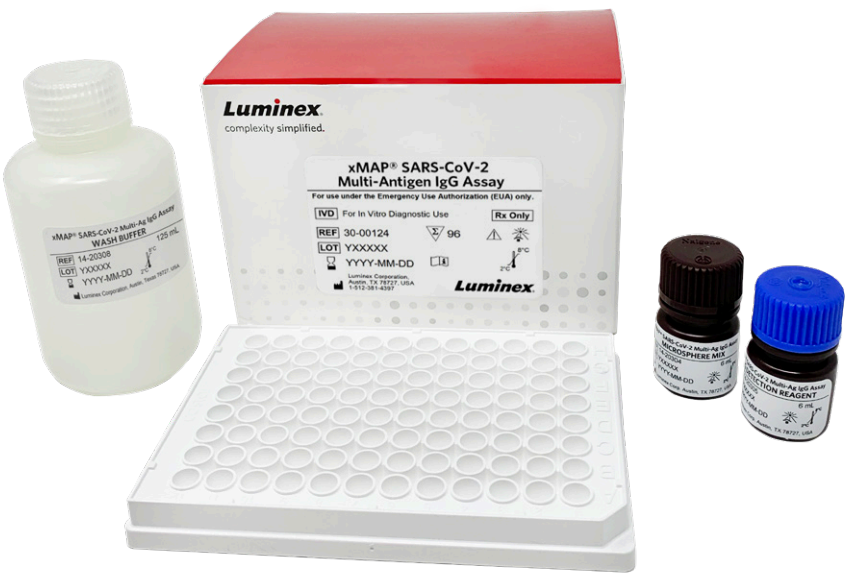
Luminex®

xMAP® SARS-CoV-2 Multi-Antigen IgG Assay (EUA-IVD)

The xMAP® SARS-CoV-2 Multi-Antigen IgG Assay is a multiplex, microsphere-based, highly sensitive and specific assay that detects the presence or absence of antibodies against 3 different SARS-CoV-2 antigens. By using multiple antigens, this assay may provide earlier, more sensitive results.

Features and Benefits:

- **Broad Coverage:** Detects IgG antibodies against 3 SARS-CoV-2 antigens, providing comprehensive results:
  - S1 subunit of the spike protein
  - Receptor Binding Domain (RBD) of the spike protein
  - Nucleocapsid protein
- **Flexible Throughput:** Test up to 96 samples per run in less than 3 hours to meet your throughput needs.
- **Versatile System Options:** Validated on MAGPIX®, Luminex® 200™, and FLEXMAP 3D® Systems so you can use the platform that best fits your lab.
- **Common Sample Types:** Designed for use with human serum and plasma samples, eliminating the need to implement additional collection protocols.



Performance

	Days From Symptom Onset*	PPA	95% CI	NPA	95% CI
MAGPIX® NxTAG®-Enabled					
Serum	≤7	71.1%	55%–83%	100.0%	99%–100%
	8–14	71.4%	50%–86%		
	>14	96.2%	87%–99%		
Plasma	≤7	100.0%	70%–100%	99.2%	96%–100%
	8–14	81.80%	52%–95%		
	>14	96.6%	83%–99%		
MAGPIX®					
Serum	≤7	71.1%	55%–83%	100.0%	99%–100%
	8–14	80.0%	58%–92%		
	>14	98.1%	90%–100%		
Plasma	≤7	100.0%	70%–100%	99.2%	96%–100%
	8–14	90.0%	60%–98%		
	>14	96.6%	83%–99%		
Luminex® 200™					
Serum	≤7	73.7%	58%–85%	100.0%	99%–100%
	8–14	80.0%	58%–92%		
	>14	98.1%	90%–100%		
Plasma	≤7	100.0%	70%–100%	99.2%	96%–100%
	8–14	90.0%	60%–98%		
	>14	96.4%	82%–99%		
FLEXMAP 3D®					
Serum	≤7	71.1%	55%–83%	100.0%	99%–100%
	8–14	80.0%	58%–92%		
	>14	98.1%	90%–100%		
Plasma	≤7	100.0%	70%–100%	99.2%	96%–100%
	8–14	90.0%	60%–98%		
	>14	96.4%	82%–99%		

**or days from molecular positive*

The performance was determined separately for each instrument (Luminex 200, MAGPIX NxTAG-enabled, MAGPIX, and FLEXMAP 3D Systems) and each matrix (serum and plasma).

Serum and plasma samples collected from individuals with known molecular positive results from an EUA PCR method were tested with the xMAP SARS-CoV-2 Multi-Antigen IgG Assay.

Negative percent agreement in serum and plasma was determined by using presumed SARS-CoV-2 IgG antibody negative samples from samples collected in the US prior to December 2019.

xMAP® SARS-CoV-2 Multi-Antigen IgG Assay Workflow

Step 1
Add sample and bead mix to the well and incubate for 60 min at room temperature.

Step 2
Add detection antibody mix to the well and incubate for 60 min at room temperature.

Step 3
Resuspend sample and transfer plate to instrument.

Step 4
Read on Luminex Instrument.

Usage and Targets

The xMAP® SARS-CoV-2 Multi-Antigen IgG Assay is a multiplex, bead-based assay for qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma (dipotassium EDTA).

Results are for the detection of SARS-CoV-2 antibodies. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high-complexity tests.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. False positive results for the xMAP SARS-CoV-2 Multi-Antigen IgG Assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The xMAP SARS-CoV-2 Multi-Antigen IgG Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

Ordering Information

Product Name	Part Number	Description
xMAP® SARS-CoV-2 Multi-Antigen IgG Assay (EUA-IVD)	30-00124	96 Tests
xMAP® SARS-CoV-2 Multi-Antigen IgG Assay Accessory Kit (EUA-IVD)*	CN-SW74-01	Data Analysis Software and Package Inserts
xMAP® SARS-CoV-2 IgG Control Kit (EUA-IVD)	30-00128	50 µL

*One-time order only

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complexity simplified.

orders@luminexcorp.com or support@luminexcorp.com

EUA - In Vitro Diagnostic Use Under Emergency Use Authorization. This test has not been FDA cleared or approved. This test has been authorized by the FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. §360bb-3(b)(1), unless the authorization is terminated or revoked sooner.

luminexcorp.com/xmap-sars-cov-2-assay/

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