FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH


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# Federal funding opportunity: Solicitation for Area of Interest (AoI) AoI-0003 FA811921SC001: SUPPLY CHAIN COVID-19 DIAGNOSTIC TESTING

Capacity expansion investment funding for vendors that have developed or are developing products relevant to COVID-19 diagnostic tests

Supply chain materials and equipment in scope (see AoI for all)

- Sample collection and testing consumables
- Raw materials, components, processes supporting diagnostics tests, kits/cartridges and related instruments
- Equipment to expand manufacturing capacity and/or increase test throughput
- Manufacturing and equipment related to temperature sensitive diagnostic testing, including their distribution and storage

Some Limitations

- Does not include distributors
- Manufacturing expansion limited to domestic or within US territories, although manufacturers may be foreign-owned

See AoI for solution brief contents

- Product description, diagnostic activity supported, technology
- Ability to ramp up production, other operational and commercial considerations
- Total proposal cost/price (requested investment, per item price quotes)

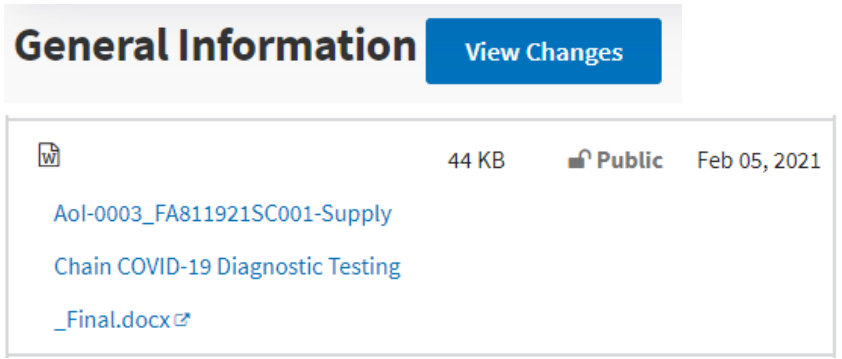
Funding: Coordinated between HHS/OASH and DoD to meet HHS COVID-19 response priorities

AoI Open Period: Closes 4:00PM CST March 7, 2021

AoI Link: https://beta.sam.gov/opp/477a27c88b634668bee5aa33532bee62/view

**DAF ACT Commercial Solutions Opening (CSO) COVID-19 Response**

Click blue “View Changes” button, scroll to Attachments/Links for document dated Feb 05, 2021




Any questions: supplychain.cso.dafact@afwerx.af.mil

# Resources for COVID-19 Test Development and Validation

- To sign up to receive emails on this CDRH topic, please subscribe to the **In Vitro Diagnostics Mailing List:** https://www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-mailing-lists
- Questions about COVID-19 IVD EUAs: CDRH-EUA-Templates@fda.hhs.gov
- Questions about laboratory data harmonization for COVID-19 testing: SHIELD-LabCodes@fda.hhs.gov
- *In Vitro* Diagnostics EUAs webpage: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
- FAQs on COVID-19 Testing: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2
- Serology Testing Performance: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance
- Independent Evaluations of COVID-19 Serological Tests https://open.fda.gov/apis/device/covid19serology/
- January 2021 HHS FAQ: COVID-19 Diagnostic Data Standards & Core Data Elements for Test Reporting:
- https://www.hhs.gov/sites/default/files/hhs-diagnostic-data-faqs.pdf
- HHS COVID-19 Testing and Diagnostics Working Group (TDWG): Additional Testing Information:
- https://www.hhs.gov/coronavirus/testing/testing-diagnostics-working-group/index.html

**Publications:**

- https://www.nejm.org/doi/full/10.1056/NEJMp2023830?query=featured_home
- https://thehill.com/opinion/healthcare/515628-fda-were-constantly-working-on-covid-testing-options

Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn

*Under Heading: Specialty Technical Topics; Subheading: In Vitro Diagnostics*

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www.fda.gov/cdrhwebinar

immediately following the conclusion of the live webinar