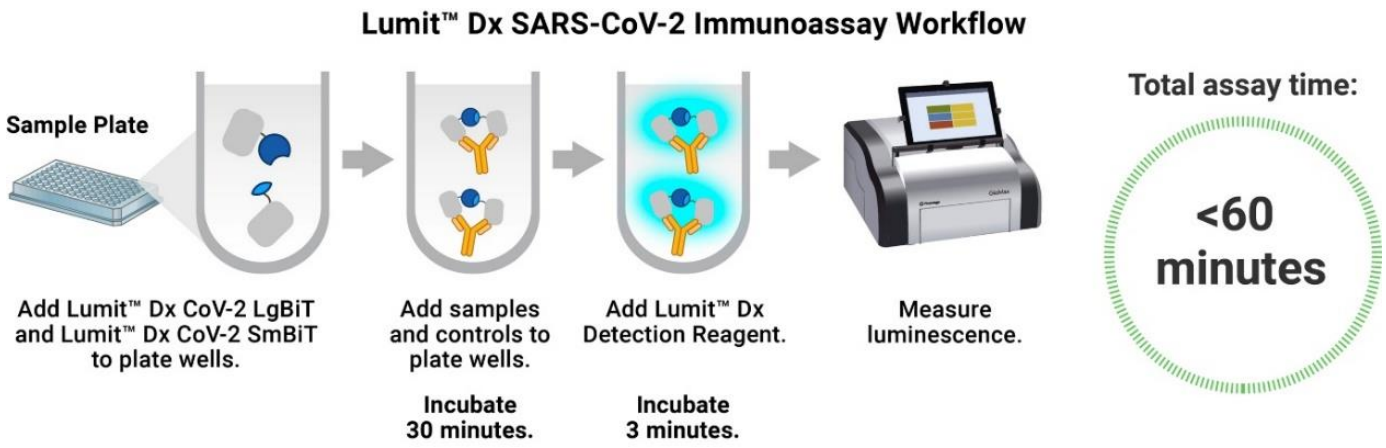
Media Backgrounder:
Promega Lumit™ Dx SARS-CoV-2 Immunoassay
CE-Marked *in vitro* diagnostic test (IVD) for SARS-CoV-2 antibody detection

The Lumit™ Dx SARS-CoV-2 Immunoassay is a qualitative in vitro diagnostic test intended to detect antibodies to SARS-CoV-2 in serum. The platform, powered by the award-winning NanoLuc® Binary Technology (NanoBiT®) offers consistent reliable results and features:[1 2 3]

- Simple workflow with no wash steps that yields results in <1 hour
- Reliably detect antibodies against the receptor-binding domain (RBD) antigen within the spike (S) protein
- Easily scalable for high-throughput needs, compatible with many automated platforms.
- CE-Marked



What does the Lumit™ Dx SARS-Cov-2 Immunoassay detect?
The Lumit™ Dx SARS-CoV-2 Immunoassay detects human antibodies against the Receptor Binding Domain (RBD) antigen within the S1 subunit of the SARS-CoV-2 spike (S) protein. Research has demonstrated that the spike (S) protein may offer better sensitivity than the nucleocapsid (N) protein for measuring SARS-CoV-2-specific antibodies.[4]

What specimen type is needed for the Lumit™ Dx SARS-CoV-2 Immunoassay?
The assay should be performed with human serum.

How long does it take to get a result?
The assay can be run manually in 96-well format in less than an hour. Running the assay on an automated platform may expedite the time to result. The result for each sample is either positive or negative for SARS-CoV-2 antibodies, based on a calculation comparing patient sample to an assay calibrator.

Are specific instruments or equipment needed to run the Lumit™ Dx SARS-CoV-2 Immunoassay?
Yes. The Lumit™ Dx SARS-CoV-2 Immunoassay produces a bioluminescent signal and requires a luminescent microplate reader that uses a photomultiplier tube for signal detection. The user must ensure the instrument is set up for use according to the manufacturer's instructions.

Where is this assay produced?
The Lumit™ Dx SARS-CoV-2 Immunoassay was developed in the United States at the Promega Headquarters in Madison, Wisconsin. This is also the location where all components and kit lots are manufactured, quality tested and distributed.

Do you have enough supply of reagents and consumable materials to manufacture the antibody test and allow laboratories to use it in large numbers?
We are confident in our abilities to manufacture the assay in large quantities to ensure the assumed demands for antibody testing for SARS-CoV-2 are met. In addition, we have secured a significant amount of raw materials at Promega Headquarters to meet demand.

[1] European Laboratory Research and Innovation Group (ELRIG) – advances in cell based screening in Drug Discovery meeting 2015: Best Technology (https://elrig.org/advances-in-cell-based-screening-in-dug-discovery-2015-technology-prize/).
[2] The Scientist: Top10 Innovation 2015 (https://www.the-scientist.com/features/top-10-innovations-2015-34435).
[3] Dixon, A.S., et al. (2016) NanoLuc Complementation Reporter Optimized for Accurate Measurement of Protein Interactions in Cells. ACS Chem Biol. 11, 400–408.
[4] Kontou, P. I., et al. (2020) Antibody Tests in Detecting SARS-CoV-2 Infection: A Meta-Analysis. Diagnostics (Basel). 10, doi:10.3390/diagnostics10050319 (2020).

Product Intended Use

The Lumit™ Dx SARS-CoV-2 Immunoassay is intended for use as a qualitative in vitro diagnostic test to detect the presence of antibodies against SARS-CoV-2 in human serum. This test is used as an aid in the identification of individuals with an immune response to SARS-CoV-2. The Lumit™ Dx SARS-CoV-2 Immunoassay uses a novel, proprietary detection system to detect the presence of antibodies to SARS-CoV-2 as a luminescent signal and requires a luminometer to measure the signal generated.

The Lumit™ Dx SARS-CoV-2 Immunoassay is intended for professional use only.

Product Use Limitations

For in vitro diagnostic use only.

This test should not be used for screening of donated blood for the purpose of preventing SARS CoV-2 transmission.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, 229E, SARS-CoV-1 or MERS-CoV.

The Lumit™ Dx SARS-CoV-2 Immunoassay is only available in certain countries. This product meets the essential requirements of EU Directive 98/79/EC on in vitro diagnostic medical devices.