FDA Update

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CLIAC
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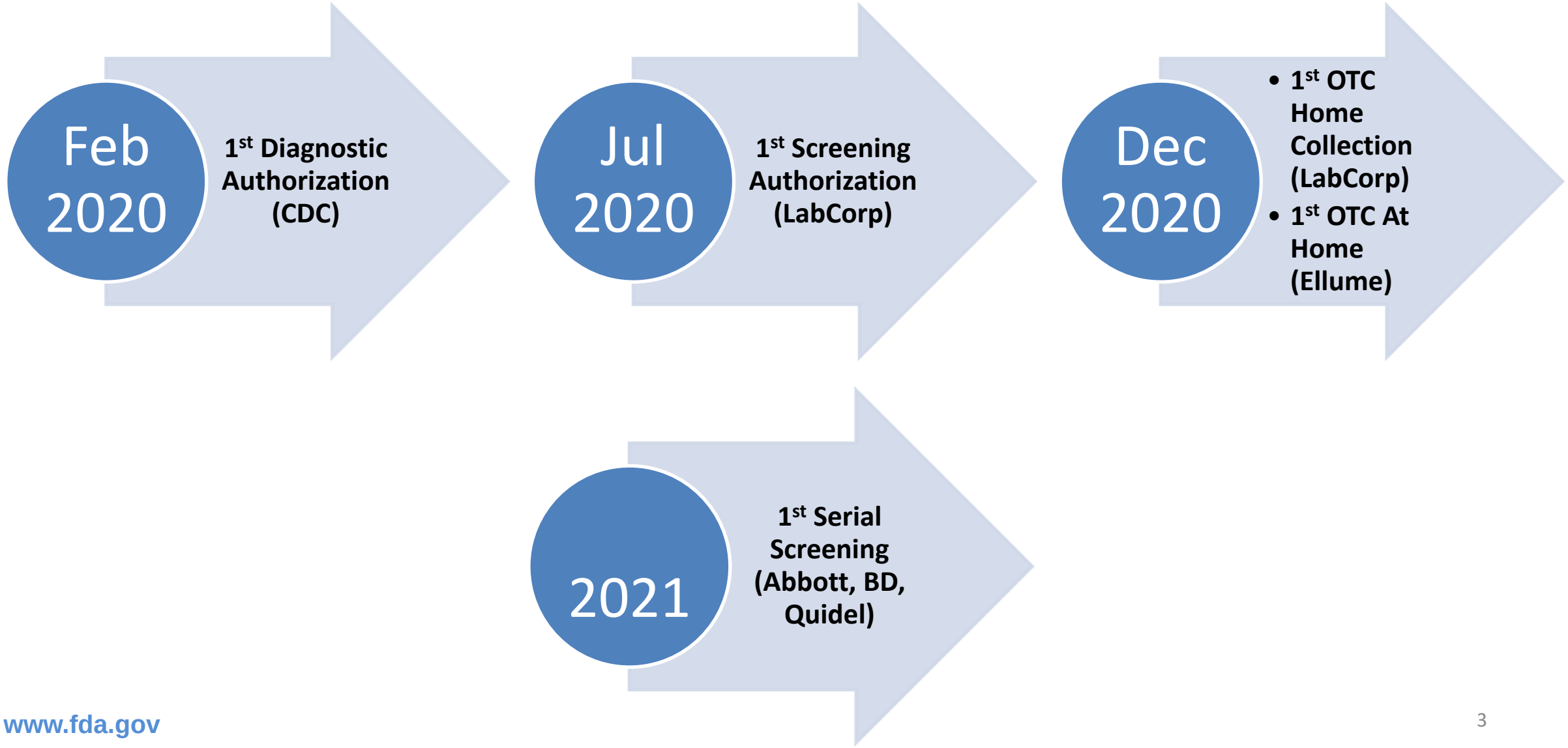
We're Constantly Working on COVID Testing Options

FDA continues to work with test developers to make more coronavirus tests available to more people

COVID-19 Testing Authorization Milestones

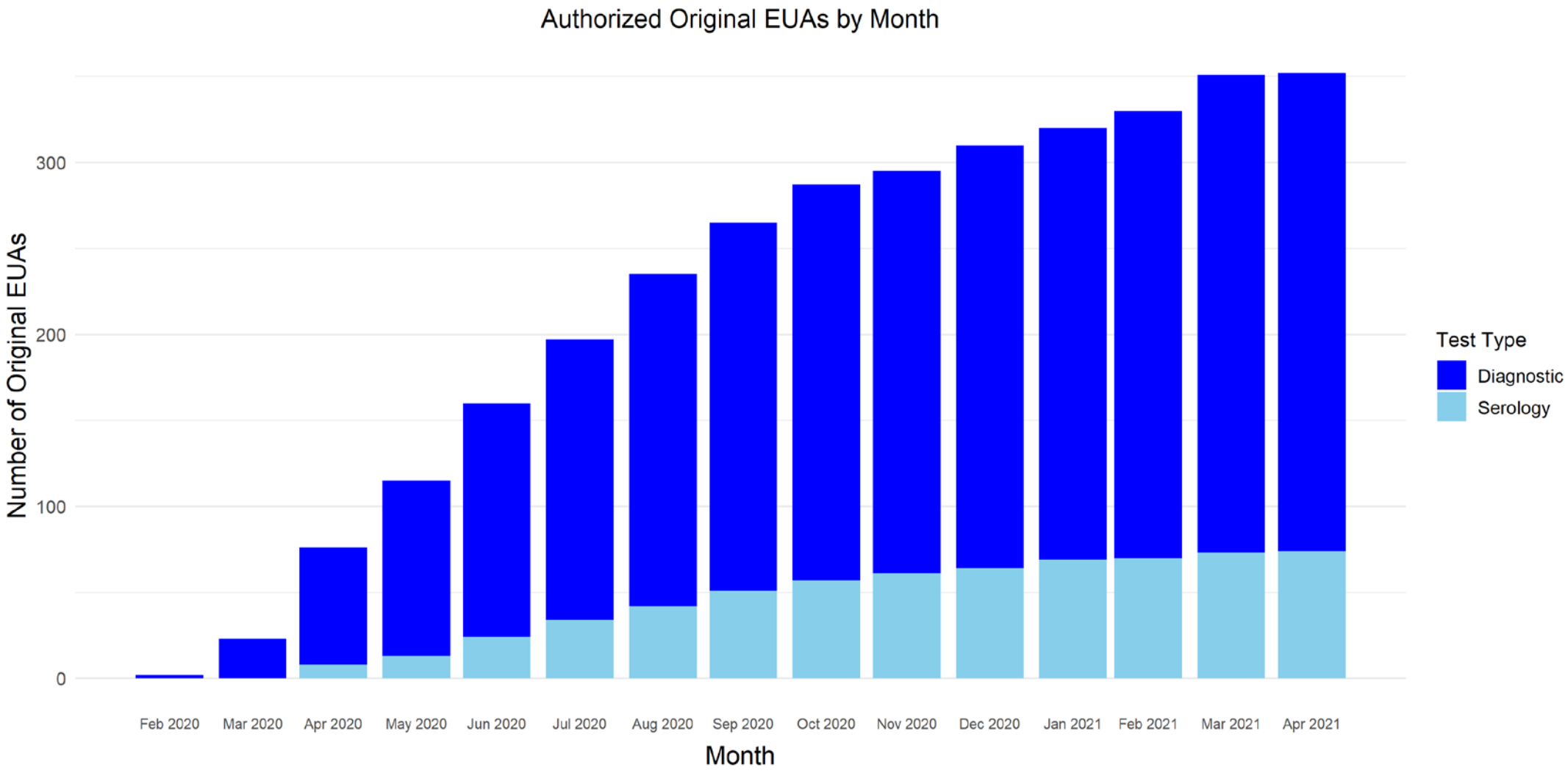


Growing US Testing Menu

COVID-19 Highlights since November 2020:

- First Test that Detects Neutralizing Antibodies from Recent or Prior SARS-CoV-2 Infection (GenScript)
- First COVID-19 Test for Self-Testing at Home (Lucira)
- First COVID-19 and Flu Combination Test for use with home-collected samples (Quest)
- First Direct-to-Consumer COVID-19 Test System (LabCorp)
- First Over-the-Counter Fully At-Home Diagnostic Test (Antigen) for COVID-19 (Ellume)
- First NGS test to aid in identifying individuals with an adaptive T cell immune response to SARS-CoV-2 (Adaptive Biotechnologies)
- First Molecular Non-Prescription, At-Home Test (Cue)
- First Over-the-Counter Tests for Serial Screening (Quidel, Abbott)

EUA Authorizations



Data as of April 8, 2021

Tests Authorized as of March 31, 2021

258 Molecular diagnostic tests

- 21 Pooling
- 25 Asymptomatic screening
- 16 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 11 Point-of-care
- 51 Home collection
  - 9 Standalone home collection kits
  - 11 Direct-to-consumer
  - 1 Multi-analyte
  - 8 Saliva home collection
- 3 Standalone saliva collection devices
- 1 Prescription at-home test
- 1 Over-the-counter at-home test

21 Antigen diagnostic tests

- 17 Point-of-care
- 2 Prescription at-home tests
- 4 Over-the-counter (OTC) at-home tests
- 5 Serial screening

74 Serology and other immune response tests

- 5 Point-of-care
- 1 Neutralizing antibody test
- 12 Semi-quantitative

150 Tests notified but EUA not yet reviewed

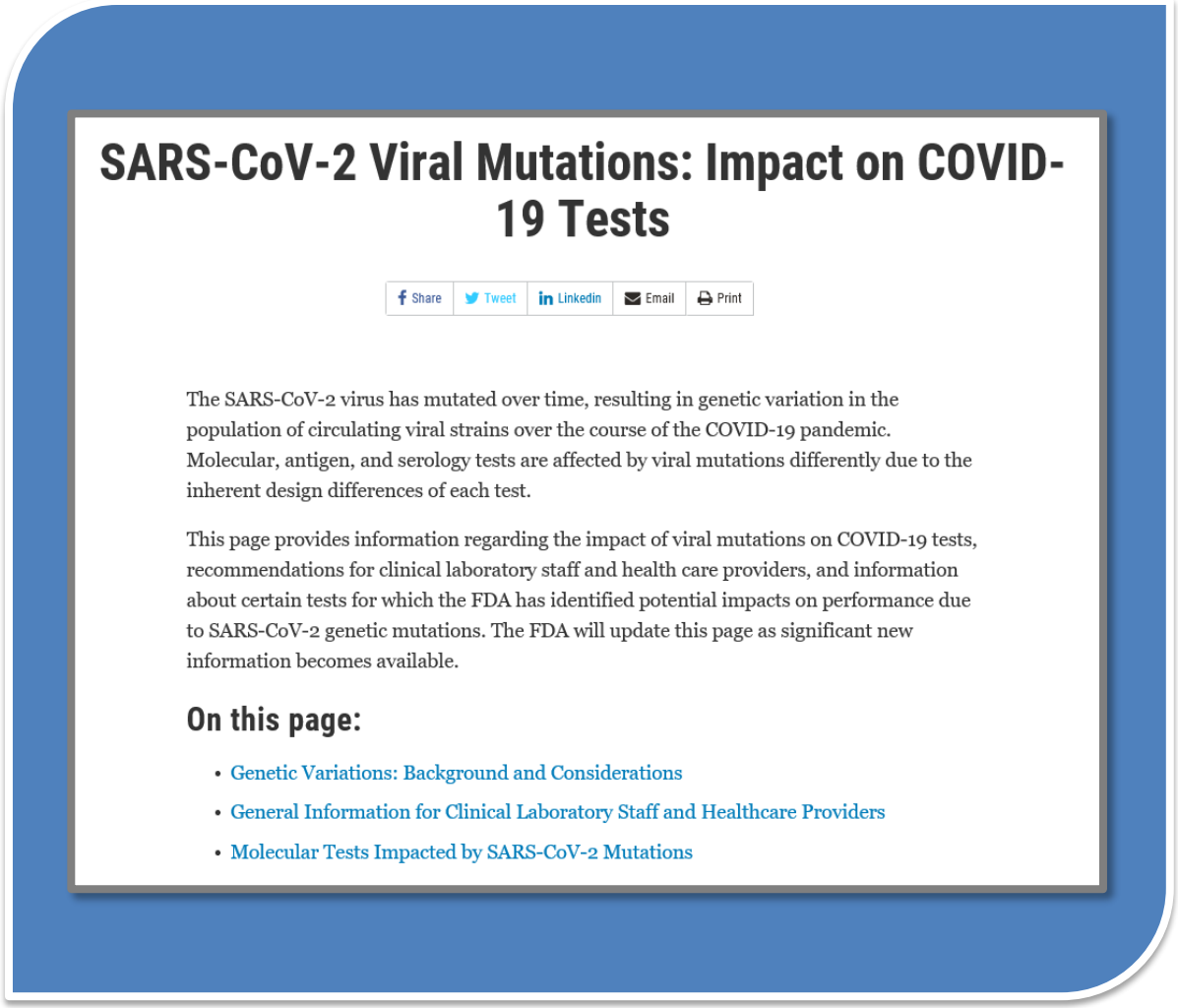
First COVID-19 Diagnostic Test Granted Marketing Authorization Using Traditional Premarket Review Process

BioFire Respiratory Panel 2.1 (RP2.1), which had an Emergency Use Authorization (EUA), was granted marketing authorization using the De Novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type.

- With granting of the De Novo, the FDA also revoked the EUA for this device
- This EUA revocation and De Novo authorization do not impact the availability other tests under EUA

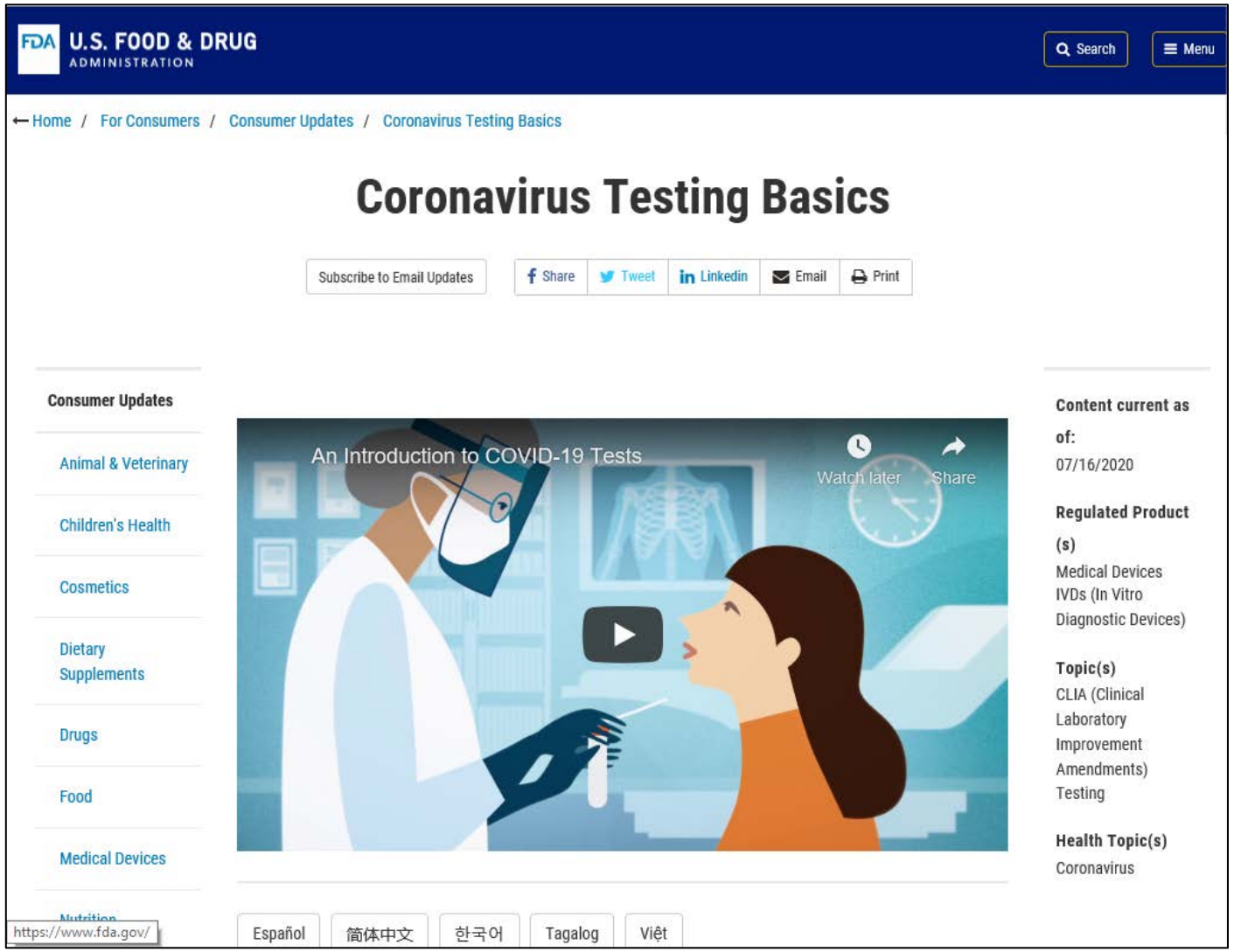
https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-sars-cov-2-diagnostic-test-using-traditional-premarket-review-process

SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests



- January 8, 2021 - FDA Issues Alert Regarding SARS-CoV-2 Viral Mutation to Health Care Providers and Clinical Laboratory Staff
- February 22, 2021 - FDA Issues Policies to Guide Medical Product Developers Addressing Virus Variants
- March 30, 2021 – FDA posts a new web page about the impact of viral mutations on COVID-19 tests
  - This page provides information regarding the impact of viral mutations on COVID-19 tests, recommendations for clinical laboratory staff and health care providers, and information about certain tests for which the FDA has identified potential impacts on performance due to SARS-CoV-2 genetic mutations

Outreach



- 50 Virtual Town Halls (>39,000 participants)
- FAQs on Testing for SARS-CoV-2
- Safety Communications
- Resources for Patients, Healthcare Providers, and Developers
- COVID-19 Diagnostics Mailbox (185,000+ inquiries)
- 2 stakeholder calls to discuss the guidance/policy
- 1 virtual town hall to discuss 3D Swabs

Increasing Access and Ensuring Reliability of COVID-19 Tests – Now and In the Future

1. U.S. government should invest in the development of truly novel technologies that can be used at POC and at home and for multiple conditions

2. Government should be equipped to independently evaluate the ability of non-laboratorian providers and consumers to use and interpret POC and at-home tests to facilitate validation of and assure confidence in the usability of these products

3. Investing in POC and at-home testing technologies now will allow rapid expansion of national testing capacity and patient access when a new public health threat emerges

4. Widely available FDA-approved POC and at-home tests could create a wealth of data, if complemented by the development of robust telehealth and application-based technologies with appropriate privacy protections

5. To shift the testing landscape, it will also be important to explore and create mechanisms that will allow for reimbursement for prescription at-home tests, over-the-counter tests, pooled testing, and screening tests

* "Bending The Arc Of COVID-19 Test Development To Increase Access And Ensure Reliability—Now And In The Future, " Health Affairs Blog, March 22, 2021. DOI: 10.1377/hblog20210318.9094

FDA Grants CLIA Waiver to Allow First Point-of-Care Chlamydia and Gonorrhea Test To Be Used More Widely

- Uses female vaginal swabs or male urine specimens
- Can detect the presence of the bacteria *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in approximately 30 min
- More convenient testing with quicker results can help patients get access to the most appropriate treatment

https://www.fda.gov/news-events/press-announcements/fda-allows-first-point-care-chlamydia-and-gonorrhea-test-be-used-more-near-patient-care-settings

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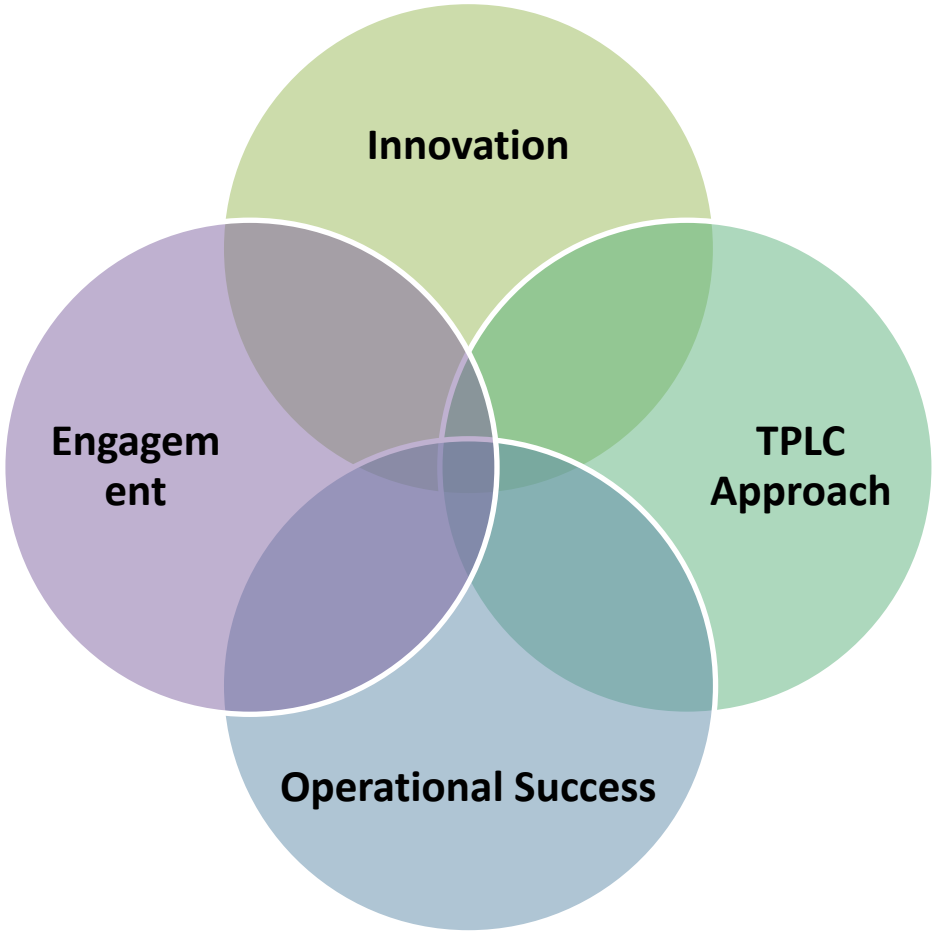
Vision for MDUFA V



- **Innovation:** Enhance operational success, reduce device development times, and further accelerate patient access to high-quality, innovative, safe and effective devices
- **Engagement:** Enrich engagement with multiple stakeholders across TPLC
- **TPLC Approach:** Evaluate device safety and performance across TPLC
- **Operational Success:** Optimize FDA infrastructure, staffing, and resources to keep pace with scientific development

Stakeholder Feedback

- Enhance FDA **engagement** with industry, patients, and physician society stakeholders
- Increase use of **real world evidence** to support regulatory decision-making across the total product lifecycle
- Focus on **device safety**, such as through **enhanced postmarket surveillance**
- Increase **investment in digital health** technology review
- Continue to advance **understanding of patient preferences** and integration of patient experience data into regulatory decision-making
- Increase **diversity** in patient engagement, clinical trials, and RWE
- Incentivize **innovation for underserved populations**, such as pediatrics and individuals with rare diseases
- Expand **Early Payor Feedback Program**

U.S. FOOD & DRUG ADMINISTRATION

Thank You