As FDA Emergency Use Authorization (EUA) Phases Out, How Do You Transition to Legal Marketing — Or Not?

Considerations for test manufacturers

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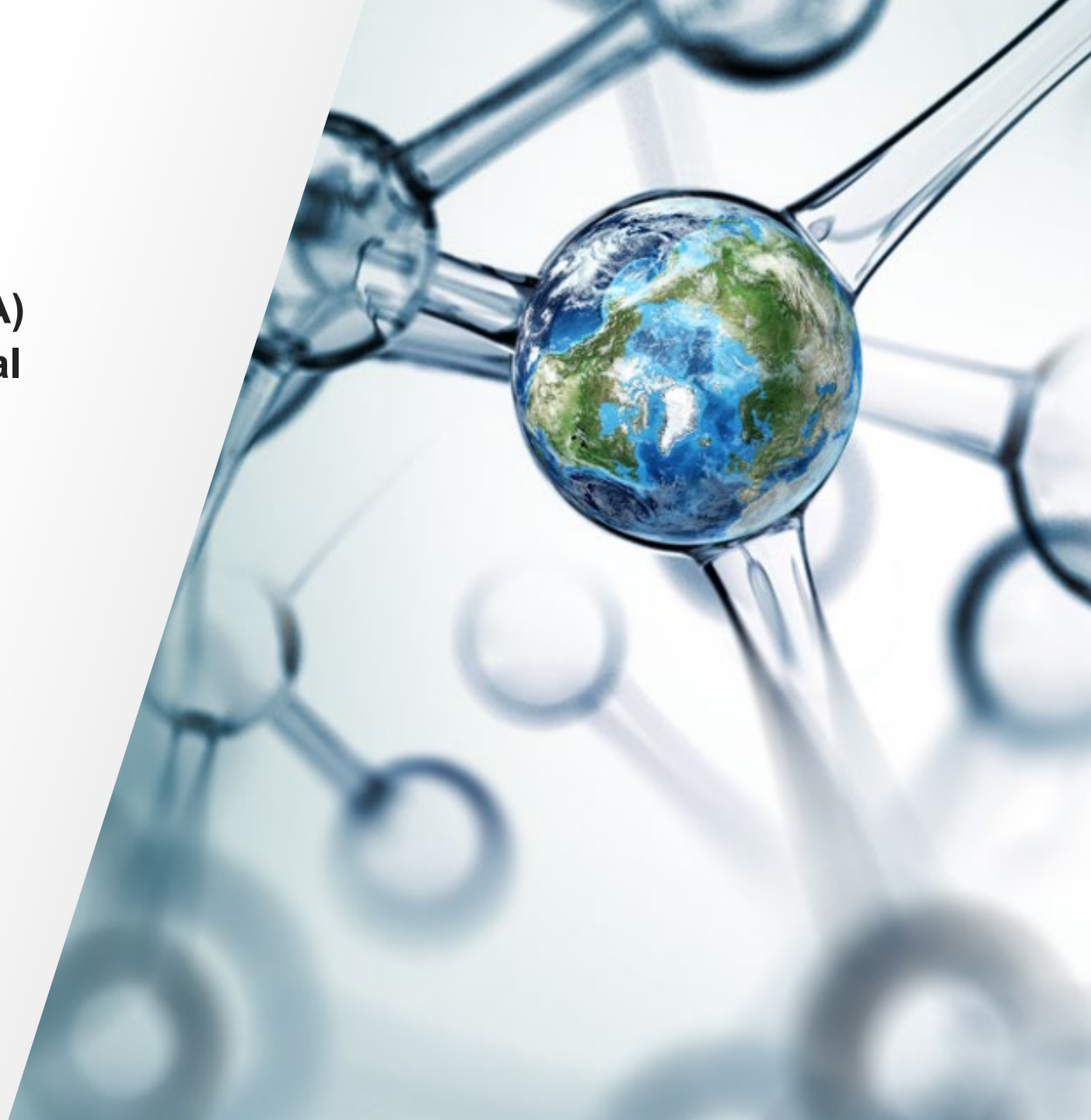

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Thermo Fisher COVID-19 EUAs

- Applied Biosystems™ TaqPath™ COVID-19 Combo Kit
  - qPCR diagnostic laboratory test
  - EUA authorized in March 2020
  - Followed by 14 supplements to date covering several post-authorization changes including addition of a specific collection kit and information on variants

- In addition to TaqPath, 6 other qPCR test EUAs including a multiplex product (Flu A/B, SARS-CoV-2), a high throughput COVID-19 solution, and a pooling solution were authorized

- Accula™ SARS-COV-2 Test
  - POC test
  - EUA authorized in March 2020
  - Followed by 16 supplements to date covering several changes including post-market clinical data and information on variants

FDA's clear and frequent guidance and communications were vital to meeting customer needs

- Guidance and templates supporting various COVID-19 diagnostic solutions
- Enforcement discretion on the use of RUO/non-IVD portions of the workflow
- FDA Town Halls provided insights on new developments and requirements
- Two-way engagement from FDA (e-mails, conference calls, informal calls) expedited development and approval of EUAs
- FDA provided continuous communication and prioritization on changing disease landscape

Future considerations for manufacturers

- Business decision points:
  - Submit 510(k)s for existing assays
  - Submit 510(k) for new assays:
    - Modify tests to make less susceptible to new variants
    - Shift to multiplex assays
  - Discontinue COVID-19 tests under EUA
- Review workflows to ensure all aspects of the tests include IVD components as enforcement discretions allowed for EUAs will end
- Develop a transition plan in support of post-EUA business strategy
- Develop a post-EUA communications plan for FDA, customers and distributors

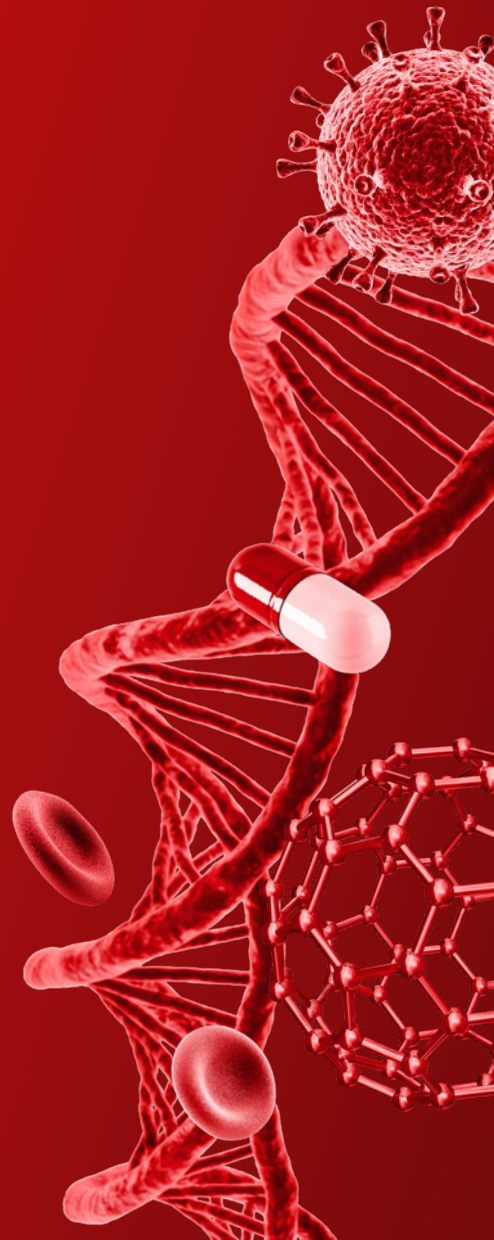
Potential challenges

- Prevalence and positivity rates are now low compared to pandemic state for upper respiratory pathogens
  - Consider Q-Sub and discuss with FDA to determine an appropriate solution
- Differences in reimbursement impacting use of multiplex vs. single-plex tests
- Market adoption of tests based on existing laboratory workflows

Conclusion: Managing EUA to 510(k) transition

- Review COVID-19 EUA product portfolios
- Determine which assays will transition to 510(k)
- Assess gaps in data required for 510(k) and develop strategy to address
- Communicate with FDA, customers and distributors on your transition plans

Thank You



The Accula SARS-CoV-2 Test has not been FDA cleared or approved but has been authorized for emergency use by FDA for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests. The test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

The TaqPath COVID-19 Combo Kit and the Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit are for In Vitro Diagnostic Use. For Emergency Use Authorization Only | Rx Only