the U.S. is performing ~160,000 tests per day with over 4.7mm tests to date.
- We see this expanding to ~500,000 tests per day in the next few weeks, moving toward the ultimate goal of 1mm tests per day in order to help ensure that any patient, health care worker or first responder who needs a test could have access with rapid turnaround of results.
- This, of course, does not include any employer-sponsored molecular testing, which has been discussed by several companies and reported to shortly begin at Amazon, where they are setting up their own internal labs.
- Finally, recent news reports suggest that saliva could be used as sample material for the molecular tests to detect SARS-CoV2. Data out of Rutgers suggests that the performance of saliva testing was as good as, if not better than, the use of nasal swab-sourced material, as per a preprint published in Medrxiv. Although we await peer-reviewed published data, this could remove the swab bottleneck and also be a major improvement for patients. That said, capacity is currently at 100,000 tests per week and, provided the supply of collection tubes could ramp up, ~1mm tests per week could be possible.

The chart on the next page depicts potential timelines for molecular diagnostic test expansion.



Source: Cowen & Company, IHME, covidtracking.com

What about serological tests? There are many low-quality tests. We are more confident in tests from Abbott Laboratories, Danaher and Roche for more reliable information on prevalence given validated specificity and sensitivity metrics that could help ensure a low false positive rate. Importantly, assessment of true immunity as measured by neutralizing antibodies as opposed to total antibodies may be limited to Roche's test at this point in time. While most of the U.S. is relying on serology testing to determine who has antibodies to SARS-CoV2 as a proposal to reopen society, we sense too much optimism in this regard, at least until a foundational test can be identified. The characteristics of such a test would be to demonstrate high specificity for this coronavirus (99.5%+) so as to reduce false positives, superb sensitivity (~ 95%+) so as to identify as many individuals as possible, be fully automated to ensure high throughput of at least 1mm tests per day (10,000 tests per day across 100 sites) and have at least a semi-quantitative nature in order to infer neutralizing antibodies within the total antibody sample.

Who are the most reputable players with solid specs as of April 24?

		Installed Base				
Vendor	**Throughput**	**US**	**OUS**	**Total**	**Test Available?**	**Comments**
Abbott						Abbott has ~22.5K immunoassay systems installed globally
ARCHITECT i1000SR	100 tests/hour	Not disclosed	Not disclosed	Not disclosed	Yes	Tests initially run on i1000SR/i2000SR & expanding to Alinity
ARCHITECT i2000SR	200 tests/hour	Not disclosed	Not disclosed	Not disclosed	Yes	There are >2,000 i1000SR/i2000SR systems installed in US
ARCHITECT i4000SR	400 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	Expected to produce ~4MM in April; ~20MM/month starting in June
Alinity i	200 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	
Beckman Coulter Dx (DHR)						
Access 2	100 tests/hour	>2,000	>9,000	>10,000	No	Manufacturing capacity not disclosed
UniCel Dxl 600	200 tests/hour	>750	>450	~1,200	No	
UniCel Dxl 800	400 tests/hour	>500	>4,000	~4,500	No	
bioMerieux						~30K VIDAS systems installed globally (includes all three configs)
MINI VIDAS	36 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	Manufacturing capacity not disclosed
VIDAS	80 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	Test expected to be introduced by summer
VIDAS 3	36 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	Vast majority of placements are OUS
Ortho Clinical Diagnostics						VITROS systems are installed in >1,000 US labs
VITROS 3600	-	>200	>400	~600	Yes	Manufacturing capacity not disclosed
VITROS 5600	-	Not disclosed	Not disclosed	Not disclosed	Yes	According to OCD, VITROS can process ~150 tests/hour
VITROS 7600	-	>100	>200	~300	Yes	
VITROS ECi/ECiQ	-	Not disclosed	Not disclosed	Not disclosed	Yes	
PerkinElmer						Manufacturing capacity not disclosed
EUROLabWorkstation	>200 tests/hour	Not disclosed	Not disclosed	Not disclosed	Yes	
EuroAnalyzer I-P	70 tests/hour	Not disclosed	Not disclosed	Not disclosed	Yes	
EuroAnalyzer 2-P	50 tests/hour	Not disclosed	Not disclosed	Not disclosed	Yes	
Roche						Roche has >40K immunoassay systems installed globally
e 411 (cobas 4000)	86 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	Ramping monthly production to "high double-digit" million tests by June
e 601 (cobas 6000)	170 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	and further scale up production "as fast as possible"
e 602 (cobas 8000)	170 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	
e 801 (cobas 8000)	300 tests/hour	Not disclosed	Not disclosed	~4,000	No	
Siemens						
Atellica IM 1300	220 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	~20K Attelica systems (chemistry and immunoassay)
Atellica IM 1600	440 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	
ADVIA Centaur XP/XPT	240 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	
ADVIA Centaur CP	180 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	
IMMULITE 2000 Xpi	200 tests/hour	>160	>2,200	~2,400	No	
IMMULITE 1000	120 tests/hour	Not disclosed	Not disclosed	Not disclosed	No	

Source: Company reports and Cowen and Company

We believe the Abbott test has utility for screening those who have been exposed to SARS-CoV2, and as long as the specificity is as good as claimed (i.e., does not cross-react with the other four coronaviruses known to circulate in the U.S. but have limited clinical sequelae), this could be a useful tool for identifying mild and asymptomatic cases. We also view this as a foundational test that, with more scientific development, could ultimately end up as the right serological test that confers immunity…just not in the current form.

Most notably, the Roche test which is expected to launch in May, has been validated with specifications as close to 100% on specificity and sensitivity for two SARS-CoV2 antigens as possible, is automated and runs on the >40,000 installed systems around the world. From a capacity perspective, Roche expects to have "high-double-digit millions" of tests/month by mid-June.

What about the other 50 or so tests that have flooded the market, including point-of-care/at home? On an earnings call a few days ago, Roche's CEO characterized the current state of COVID-19 antibody testing as "a disaster." Specifically, he was highlighting the plethora of serological tests that have flooded the market with claims that are simply nonsensical and, quite frankly, could result in false positives that could have devastating consequences, in our view. To this end, commentary out of the new FDA commissioner, Dr. Stephen Hahn, points to the agency's tightening restrictions going forward for new COVID-19 serology tests and internally validating many of the currently marketed tests, most likely resulting in rescinding marketing authorization for many.

So what does this mean for immunity and getting back to work? Not all positive serology tests equal immunity against SARS-CoV2, unfortunately, with a recent study showing that ~1/3 of all antibody-positive individuals may not be immune (lower titers could mean lower neutralizing antibodies as a percent of the total)—a staggering statistic if corroborated by other groups/studies. Still, it seems to be all we have to begin to dissect the true infection rate of this virus and hence the true fatality rate, both of which could help the country move forward.

Employer testing? While we recognize the interest from employers who may want to implement serological sample collection in the workplace, we remind all that the preference for serology testing as laid out in the CDC guidelines is for health care workers first (8 – 9mm in the U.S.), and nursing homes, day care centers and schools next (~77 – 80mm), before the rest of the U.S. workforce (before COVID-19) of ~150 – 160mm. Employers would typically have to engage with a testing facility, which possibly could be facilitated by their managed care contractor.

Finally on treatments: So much leaked data, let's just wait for the controlled studies. We have written extensively about the remdesivir "Watergate" situation, so I won't opine here. Disappointing data out of a segment of the NYPH study for hydroxychloroquine has tempered our cautious optimism for treatment, but the prophylactic study at the University of Minnesota has passed an interim safety look with final data readout in late May. We doubt either of these two treatments is likely a magic bullet, and are more positively inclined on passive antibody programs out of Regeneron, Vir Biotech, Eli Lilly with Abcellera and Amgen. We are branching out and looking at other modalities for treating this beast of a virus, such as cell-mediated therapies and other anti-inflammatory agents, as well as carefully designed anti-virals directed against SARS-CoV2 specifically and would expect to hear of clinical advancement sometime in the next month or so.

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For more information on COVID-19, please refer to the Center for Disease Control and Prevention at cdc.gov.

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