What Happened Last Week

The FDA issued one new EUA, seven amendments to existing EUAs, and no new safety/policy communications in the past week:

- **New EUAs (1):**
  - Antigen Tests (1): Oceanit Foundry ASSURE-100 Rapid Test

- **New Amendments to Existing EUAs (7):**
  - Molecular Tests (2): Thermo Fisher TaqPath RNase Combo Kit 2.0 | Cue Health
  - Serology Tests (4): Bio-Rad Laboratories Platelia Total Ab | QIAGEN QIAreach Total Test | Jiangsu Well Biotech Orawell IgM/IgG Rapid Test | EUROIMMUN S1 Curve ELISA (IgG)
  - Collection Kits (1): Yale SalivaDirect

New & Noteworthy

**Last season: NFL used Ct counts to end COVID time-outs**

*Kaiser Health News* reported that the NFL released players from quarantine early this past season if the Ct count of their last positive PCR test was only "faintly positive" (>35). The result: 70% of players went back to the game before the 10-day quarantine (recommended by CDC at that time) was up.

*Commentary:* This is an appropriate protocol assuming that it is thoughtfully implemented, as we know that PCR is oversensitive to non-infectious individuals’ post-recovery. As we have discussed in a series of blogs, reluctance to release Ct data even to physicians is unjustified. Yes, Ct values vary by test protocol, but creating a standard curve translates Ct count into comparable viral load. Yes, SARS-CoV-2 is a tissue-resident virus, so sampling can be variable, but that is a risk for positive/negative calls in any case. If Ct is low, the risk of infection is much higher than if Ct is high - why throw this essential information away?

**Next season: NFL suspends all COVID testing and protocols**

Mandatory testing is being discontinued in many arenas - and as of now that will include the NFL arenas, as the league has reached an agreement with its players association to eliminate all COVID surveillance testing. They have taken a prudent approach, however, by requiring teams to continue reporting positives and testing symptomatic people, as well as maintaining a physical space for rapid testing, should it be needed in the future. They also acknowledge that if the prevalence of the virus changes, they may re-impose testing and other protocols, including masking.
**We’re looking at a lot of Long COVID**

A nationwide study in Denmark has documented Long COVID symptoms six to 12 months after infection in nearly 30% of people who tested positive between September 2020 and April 2021. The questionnaire-based study, which hasn’t yet been peer-reviewed, involved more than 61K adults (ages 15 and up) who’d had PCR-confirmed COVID, and more than 91K who tested negative. Of those who tested positive, 53% (compared to 11.5% of those who tested negative) reported at least one of the following conditions: difficulty concentrating, memory issues, sleep problems, or mental or physical exhaustion. Other common symptoms: lack of smell or taste, fatigue, shortness of breath, and decreased arm and/or leg strength.

**Filling in the insurance-coverage gaps**

First it was folks with private insurance. Next, folks with Medicare. Now, another group will be able to access eight free rapid tests per month: military beneficiaries.

**Food for Thought**

**Where, why and how did this all start?**

The more we learn, the more it looks like the essential jump from animals to humans happened at the Wuhan wet market - and the more unlikely it seems that a laboratory leak - whether accidental or intentional - was involved. Unfortunately, the mystery persists because we have not figured out which species bridged the gap. By the time testing at the wet market was carried out - in early 2020 - the jump was months in the past. We may never know for certain exactly how COVID-19 began, but recent work provides compelling evidence that human-to-animal-to-human transmission is in our immediate future. (Mara published a piece on this in The Timmerman Report.)

**Applying the Lessons of the Pandemic: Testing Edition, Episode 5**

**If it ain’t broke**

Folks in Utah developed the first Test to Stay program, which worked so well in the fall and winter of the 2020-21 school year that the CDC published a MMWR documenting its success. The original protocol was a school-wide, voluntary testing program that kicked in only if cases reached a certain threshold: 1% of students in a large school (>1500 students) testing positive, or >15 students in a smaller school. If that threshold was crossed, students who wanted to come to school in person had to test.

Legislators in Utah changed that threshold to 2% / 30 students last March, against expert advice. And then they forbade schools from requiring masks in the 2021 - 22 school year. As the Salt Lake Tribune recently reported, the one-two punch, coupled with the increased transmissibility of the Delta and Omicron variants, knocked Test to Stay flat. Instead of roughly 1% of students testing positive during Test to Stay, as they had before, positivity rates in the fall “were typically closer to 5%,” and in some cases reached over 10%. Eventually, the state ran out of tests, and in January 2022, the program was suspended.

**Commentary:** Test to Stay wasn’t designed to work in a mask-free environment during a surge. None of our COVID precautions work 100% on their own; that’s why the Swiss Cheese model is so critical when surges happen. As we head into what we hope will be a lull, we need to remember that for the future.

**K-12 Round Up:**

**If we can unmask there, we’ll unmask anywhere**

The nation’s largest school district, New York City, became mask-optional on Monday. Burbio reports that 292 of the nation’s 500 largest districts have done the same, the highest number yet.

**The Good News is…**

**Pre-pregnancy vaccination doesn’t affect IVF outcomes**

Three weeks ago, we reported on research showing that vaccination during pregnancy protects the baby as well as the mother. This week, a retrospective study soon to appear in Fertility and Sterility indicated that vaccination doesn’t impede women’s ability to become pregnant via in vitro fertilization. The research involved 400 age-matched women (200 vaxxed, 200 non-vaxxed), all of whom underwent IVF between January and April 2021 at Shamir Medical Center in Israel.
# Latest Monthly Capacity Estimates

## Estimated Monthly Capacity of All Tests (M)

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Nov '21</th>
<th>Dec '21</th>
<th>Jan '22</th>
<th>Feb '22</th>
<th>Mar '22</th>
<th>April '22</th>
<th>May '22</th>
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<tbody>
<tr>
<td><strong>ANTIGEN</strong></td>
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<td></td>
<td></td>
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<tr>
<td>Antigen Professional + Point of Care EUA</td>
<td>174</td>
<td>185</td>
<td>187</td>
<td>187</td>
<td>181</td>
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<td>156</td>
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<tr>
<td>Antigen OTC: Home/Self EUA</td>
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<td>260</td>
<td>535</td>
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<td><strong>Antigen Total</strong></td>
<td>315M</td>
<td>401M</td>
<td>447M</td>
<td>722M</td>
<td>643M</td>
<td>580M</td>
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<td><strong>MOLECULAR</strong></td>
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<tr>
<td>Molecular Professional, Point of Care, OTC EUA</td>
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<td>36</td>
<td>36</td>
<td>36</td>
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<td>Lab Based PCR</td>
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<td>108</td>
<td>90</td>
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<tr>
<td>Add'l Lab Based PCR with Pooling</td>
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<tr>
<td><strong>Molecular Total</strong></td>
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<td>182M</td>
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<td>151M</td>
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<td><strong>Total Test Capacity</strong></td>
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<tr>
<td></td>
<td>505M</td>
<td>586M</td>
<td>624M</td>
<td>904M</td>
<td>814M</td>
<td>731M</td>
<td>683M</td>
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</tbody>
</table>

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