FDA EUA approved antibody tests

- **Only 4 serological tests have been approved for use:**

Manufacturer	Test Name	Type of Test	Detection
Ortho Clinical Diagnostics	VITROS® Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	Luminescence detection, automated, high-throughput, lab-based	Total Antibody (IgM & IgG)
Cellex	qSARS-CoV-2 IgG/IgM Rapid Test	Rapid Test	Separate IgG and IgM detection
Chembio Diagnostics Systems	DPP COVID-19 IgM/IgG System	Dual Path Platform Rapid Test with Reader	Separate IgG and IgM detection
Mt Sinai Laboratory	COVID-19 ELISA IgG Antibody Test	ELISA, Lab-based	IgG

FDA Key Recommendations for Health Care Providers:

- Continue to use serological (antibody) tests, as appropriate, and be aware of their limitations.
- Do not use serological (antibody) tests as the sole basis to diagnose COVID-19 but instead as information about whether a person may have been exposed.
- Be aware that not all marketed serological tests have been evaluated by the FDA. Such tests have not been reviewed by the FDA, unless an EUA has also been submitted and reviewed by FDA.

ICAP
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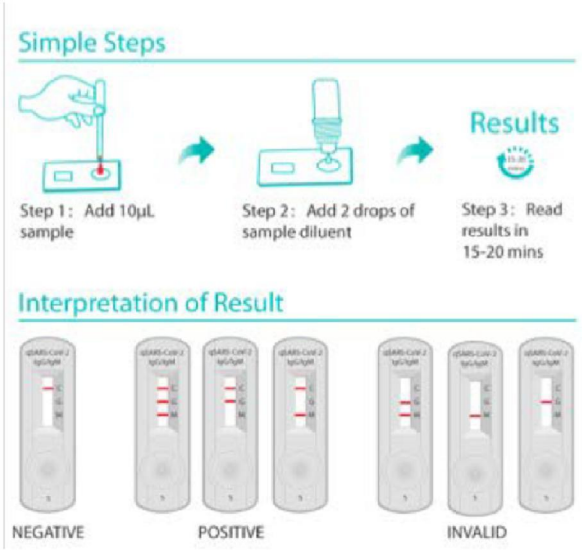
Only approved RDT

Chembio DPP COVID-19



Cellex qSARS-CoV-2 IgG/IgM Rapid Test