A Plan to Increase COVID-19 Testing in the U.S. – Accelerated EUA Authorization Pathway for High-Complexity Molecular Diagnostics CLIA-Certified Laboratories

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With the recent emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Wuhan, China, the virus has caused over eighty thousand cases of illness in over forty countries, demonstrating human-to-human transmission with severe illness. SARS-CoV-2 has demonstrated the capability to rapidly spread, leading to significant impact on healthcare systems and causing societal disruption. Critical to control of SARS-CoV-2 is the rapid detection of cases and contacts, appropriate clinical management and infection control, and implementation of community mitigation efforts. This is only possible with wide availability of testing capabilities in healthcare settings, reference and commercial laboratories, and at the point of care.

CDC has worked with FDA to assure testing is available at Public Health Laboratories to support public health investigations and control efforts; however, a much broader interagency approach is needed to fill the greater need for diagnostics by commercial manufacturers and laboratories capable of developing their own tests. BARDA is working with manufacturers to bring new SARS-CoV-2 tests to hospitals and at the point of care. Further effort is needed to rapidly expand testing capacity by facilitating CLIA-certified, high-complexity laboratories to develop tests under an Emergency Use Authorization (EUA). This document outlines a concept of operations for achieving more rapid testing capacity in the U.S.

1. **Target Laboratories** – Laboratories targeted with this guidance are those that are CLIA-certified as high-complexity laboratories. These laboratories include academic, commercial, reference and large healthcare system laboratories. The expected rapid surge in cases can be mitigated by focusing on these high-volume, competent laboratories that have experienced trained staff and maintain high quality standards.
2. **Pathway for Implementing Testing** – Target laboratories follow these steps to rapidly begin testing:
    a. **Order Test Materials** – Laboratories are given latitude to:
        i. Design their own tests and make or order the individual components (e.g., primers/probes), or
        ii. Order prepared Research Use Only (RUO) kits from third party assemblers.
        iii. Time Needed: 1-5 days minimum estimate
    b. **Validate Test** – Laboratories will evaluate the test according to newly developed FDA/CDC-established minimal, preset, acceptable performance criteria
        i. Time Needed: 5-7 days minimum estimate
    c. **Notify FDA** – Laboratories will notify FDA after validation of test performance.
    d. **Begin Testing** – Use of the test for patient management can immediately begin.
        i. Testing can continue indefinitely until a determination by FDA is provided.
        ii. The first 5 positive and first 5 negative specimens must be confirmed by an EUA-authorized lab or with an EUA-authorized kit. Stop testing if not confirmed. Inform patients already tested and notify FDA.
    e. **Submit EUA Package** – Laboratories are given 15 days after notifying FDA to submit a modified EUA package to FDA while continuing to test and while FDA reviews the submission.
    f. **Receive Authorization** – FDA will follow up with any questions or concerns or EUA authorization. If FDA is not able to authorize, the FDA will notify the lab, the lab will stop testing and notify patients of this decision.
3. **Stakeholders in Implementation**
    a. **Laboratories** – CLIA-certified, high-complexity laboratories in the U.S. and Department of Defense CLIA-certified, high-complexity laboratories outside the U.S.
    b. **Federal Government** – FDA, BARDA, CDC, CMS