

**Laboratory Communication - COVID-19 Testing**

* Cepheid COVID-19 FDA approved under EUA on the Gene Expert and Gene Expert Express
* BioFire COVID-19 FDA approved under EUA on Film Array units
* GenMark COVID-19 FDA approved under EUA
* Roche COVID-19 FDA approved on 6800 and 8800 platforms
* Abbott M2000 COVID-19 FDA approved

**Testing in your Lab**

* BioSafety Hood Level 2 is REQUIRED
  + Prep all specimens under the hood
* Perform a **Risk Assessment** prior to in-house testing
  + Template forthcoming
* Glove use:
  + Cepheid: you must change gloves with each patient sample
  + BioFire: change gloves frequently
  + GLOVES ARE NOT IN SHORT SUPPLY
* Add the test to your CLIA Test Menu
  + Also follow all state guidelines
* Submit notification to the CDC that you are performing the test
  + Instructions forthcoming
* As with all lab testing, follow the instructions in the Interim Package Inserts.
* Proficiency Testing guidelines coming from CLIA
* The FDA requires every patient being tested for COVID-19, receive a ***Fact Sheet for Patients***
  + CSH Lab Leadership will provide

**Resources:**

* **Interim Guidance for Laboratories**
  + <https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>
    - Interim Guidance of Collection, Handling and Testing Clinical Specimens
    - Interim Laboratory Biosafety Guidelines
    - Laboratory Biosafety FAQs
* **List of FDA approved EUA COVID-19 Tests**
  + <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>
* **CAP**
  + https://www.cap.org/laboratory-improvement/news-and-updates/guidance-for-covid-19-testing-for-cap-accredited-laboratories

**SPECIAL NOTES:**

Just because a vendor has claims of having a COVID-19 test does not mean you should use it. Nor does it mean the test is FDA approved under Emergence Use Authorization.

Just because a vendor has FDA approved EUA for Point of Care, does not mean you can perform the test in any setting. A Biosafety Hood is required for personnel safety.

At this time there are no waived tests available in the US.

Do not put any Rapid Kits for COVID-19 in use without the approval of the Common Spirit Lab Services Leadership.

Distributed by Karen Smith, VP Laboratory Services March 24, 2020