# FDA Update

Tim Stenzel, Director
Don St. Pierre, Deputy Director
**Office of In Vitro Diagnostics and Radiological Health (OIR/OHT7)**
IVD Roundtable
June 15, 2021

# Mission, Vision, & Shared Values

**CDRH Mission**

"…to protect and promote the public health…"

**CDRH Vision**

"Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world…"

**CDRH Shared Values**

Public Health Focus
Science-Based Decisions
Our People
Innovation
Transparency
Honesty and Integrity
Accountability

# Key Office IVD Activities

- Premarket – Pre-submissions, Breakthrough Designations, CLIA Waiver Reviews and complexity determinations, 510(k), De Novo, PMA, EUA, IDE, and HDE
- Relevant Guidance Documents
- Third Party Review Program
- Surveillance
- Compliance
- Community Outreach

# OHT7: Office of In Vitro Diagnostics & Radiological Health (OIR)

Office Director: **Timothy Stenzel**
Deputy Director New Product Evaluation: **Donald St. Pierre**
Deputy Director Patient Safety & Product Quality: Vacant
Deputy Director Radiological Health: **Robert Ochs**
Deputy Director Personalized Medicine: **Wendy Rubinstein**
Associate Director for Regulatory Programs: **Toby Lowe**
Associate Director Strategic Initiatives: Vacant
Associate Director for Regulatory Counsel: **Scott McFarland**
Associate Director for Medical Affairs: **Sara Brenner**
Chief Medical Officer for Radiological Health: **Donald Miller**
Associate Director for Operations: **Michelle Sutter**
OIR Immediate Office Staff:
**Stacey Borenstein, Jennifer Campbell, Daniel Edelman, Dina Jerebitski, Rebecca Keenan, Marina Kondratovich, Ryan Lubert, Zivana Tezak**, Vacant

**Division of Chemistry and Toxicology Devices (DCTD)**

**Director – Kellie Kelm**
**Deputy – Marianela Perez-Torres**

**Division of Immunology and Hematology Devices (DIHD)**

**Director – Lea Carrington**
**Deputy – Takeesha Taylor-Bell**

**Division of Microbiology Devices (DMD)**

**Director – Uwe Scherf**
**Deputy – Kristian Roth (Acting)**

**Division of Molecular Genetics and Pathology (DMGP)**

**Director – Reena Philip**
**Deputy – Donna Roscoe**

**Division of Mammography Quality Standards (DMQS)**

**Director – David Lee**
**Deputy – Preetham Sudhaker**

**Division of Program Operations and Management (DPOM)**

**Director – Rob Sauer**
**Deputy – Vacant**

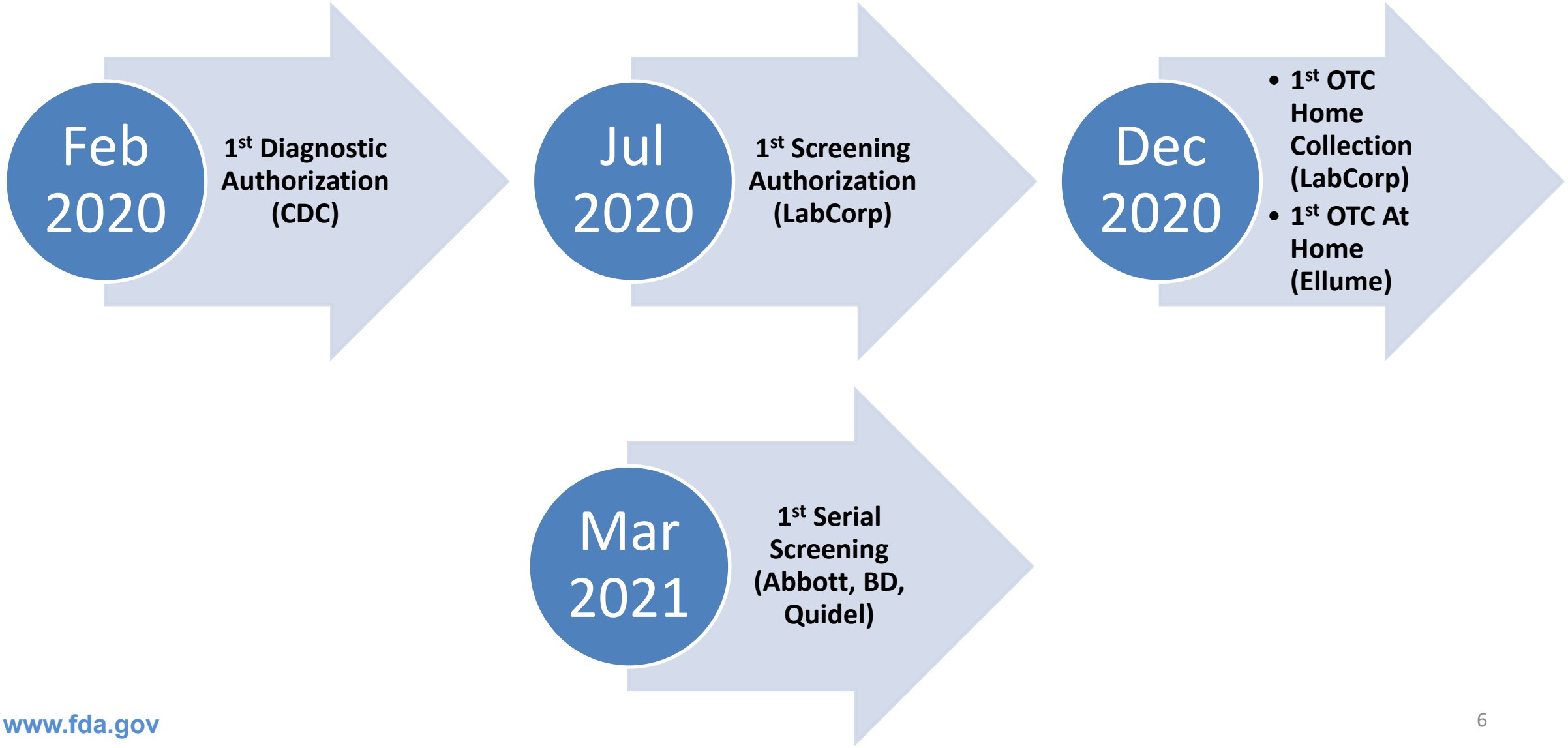
**Division of Radiological Health (DRH)**

**Director – Thalia Mills**
**Deputy – Michael O'Hara**
**Deputy – LCDR David Dar (Acting)**

# 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

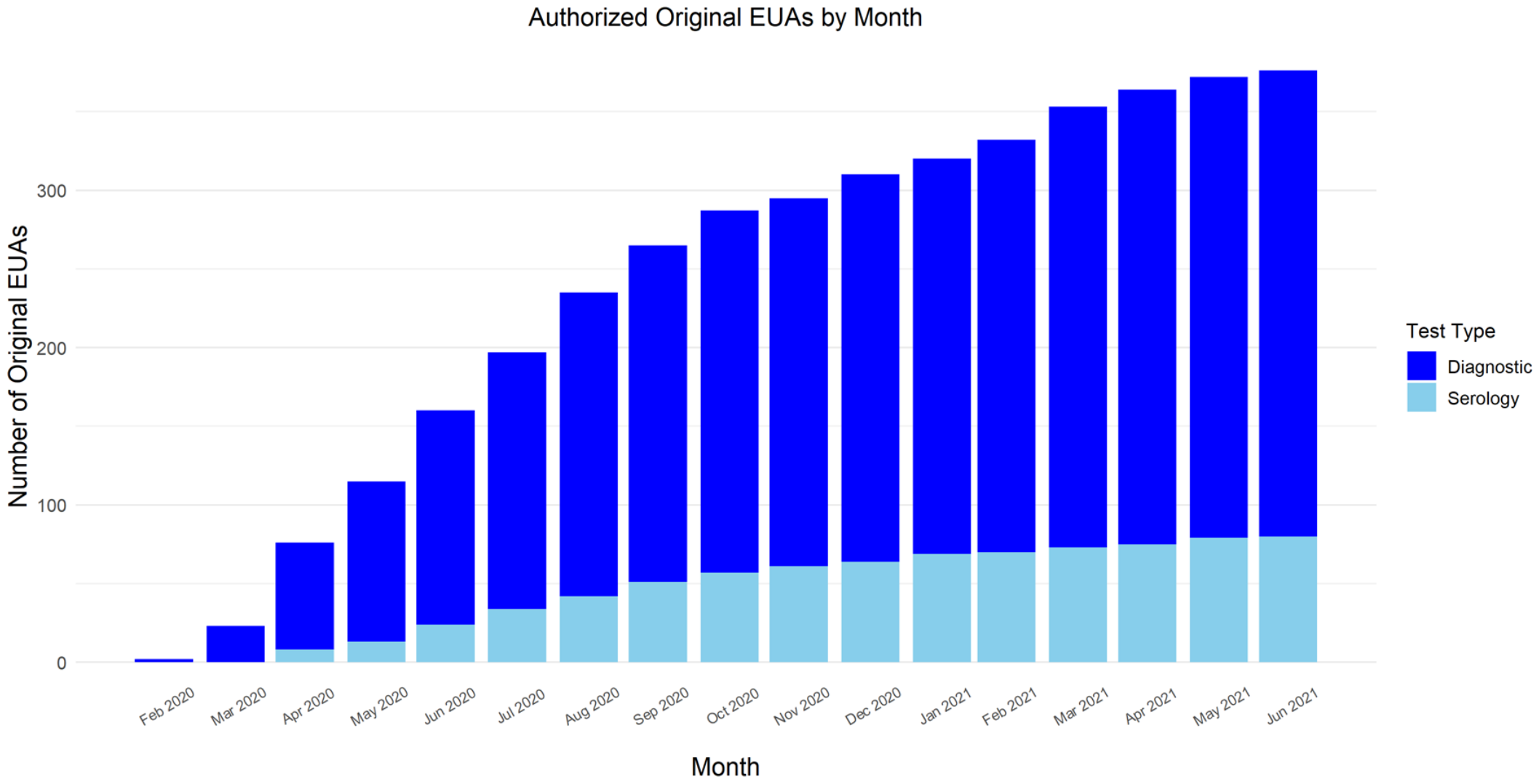


# Growing US Testing Menu

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)
- First antibody test for use with home collected dried blood spot samples (Symbiotica)

# EUA Authorizations




Data as of June 10, 2021

# Tests Authorized as of June 11, 2021

**275**

## Molecular diagnostic tests

- 25 Pooling
- 40 Asymptomatic single use screening
- 3 Serial screening
- 15 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 13 Point-of-care
- 63 Home collection
  - 12 Standalone home collection kits
  - 16 Direct-to-consumer
  - 1 Multi-analyte
  - 11 Saliva home collection
- 5 Standalone saliva collection devices
- 1 Prescription at-home test
- 2 Over-the-counter at-home test

**28**

## Antigen diagnostic tests

- 23 Point-of-care
- 3 Prescription at-home tests
- 5 Over-the-counter (OTC) at-home tests
- 11 Serial Screening

**81**

## Serology and other immune response tests

- 9 Point-of-care
- 1 Neutralizing antibody test
- 14 Semi-quantitative

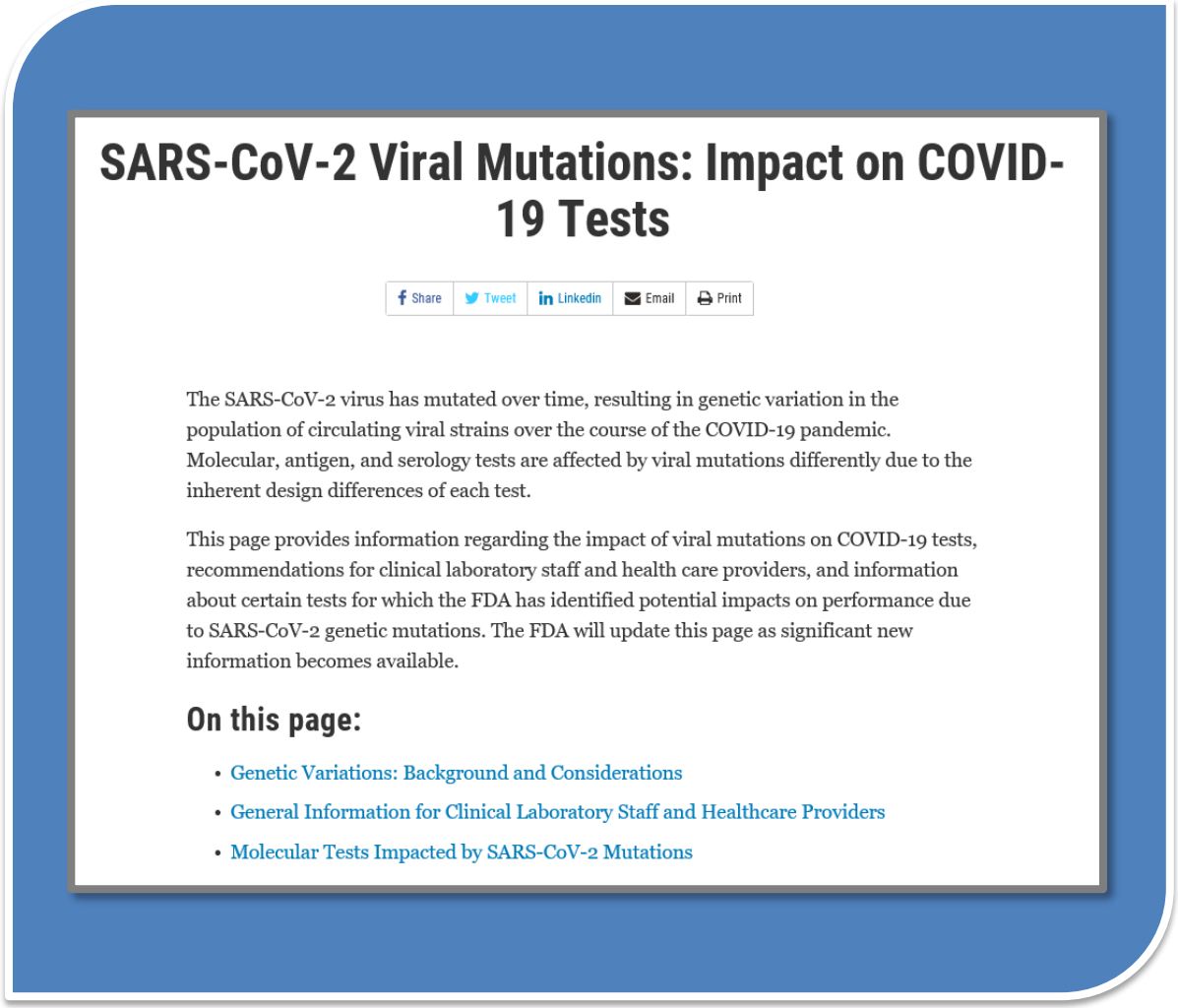
# First COVID-19 Diagnostic Test Granted Marketing Authorization Using Traditional Premarket Review Process

**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



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

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The SARS-CoV-2 virus has mutated over time, resulting in genetic variation in the population of circulating viral strains over the course of the COVID-19 pandemic. Molecular, antigen, and serology tests are affected by viral mutations differently due to the inherent design differences of each test.

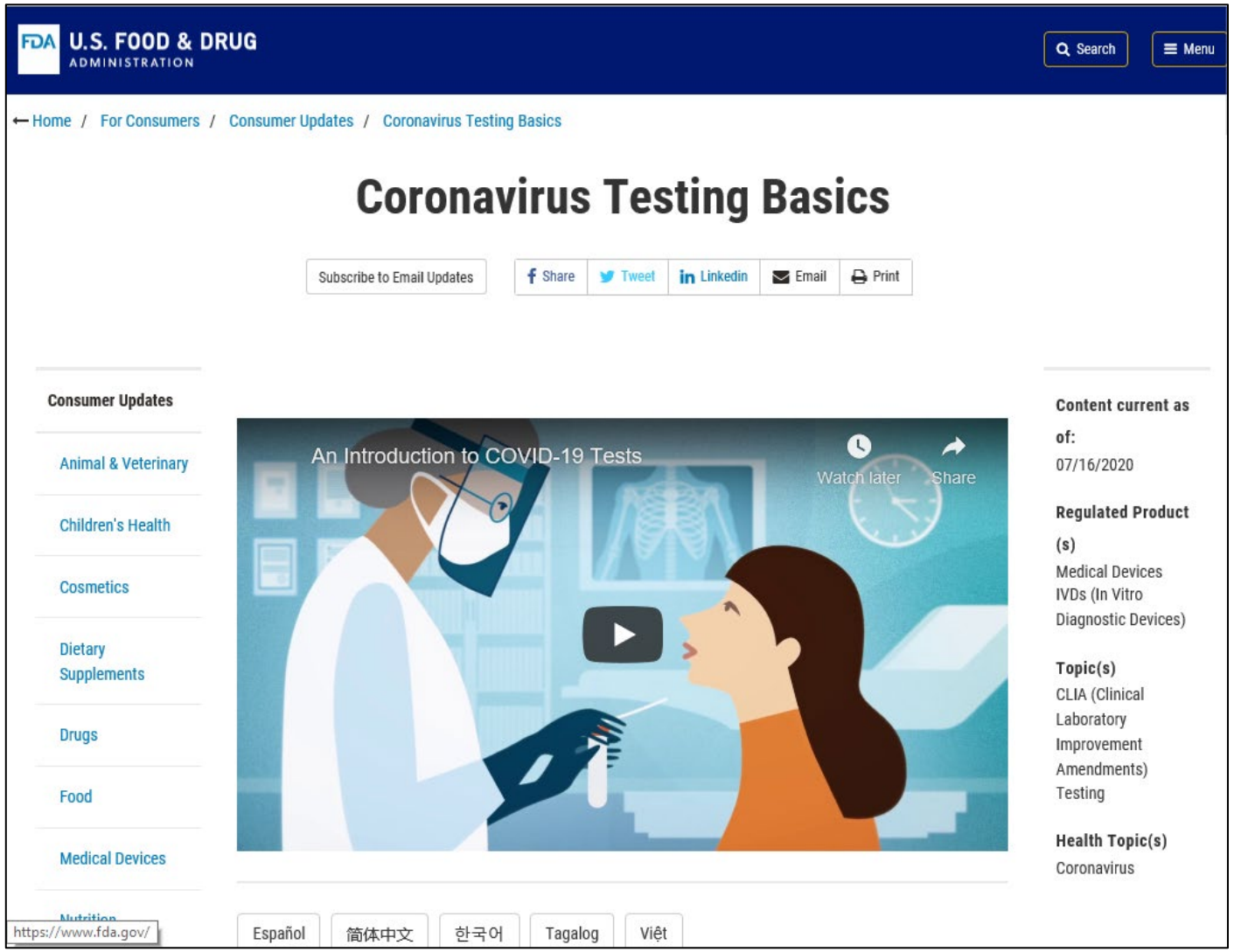
This page provides information regarding the impact of viral mutations on COVID-19 tests, recommendations for clinical laboratory staff and health care providers, and information about certain tests for which the FDA has identified potential impacts on performance due to SARS-CoV-2 genetic mutations. The FDA will update this page as significant new information becomes available.

On this page:

- Genetic Variations: Background and Considerations
- General Information for Clinical Laboratory Staff and Healthcare Providers
- Molecular Tests Impacted by SARS-CoV-2 Mutations

- 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

# Lessons Learned from COVID-19

- **The value of regulatory flexibility**

  During the pandemic we were able to act quickly and better tailor our oversight to facilitate the availability of critical devices while assuring they are safe and effective due to the flexibility providing to us through our emergency use authorization authorities

- **The power of engagement**

  During the pandemic we provided multiple ways for technology developers to work with our scientific, engineering, and clinical experts in real or near-real time

**Together, regulatory flexibility and engagement transformed the medical device landscape resulting in ~1300 new devices for COVID-19 in the first year**

# 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


**binx *io* CT/NG**

# Challenges and Solutions to Workload Impact

## A Year Into the Pandemic: How the FDA's Center for Devices and Radiological Health is Prioritizing its Workload and Looking Ahead

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Content current as of: 04/15/2021

Regulated Product(s) Medical Devices

Health Topic(s) Coronavirus

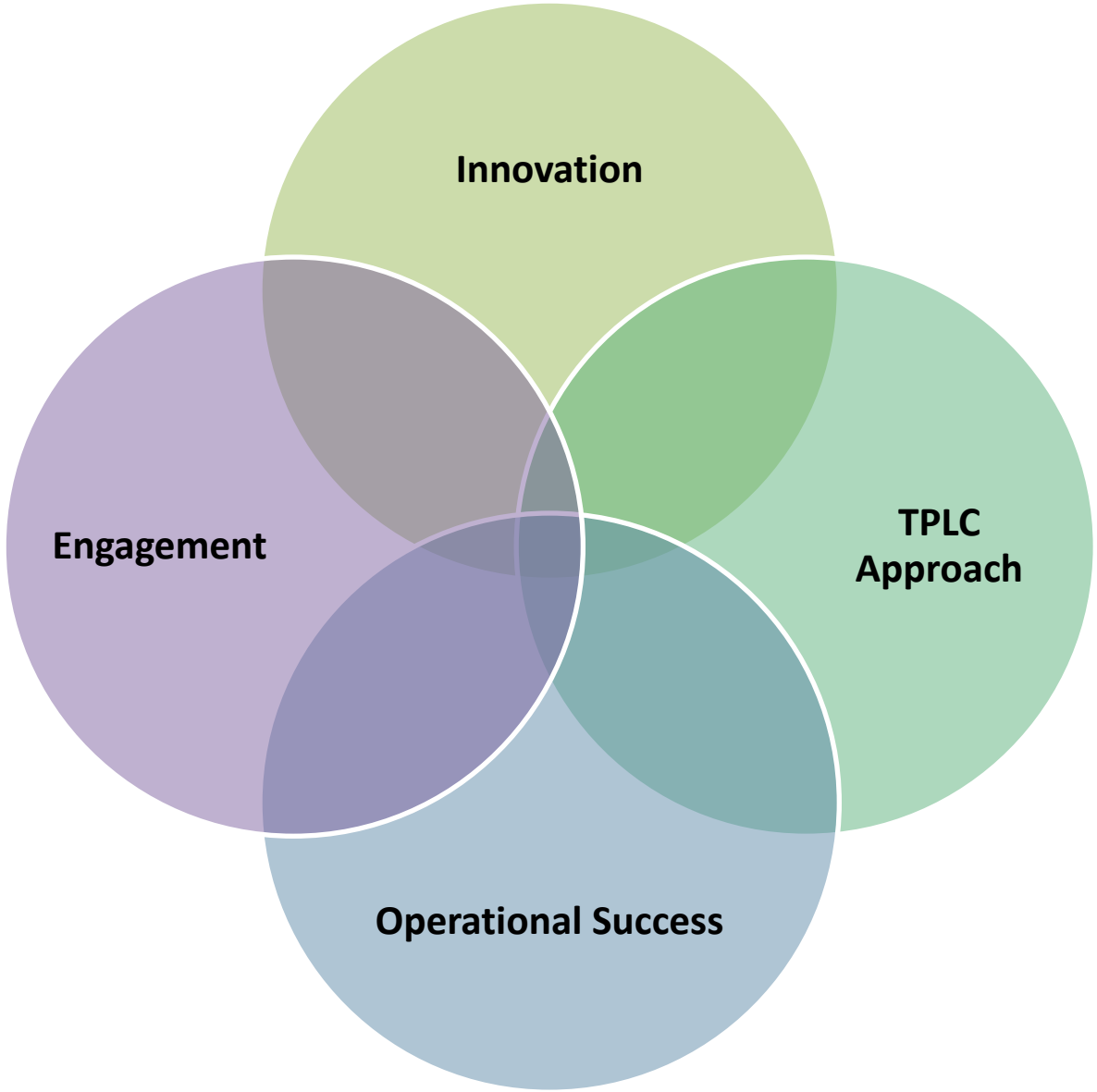
*By: Jeff Shuren, M.D., J.D., Director, Center for Devices and Radiological Health (CDRH) and William Maisel, M.D., MPH, Director, Office of Product Evaluation and Quality, CDRH*

- More than 50% of our staff and managers have been directly involved in CDRH's COVID-19 response, while many others picked up extra non-COVID-19 work to support the response
- Paused submissions have resumed active review as of June 10, 2021
- Lead reviewers will contact sponsors with projected timelines

*"Unless IVD pre-submissions are related to COVID-19, companion diagnostics, a breakthrough designation request, or have a significant public health impact, we have been unable to review them. We have tried to utilize all the tools at our disposal."*

https://www.fda.gov/news-events/fda-voices/year-pandemic-how-fdas-center-devices-and-radiological-health-prioritizing-its-workload-and-looking

# 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