U.S. FOOD & DRUG ADMINISTRATION & Devices

FDA Overview of Point-of-Care and Home Collection and Testing

Timothy Stenzel, M.D., Ph.D.
Director, Office of In Vitro Diagnostics and Radiological Health (OIR)
CLIAC
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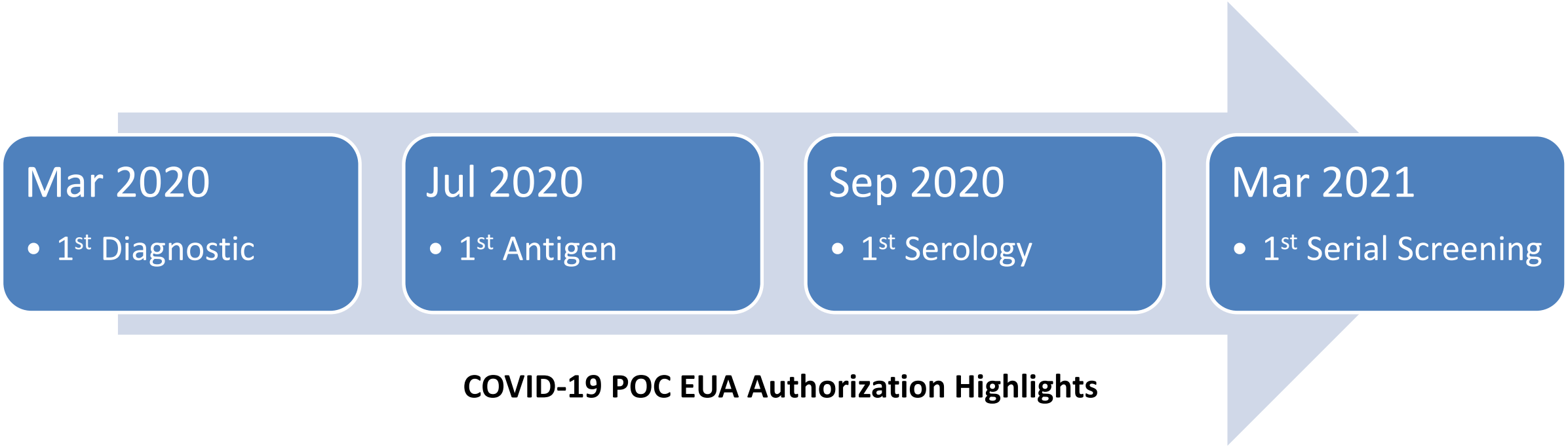
Increasing Access to COVID-19 Testing

Point-of-Care (POC)

Home Collection

At-Home

COVID-19 Point-of-Care (POC) Testing Enables Patient Access to Faster Results



COVID-19 POC EUA Authorization Highlights

COVID-19 EUA POC Recommendations

- **POC EUA requests should include:**
  - Data to demonstrate that non-laboratory personnel can perform the test accurately in the intended use environment, and
  - Data to demonstrate the robustness of the device for near patient testing, i.e., that the device is not sensitive to environmental and usage variation

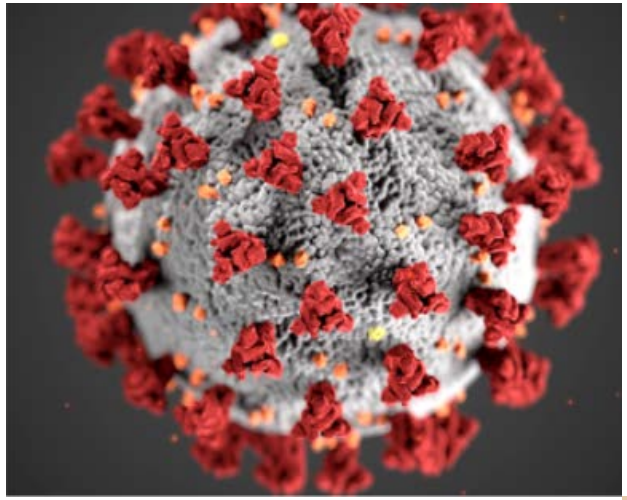
- **Molecular diagnostic tests are generally expected to demonstrate positive and negative agreement of ≥ 95%, however, in light of increased patient accessibility a PPA of ≥ 80% may be acceptable for POC tests**
  - A positive agreement of ≥ 80% may be acceptable for POC with appropriate limitations added to the intended use that would mitigate the risk of false negative results

COVID-19 EUA POC Recommendations Cont.

- **Simple and Clear User Instructions**
- **POC Clinical Evaluation**
  - Includes POC sites (e.g., sites operating under a CLIA Certificate of Waiver) with representative non-laboratory healthcare workers
  - Comparator Method should be sensitive FDA authorized SARS-CoV-2 molecular assay
  - Also includes testing prepared samples to evaluate performance near Limit of Detection (LoD)
- **Flex Studies based on a risk analysis, such as:**
  - 40°C and 95% room humidity (RH) (mimicking hot and humid climates)
  - Delay in sample testing or reading time
  - Delay and/or disturbance in operational steps
  - Sample volume variability
  - Buffer volume variability
- See the EUA templates for more details about POC recommendations for molecular, antigen and serology tests

Advantages of At-Home Testing and Home Collection

- **Immediate Results**
  - At-Home testing provides results within minutes
- **Reduced Risk of Transmission**
  - Potentially infected individuals can be tested without traveling to a healthcare site
- **Preservation of Personal Protective Equipment (PPE) Supplies**



Home Collection Considerations

- **Can a lay user safely and properly collect the specimen?**
  - A healthcare provider watching the collection by way of telemedicine may mitigate this issue
- **Are the components of the specimen transport media safe for use in the home environment?**
- **Does the device ensure adequate stability of the specimen?**
  - Including both the time lapse between collection and testing and the potential impact of shipping conditions (e.g., if the specimen sits in a hot truck)

Home Collection Recommendations

Authorization of a home collection kit must be accompanied by authorization of one or more assays that have been validated with specimens collected and transported with the subject home collection kit

Additional recommendations for Home Collection Kits:

- Collection Device: Stability and Shipping Studies
- Specimen: Stability and Shipping Studies
  - *Kits using foam or wrapped polyester nasal swabs transported in 0.9% saline, PBS or dry tubes may be able to reference stability studies conducted by Quantigen Biosciences*
  - *Developers should contact the Pipeline and Hazardous Materials Safety Administration (PHMSA) to ensure compliance with the hazardous materials regulations for shipping medical material (HMInfo@dot.gov)*
- Simple and Clear User Instructions
- Human Usability Study covering the entire workflow
- See the EUA templates for more details

At-Home Recommendations

Additional recommendations for At-Home Tests:

- Simple and Clear User Instructions
- Clinical Evaluation using natural clinical specimens
  - Including symptomatic and asymptomatic individuals
  - Comparator samples should be collected at home using an FDA authorized home collection kit and SARS-COV-2 molecular assay
- Human Usability Study covering the entire workflow
- Flex Studies based on a risk analysis
- Test Result Reporting Plan (e.g., automatic reporting through a mobile app)
- See the EUA templates for more details

Thank You