COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #33

Thursday, *July 1, 2021, 12-1 PM ET*

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting #33

This week's Diagnostics Evidence Accelerator meeting consisted of 1 presentation:

1. Diagnostics: The Key to the Beginning, Middle, & End of the Pandemic (Prof. Mara Aspinall, Arizona State University (ASU))

As always, thank you to all of the analytic partners, strategic advisors, and scientific advisors that are participating in Project One of Diagnostics Evidence Accelerator.

Diagnostics: The Key to the Beginning, Middle, & End of the Pandemic

In collaboration with the Rockefeller Foundation, ASU is working on four programs (Figure 1). This presentation focused on COVID-19 Testing Commons and COVID-19 Evidence Commons.

Figure 1: COVID-19 Diagnostics Commons, Arizona State University (ASU).

Testing Commons is the largest database worldwide containing information on COVID-19 tests that have been authorized or are under development. Of the 2418 tests currently in the database, approximately half are authorized for use around the world and half are in development. Testing Commons is an interactive database where users can search for regulatory status, platform, sensitivity (as per the

Emergency Use Authorization (EUA)), specificity / specificity (EUA), company, diagnostic target, analysis location, specimen collected, and region.

Figure 2 gives an overview of the tests that have been authorized in the world since the beginning of the pandemic (figure 2).

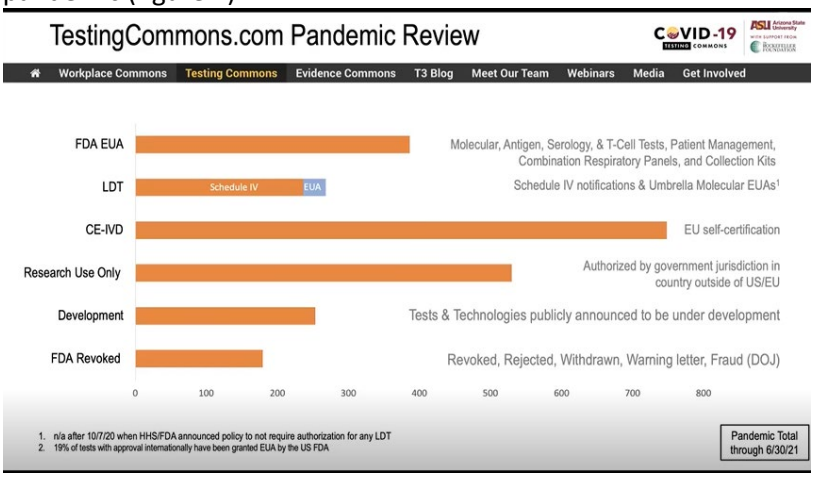

Figure 2: Number of COVID-19 tests authorized around the world.

The US FDA classifies tests based on 4 parameters: Molecular tests (including Appendix A LDTs and Flu panels); Antigen Tests (including Flu panels); Patient Management Tests (mostly IL6 based); and Serology (Antibody) Tests (including cellular immunity). There are also home collection kits. The US FDA also divides tests into test attributes. The attributes are test location (Lab vs. POC vs. Home), screening (asymptomatic), serial screening, pooling, and OTC vs prescription. Figure 3 shows the break down of the number of tests that have EUAs in the US.

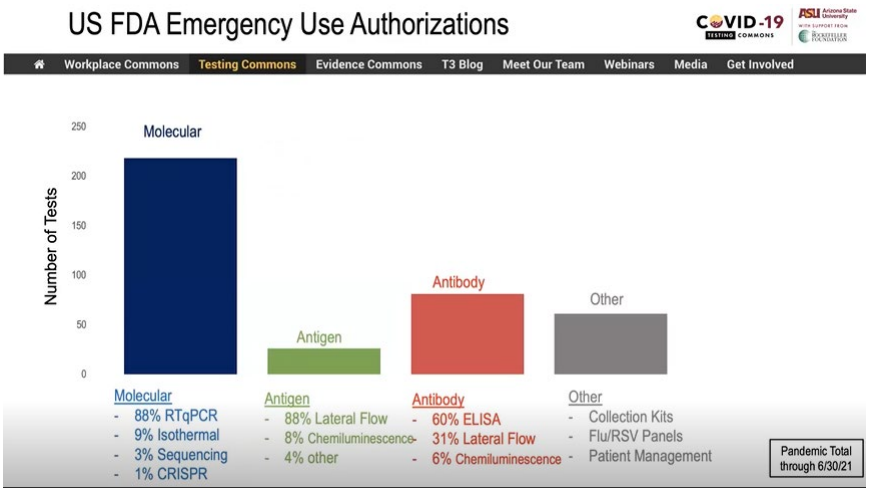

Figure 3: Breakdown of the tests that have received an EUA.

The number of labs authorized to analyze samples, sample type collected, and persons to collect samples can be seen in Figure 4. Since the pandemic is, hopefully, close to the end, the area where we need to focus today is self-tests that utilize anterior nasal swabs and saliva-based samples.

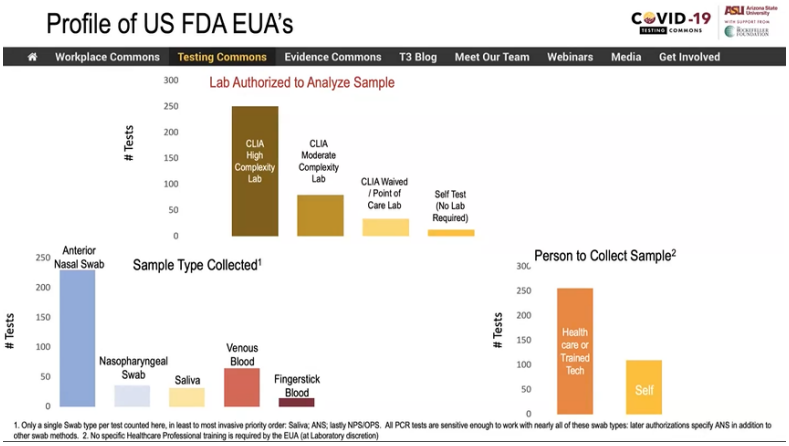

Figure 4: Profile of US FDA EUAs

Today, there are a total of 11 EUAs for comprehensive at-home testing. These tests provide the results at home instead of sending the sample to a lab. US FDA released guidelines to facilitate the development of tests. They released EUA guidelines for asymptomatic screening and serial screening, testing of pooled samples, respiratory panels (to include Flu, RSV, etc.). The companies with the largest number of US FDA EUAs are Abbott (12 EUAs), Siemen (11 EUAs), then Danaher, Quidel, Roche, and Quest.

The breakdown of the CE-IVD authorized tests can be seen in Figure 5. As shown, there has been a focus on developing antibody tests, which has proven to be less useful in most markets.

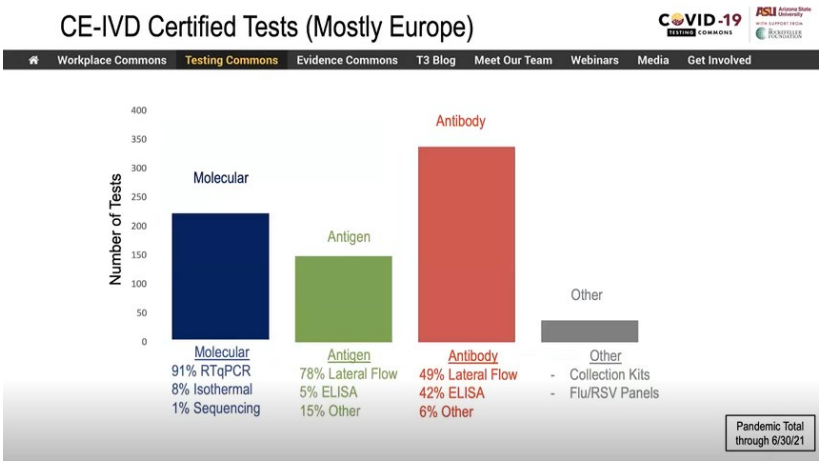

Figure 5: Breakdown of CE-IVD certified test.

Figure 6 shows the breakdown of tests outside of the US and Europe. Researchers focused on molecular and antibody tests.

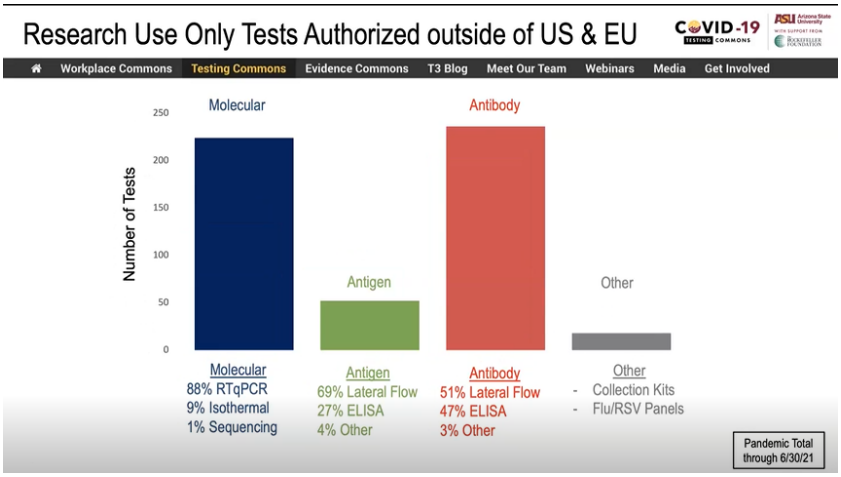

Figure 6: Tests authorized outside of the US and Europe.

The tests in development around the world can be seen in Figure 7. There is a continued focus on molecular tests, specifically genome sequencing and CRISPR based tests, as well as new technologies including breath tests.

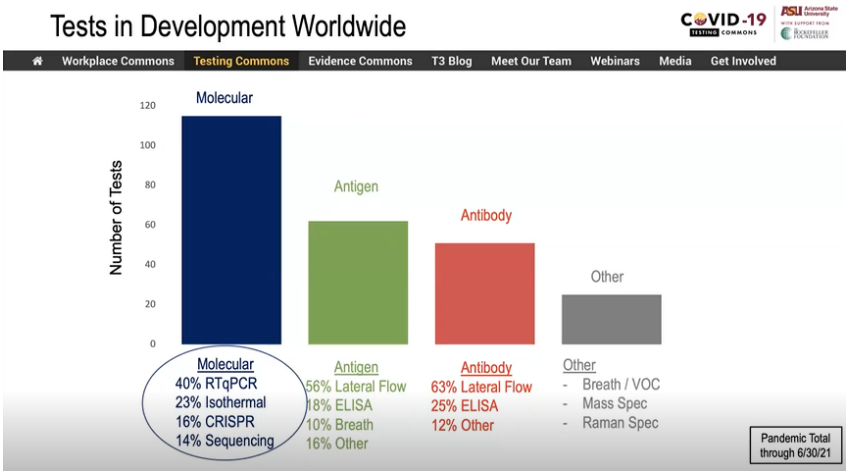

Figure 7:Test in development worldwide.

Prof. Aspinall highlighted a number of the FDA and CDC achievements and opportunities (Figure 8).

Comprehensive Web site - up to date with hyperlinks	
Relaxed validation rules - n=30, spiked etc	Enough Phase IV like data collection? Too much reliance on academic studies that were forthcoming but not prioritized?
Responsive to submissions	Reactive to submissions? Proactive prioritized outreach?
Reward fast movers in crisis mode	Early versus better later?
Fast response to submitted EUA applications	Still too slow for the nature of the pandemic, compares unfavorably to the 10x acceleration of vaccine approvals?
FDA Viral Load evaluation panels provided and executed for molecular tests	Great – but late, incomplete and not continuing? This could have been important source of a prioritized recommendations for strongest tests
Applied the best clinical test standards possible in the circumstances	No explicit recognition of differences between Public Health versus Clinical Care differing needs, objectives and means.
Inaccurate test authorizations revoked	Logic unclear - why this one, why now?
Added new classifications for surveillance and screening	Opportunity to adapt much earlier?
Resisted less useful Ab tests - widespread in Asia, Europe	Still many less irrelevant Ab tests - no clinical case, limited epidemiological case only
EUA absolutely the right decision at the beginning	Need a pathway from EUA to Approval.

Figure 8: FDA and CDC achievement and opportunities.

In Evidence Commons, the objective is to create an interactive global repository of research findings on COVID-19 tests and testing protocols with a searchable database on completed research, operational, and clinical studies. Users can search and filter fields including trial/study type, tests and protocols evaluations, sample populations, and more. Evidence Commons is housed at Arizona State University in partnership with RADxUP team at Duke University. Figure 9 shows the different views of the dashboard. Evidence Commons will be something that can be leveraged for years to come to learn about the COVID-19 pandemic and diagnostics to address future epidemics / pandemics.

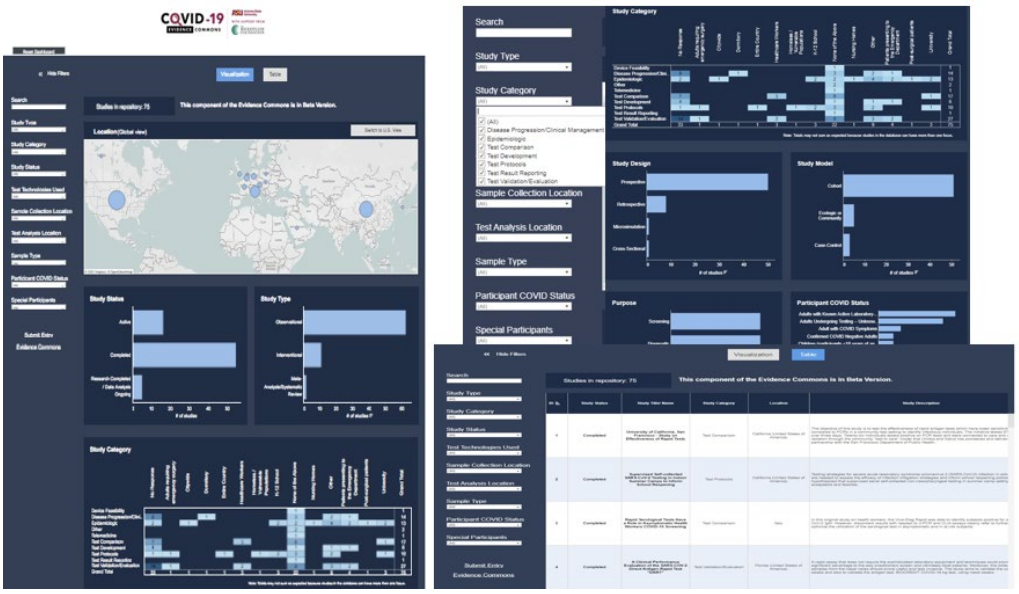

Figure 9: Evidence Commons Dashboard

Discussion:

- TestingCommons.com is an example of the effort and collaboration of the Evidence Accelerator workstream. Testing Commons is a source of information, data, and clearing house of the different test in the world.
- The ability to collaborate with a sense of urgency during the pandemic has provided opportunities to leverage the learning and collaborations for other disease areas. Testing Commons can be a useful

product to leverage in other diseases. Additionally, Testing Commons consist of a global dataset. This helps researchers understand and collaborate better in the COVID-19 space.

Questions and Answers:

- How many test results do you have in total [in the Testing Commons]? Do you know if they're linked to an individual? Can you see if someone has multiple tests in one day or over the course of months?
    - Testing Commons is focused on the tests themselves not about the results of the tests. Testing Commons uses the data that test developers submit in their EUA filings or research publications for those tests in development.
- Can Testing Commons be leveraged in other tests/disease areas?
- How do you cope with a lack of centrally calibrated test results?

Next Steps

- Continue making data connections through the Evidence Accelerator and through www.EvidenceAccelerator.org.

Next Meeting: Thursday, July 15, 2021 12-1 pm ET