U.S. FDA Response to COVID-19

16 March 2021

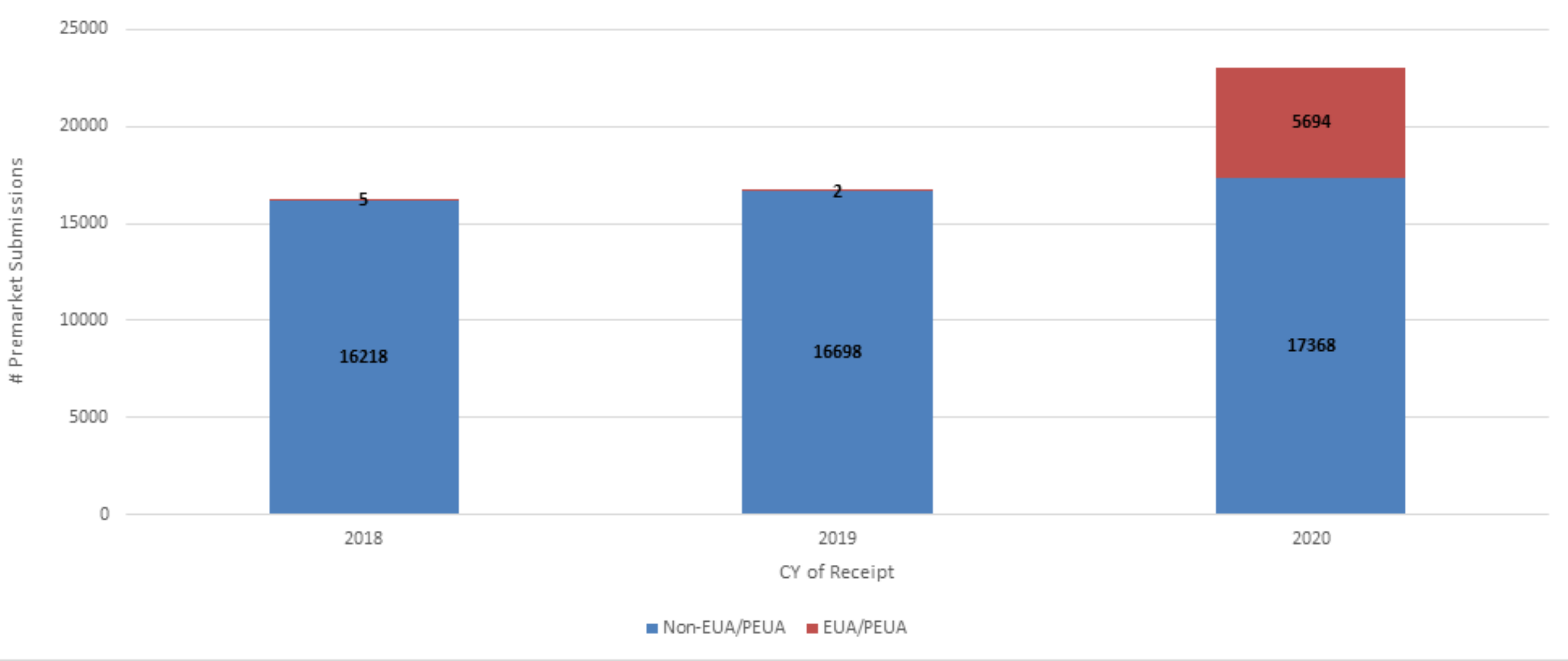
FDA Roles

- **Facilitate availability of and access to medical devices**
  - Use of Emergency Use Authorization authority

    Standard: the product may be effective and the known and potential benefits outweigh the known and potential risks
  - Engagement

- **Mitigate supply chain shortages**

Submissions



COVID Medical Devices as of February 28, 2021

	Tests/Supplies	PPE	Ventilators	Other Devices
EUA Originals	336	201	107	40
EUA Supplements*	395	4	13	3
510(k) clearances	33	131	60	392
Total	**764**	**336**	**180**	**435**

*EUA supplements are for modifications to EUA authorized devices, including new uses such as asymptomatic screening or home collection

Authorized Tests as of February 28, 2021

249 Molecular diagnostic tests

- 20 Pooling
- 18 Asymptomatic screening
- 13 Multi-analyte (i.e., SARS-CoV-2 + Influenza)
- 10 Point-of-care
- 45 Home collection
  - 7 Standalone home collection kits
  - 7 Direct-to-consumer
  - 1 Multi-analyte
  - 8 Saliva home collection
- 3 Standalone saliva collection devices
- 1 Prescription at-home test
- 1 OTC at-home test*

14 Antigen diagnostic tests

- 11 Point-of-care
- 2 Prescription at-home test*
- 1 Over-the-counter (OTC) at-home test

*1 authorized in March 2021

70 Serology tests

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

*authorized in March 2021

Other Authorized Devices as of February 28, 2021

Personal Protective Equipment

- Umbrella EUA for face shields
- Umbrella EUA for NIOSH approved respirators
- 14 sterilization/decontamination systems
- 38 non-NIOSH approved respirators
- 167 non-NIOSH approved respirators manufactured in China
- 19 surgical masks

Umbrella EUA for Ventilators

- 84 ventilators
- 4 tubing connectors
- 17 accessories

Other Medical Devices

- 4 extracorporeal blood purification devices
- 2 diaphragmatic pacing therapy systems
- 3 respiratory assist device
- 1 infusion pump
- 3 Continuous replacement therapy and hemodialysis devices
- 6 remote or wearable patient monitoring devices

Engagement

380,000 Inquiries addressed through

- 17 mailboxes
- 2 phone lines

321 Frequently Asked Questions

- 3D Printing
- Diagnostic Testing
- Face Masks (Non-Surgical)
- Shortages of Medical Gloves
- Home-use Blood Glucose Meters Utilized Within Hospitals
- Shortages of Surgical Masks and Gowns
- EUAs for Devices
- Personal Protective Equipment (PPE)
- Non-NIOSH Approved Respirators
- Ventilators

Participation in RADx

63 Webinars & Virtual Town Halls

- 46 Diagnostic Tests
- 15 PPE
- 2 other

11 Templates

- 5 Diagnostic Tests
- 2 Antibody Tests
- 2 PPE
- 2 other

19 Letters to Healthcare Providers & Safety Communications

- 7 Diagnostic Tests
- 2 Antibody Tests
- 8 PPE
- 2 ventilators

Engagement

21 Device-Specific Guidances

- PPE (4)
- Tests (4)
- Ventilators
- Clinical electrical thermometers
- Sterilizers, disinfectant devices, and air purifiers
- ECMO and cardiopulmonary bypass
- Non-invasive remote monitoring
- Coagulation systems
- Remote digital pathology
- Imaging systems
- Non-invasive fetal and maternal monitoring
- Telethermographic systems
- Digital health devices for psychiatric disorders
- Remote ophthalmic assessment and monitoring
- Infusion pumps

6 Guidances on General Processes

- Adverse event reporting
- Clinical trials (2)
- PMA and HDE supplements
- Formal meetings and user fee applications
- Mammography Quality Standards Act

1 Guidance on Shortages

= 28 Guidance Documents
+ 17 Revisions

Shortage Mitigation

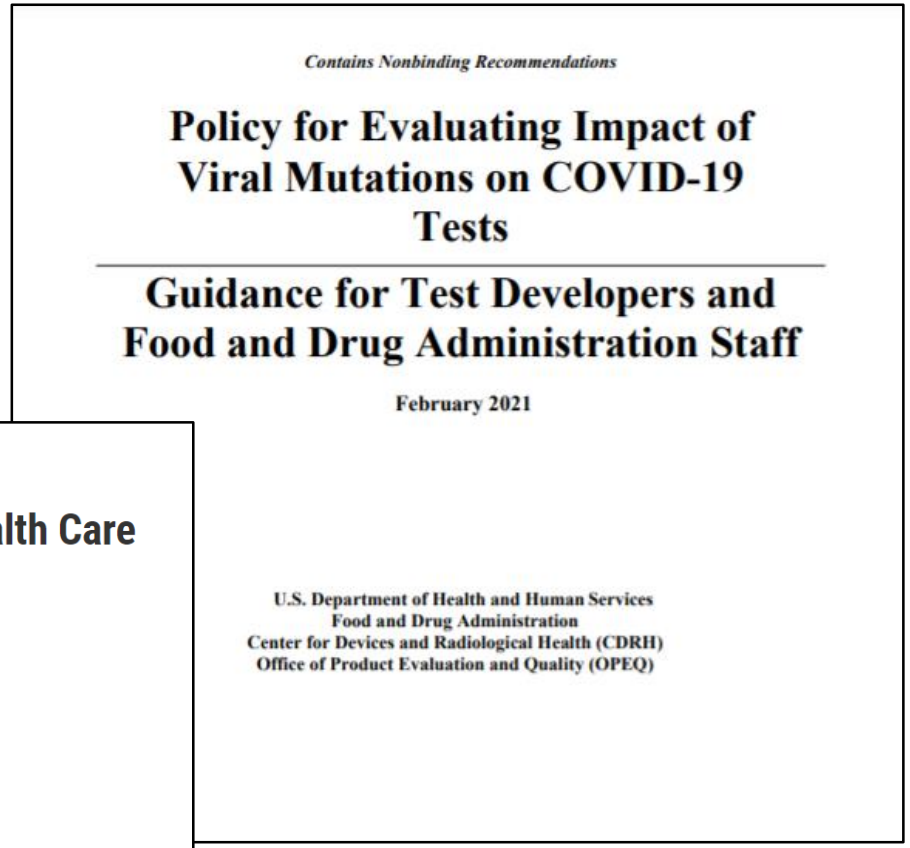
- Outreach to >1,000 manufacturing sites across 12 countries to assess supply chain vulnerabilities
- Horizon scanning to assess demand for devices needed to respond to the pandemic, including: PPE, ventilators, diagnostic supplies, infusion pumps, non-contact infrared thermometers, ECMO
- Established tiger team working with field personnel to address fraudulent imports
- Expanded device availability and sought out acceptable alternatives to certain diagnostic supplies

FDA Actions to Prevent or Mitigate Testing Supply Shortages

- **Regulatory**
  - FDA serving as a clearinghouse for testing supply alternatives since March 2020
  - Expanding allowable specimen types for swabs (e.g., anterior nares (AN) in place of nasopharyngeal (NP) and swab types (spun fiber as well as foam))
  - New notification pathway for VTM allowing distribution after validation and notification
  - FDA Guidance for viral transport media during COVID-19 PHE
  - EUA prioritization based on current needs
  - Identifying and helping to correct/remove unsafe supply products from the market
- **Communications/FAQs**
  - 3D printing of swabs and acceptable specimen types to increase swab supply
  - Use of VTM during COVID-19
  - COVID-19 Testing Supplies: Validated substitutions for CDC assay components and extraction kits
  - App: “Testing Supply Substitution Strategies”
- **Industrial Base Expansion**
  - Support HHS/DoD in IBx prioritization
  - IBx awards for swabs (3), pipette tips (3), COVID test kits (9)
- **Partnerships**
  - Airlifting supplies: swabs (Copan) and pipette tips (Tecan)
  - Imbed with DoD Clinical Lab to provide regulatory assistance to DoD labs

Viral Mutations

- FDA monitors global databases for emerging mutations and conducts in silico analyses of target sequences for all authorized molecular tests
- FDA Guidance recommends that test developers conduct their own surveillance and analyses and design their tests to minimize adverse impact
- FDA communicates with the public, as appropriate



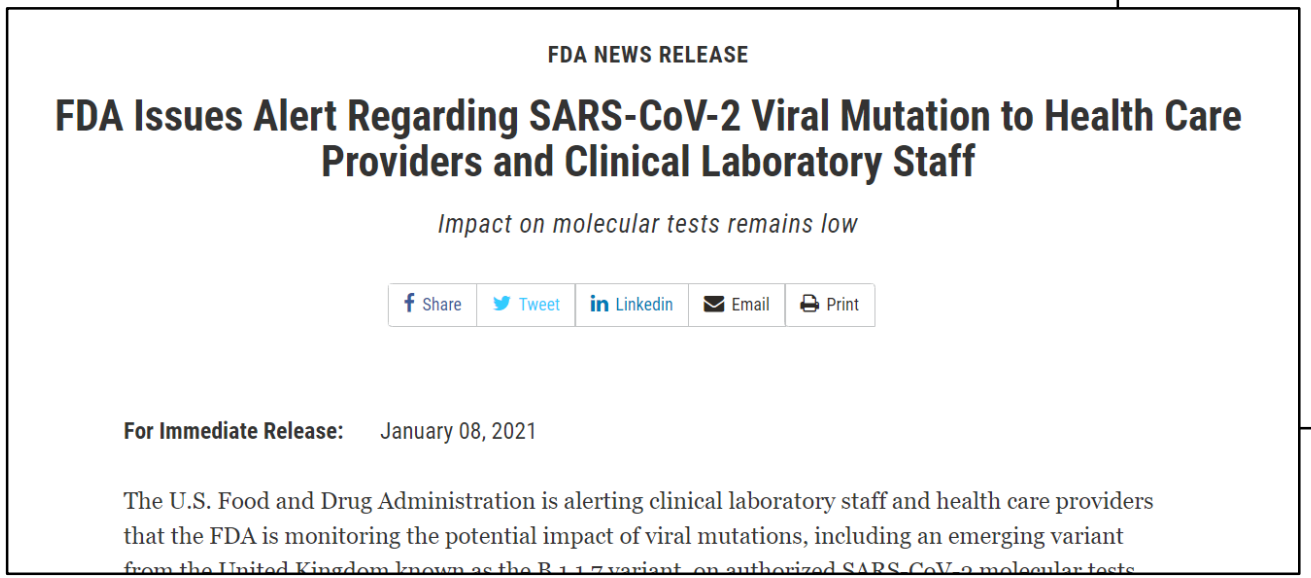
Contains Nonbinding Recommendations

Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests

Guidance for Test Developers and Food and Drug Administration Staff

February 2021

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)



FDA NEWS RELEASE

FDA Issues Alert Regarding SARS-CoV-2 Viral Mutation to Health Care Providers and Clinical Laboratory Staff

Impact on molecular tests remains low

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For Immediate Release: January 08, 2021

The U.S. Food and Drug Administration is alerting clinical laboratory staff and health care providers that the FDA is monitoring the potential impact of viral mutations, including an emerging variant from the United Kingdom known as the B.1.1.7 variant, on authorized SARS-CoV-2 molecular tests

Next Steps

- **Continue review of EUAs (backlog >400)**
- **Continue to monitor the potential impact of new mutations**
- **Transition draft guidance**
- **Conversion of EUAs to full marketing authorizations**
  - 2 Surgical Masks cleared under 510(k)
  - Several EUA products under 510(k) or de novo review
- **Consider application of lessons learned**
  - Regulatory flexibility
  - Engagement


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