



USAMRDC COVID-19 Response



USAMRDC is leading RDA efforts to **Prevent, Detect, and Treat** COVID-19

The U.S. Army Medical Research and Development Command is leading research efforts to Prevent, Detect, and Treat COVID-19 by applying existing field-leading research capabilities, a global research network, and established partnerships with industry and academia to support the whole-of-government response to COVID-19.

PREVENT

Objective: Expedite the development of a safe, effective vaccine, prophylaxes, and other preventive measures against COVID-19.

Approach:

- **Vaccine Development:** Vaccine candidate will move forward into initial clinical testing in humans. USAMRDC is actively working with the National Institutes of Health and industry partners to evaluate other promising vaccines.
- **Animal Model Development:** Evaluating animal models to identify a suitable correlate of human disease to test COVID-19 medical countermeasures.
- **Monoclonal Antibodies:** To help protect (and potentially treat) cells from COVID-19 infection we are partnering with government and industry to develop monoclonal antibodies (man-made proteins engineered to optimize the body's natural response to fight infection by preventing the virus from entering and replicating within human cells).
- **Protective Equipment:** We are testing portable isolation units, masks, and other protective equipment to determine air worthiness for MEDEVAC and other flight operations and also leading an inter-service group, the USAMRDC Additive Manufacturing (AM) Working Group (WG), to assist with the development, manufacturing, testing, and regulatory submission of PPE seeking FDA Emergency Use Authorization.



DETECT

Objective: Develop a validated test or series of tests for COVID-19 diagnostic, transmissibility, exposure, and/or recovery decisions.

Approach:

- **Diagnostics:** USAMRDC is collaborating with government, academia, and industry to quickly identify, develop, and validate diagnostic capabilities to detect the virus in a high throughput capacity as well as research tests to support medical countermeasure development. USAMRDC also assists with the manufacturing, testing, and regulatory submission of 3D-printed swabs and alternative Viral Transport Media to the FDA.
- **Clearance Tests:** Assays are under development that confirm clearance of the virus, which are critical for making return-to-duty or continued isolation recommendations.
- **Immunoassays:** Along with multiple government and industry partners, USAMRDC is developing/evaluating immunoassays to detect COVID-19 antibodies, which will inform exposure and immunity status.
- **Point-of-Care, Rapid Testing:** Evaluating antibodies for use in a point-of-care, rapid test device to identify COVID-19 infection in resource-constrained environments.



TREAT

Objective: Develop safe, effective, and accessible treatments for those diagnosed with COVID-19.

Approach:

- **Remdesivir:** Offering patients diagnosed with moderate to severe COVID-19 an additional treatment option using Remdesivir (Gilead Sciences).
- **Convalescent Plasma:** Offering patients with serious/life-threatening infections plasma from those who have recovered from COVID-19.
- **Monoclonal Antibodies:** USAMRDC and industry partners are developing monoclonal antibodies that can neutralize the virus while also fighting harmful inflammation.
- **Drug Discovery:** Collaborating with industry partners on drug discovery using cutting-edge artificial intelligence and machine-learning techniques.
- **Small Molecules:** Screening for additional therapeutics.
- **Medical Equipment:** In coordination with the Army logistics community, is filling shortages of needed medical equipment for deploying medical units.
- **Telecritical Care:** Collaborating with DOD, Federal agencies and civilian counterparts to develop a National Emergency Telecritical Care Network to provide virtual care in global emergency situations, at the point of need.



USAMRDC ensures that all RDA strictly conforms to all regulatory guidance. Oversight and coordination are provided by

- Office of Regulated Activities
- Office of Research Protections
- Office of Regulated Quality Activities
- Staff Judge Advocate Office
- Sponsor's Authorized Representative (FDA)



Efforts are also supported by other offices and organizations within the Command, including

- Strategic Communications
- Resource Management
- Information Management
- Logistics
- Facilities



Grants & Contracts with Academia, Industry, and Other Partners

- Congressionally Directed Medical Research Programs released two Program Announcements for COVID-19 RDA for up to \$75 million.



Business Management Support

- The Office of Research and Technology Applications coordinates intellectual property licensing developing CRADAs, Material Transfer Agreements, Interagency Agreements, Nondisclosure Agreements, and other tech transfer transactions.



USAMRDC COVID-19 Other Transaction Authority (OTA)

- **Medical Technology Enterprise Consortium**
- Through OTAs, USAMRDC can move quickly and have the flexibility to enable awards that involve complex collaborations with multiple companies and government laboratories working together to further develop and implement solutions.