CDRH Virtual Town Hall Meeting

For developers of tests for SARS-CoV-2

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February 10, 2021
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

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](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](mailto:CDRH-EUA-Templates@fda.hhs.gov)
- Questions about laboratory data harmonization for COVID-19 testing: [SHIELD-LabCodes@fda.hhs.gov](mailto:SHIELD-LabCodes@fda.hhs.gov)
- January 2021 HHS FAQ: COVID-19 Diagnostic Data Standards & Core Data Elements for Test Reporting:
- HHS COVID-19 Testing and Diagnostics Working Group (TDWG): Additional Testing Information:
  - [https://www.hhs.gov/coronavirus/testing/testing-diagnostics-working-group/index.html](https://www.hhs.gov/coronavirus/testing/testing-diagnostics-working-group/index.html)

Publications:

- [https://thehill.com/opinion/healthcare/515628-fda-were-constantly-working-on-covid-testing-options](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](http://www.fda.gov/training/cdrhlearn)

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

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immediately following the conclusion of the live webinar