SARS-CoV-2 | RESEARCH

[Fast. Sensitive. Reproducible.]

Introducing a SARS-CoV-2 ELISA kit that delivers results in 45 minutes

Continued serological testing and research on SARS-CoV-2 is essential in understanding the spread of infection. Additionally, continued investigation of SARS-CoV-2 is important for understanding antibody responses to viral mutations and their impact on long-term immunity—ultimately aiding vaccine design and new therapeutic discoveries.

To aid this research, and in response to a growing need for a faster, more agile testing method without compromising quality, the new **Invitrogen™ Dynabeads™ SARS-CoV-2 spike ELISA kits** use a new, innovative plates-to-beads concept.

Three Dynabeads SARS-CoV-2 spike ELISA kits are used to detect and quantify human IgG, IgM, or total Igs from serum or plasma samples from individuals who tested positive for SARS-CoV-2, and can be used for both qualitative and quantitative assays.

The spike protein, consisting of a recombinant trimeric structure combining the S1 subunit, the receptor binding domain (RBD), and the S2 subunit found on the surface of SARS-CoV-2 viruses where antibody binding occurs, is covalently bound to Invitrogen™ Dynabeads™ magnetic beads.

This new technology can reduce assay time by 2- to 7-fold in contrast to conventional plate-based ELISAs where the spike protein is coupled to the bottom of microtiter plates.

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Plates-to-beads concept

The conventional plate-based ELISA method is associated with lengthy protocols requiring many wash steps, long incubation times, and a lot of hands-on work, leading to a total run time of at least 2–6 hours. The plates are coated with immobilized molecules with the goal of capturing antibodies, antigens, or other proteins from serum, plasma, or cell culture media. By binding an enzyme-bound secondary antibody to the complex and adding a substrate solution to initiate the reaction, the activity of the microplate well–bound reaction can be measured by absorbence at 450 nm.

The new plates-to-beads concept simplifies the ELISA protocol and removes the need for long incubations and countless manual interventions. This is achieved through combining Dynabeads magnetic beads with the ELISA method, a unique solution that can be automated on Thermo Scientific™ KingFisher™ systems.

In this new bead-based ELISA method, the antigen is covalently bound to 2.8 µm of Dynabeads magnetic beads. The perfectly spherical shape of the beads leads to an increased binding capacity as a larger surface area is available to bind antibodies. In addition to this, the kinetics are vastly improved, as the antibodies are captured by the beads while in suspension, greatly reducing incubation times. This stands in strong contrast to conventional plate-based ELISA assays where long incubation times are necessary to ensure the antibody settles at the bottom of the well to find its antigen.

This plates-to-beads ELISA method reduces the assay time to only 45 minutes. The concept was also created with manual protocols in mind. Easily perform wash steps with Invitrogen™ DynaMag™-96 magnets.

Thermo Scientific™ KingFisher™ Apex system

Thermo Scientific™ KingFisher™ Flex system

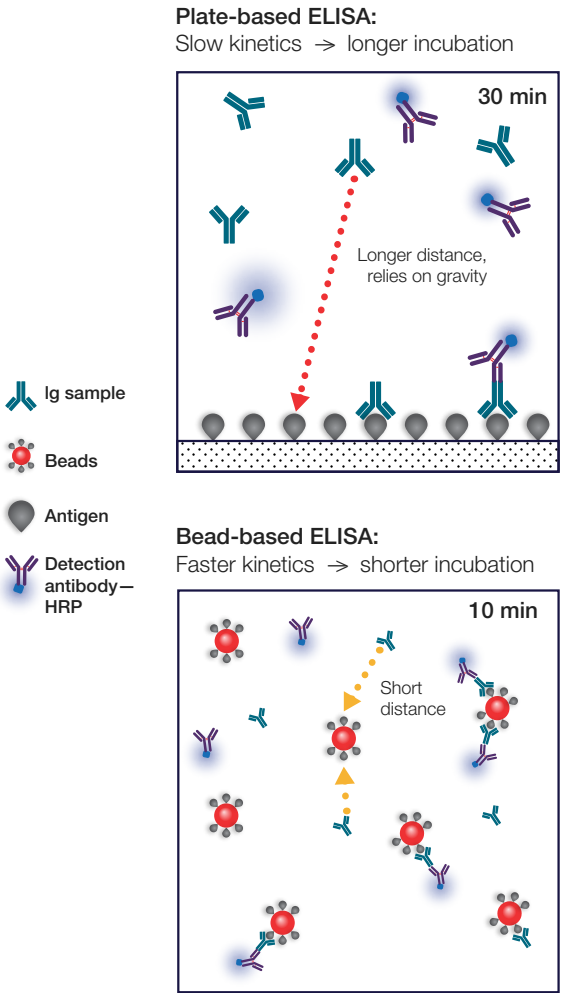


Figure 1. Rapid binding kinetics are at work in the bead-based ELISA method due to the relatively short distance between beads in suspension and the antibody. This leads to a much shorter incubation time compared to a plate-based ELISA method where the antibody must rely on gravity and cover a larger distance to find its antigen at the bottom of the well.

Automation with KingFisher Flex and Apex systems

Dynabeads magnetic beads facilitate automation. The bead-based ELISA method can therefore be automated with KingFisher instruments, resulting in a rapid walk-away ELISA solution. This solution drastically improves reproducibility because most operating errors are reduced, providing typical intra-assay CV values at <4%, and typical inter-assay CV values at <10%. Please see Figures 2 and 3 for more details.

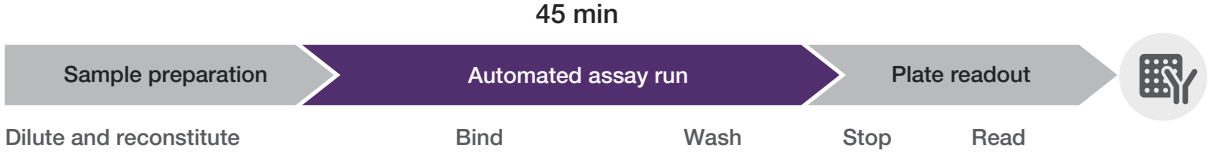


Figure 2. Fast processing of bead-based ELISA kits.

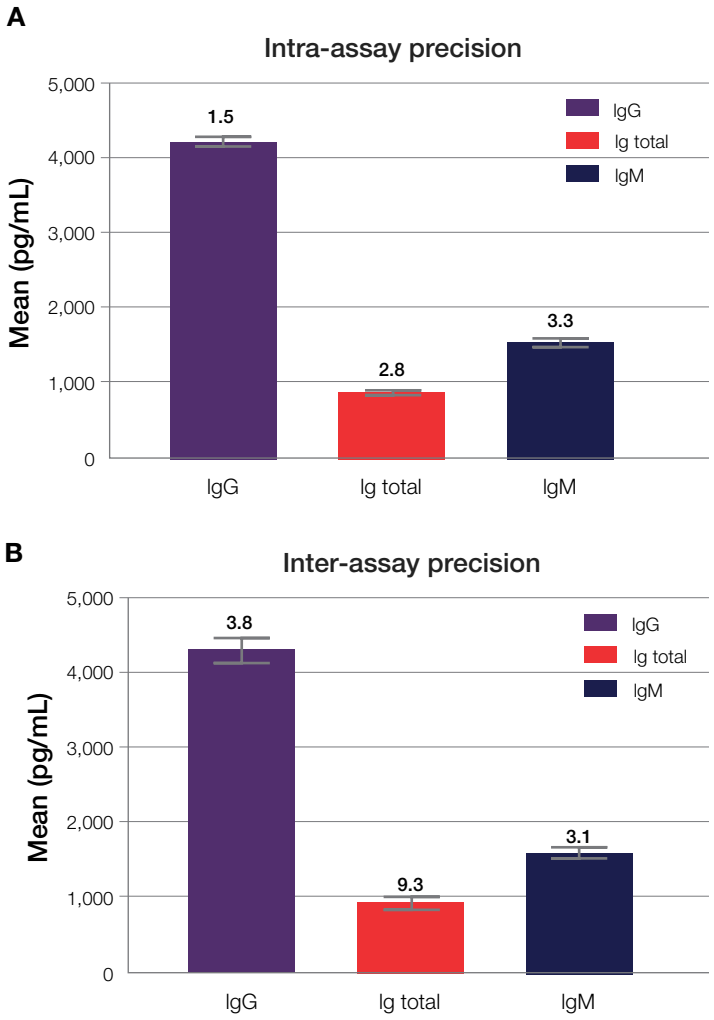
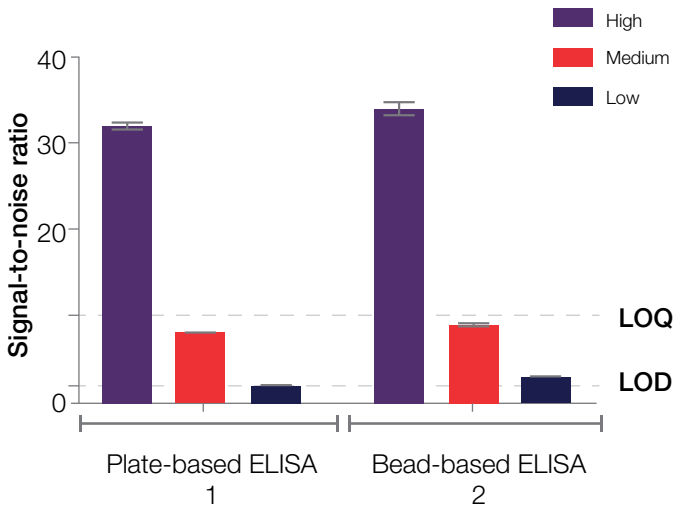


Figure 3. Intra-assay and inter-assay precision demonstrate low variations between replicas for each of the Dynabeads SARS-CoV-2 Spike ELISA kits. Operator pipetting, instrument performance, and minimal variation between critical reagent batches—all contribute to the high assay precision of <3.3% (range 1.5–3.3%) and <9.3% (range 3.1–9.3%) for (**A**) intra and (**B**) inter assays, respectively.



Target	Plate-based ELISA (pg/mL)	Bread-based ELISA (pg/mL)
High	13,190	14,360
Medium	3,578	4,007
Low	946	1,082

Figure 4. The sensitivity and recovery range for bead-based ELISA. The data are well within acceptable ratios and industry standards, suggesting an equal or better performance when using the Dynabeads beads–based automated ELISA kit vs. the plate-based ELISA kit. The sensitivity of the Dynabeads beads–based automated ELISA is presented as a signal-to-noise ratio according to the ICH Topic Q 2 (R1) guidelines. The signal-to-noise ratio was determined by comparing measured signals from samples spiked with high (15.00 pg/mL), medium (3,750 pg/mL), and low (937.5 pg/mL) concentrations of IgG with those of blank samples. The low concentration (purple bars) is within the acceptable ratio of 2:1 (limit of detection, or LOD) and can be reliably detected by the Dynabeads beads–based automated ELISA. The medium concentration (red bars) is within the acceptable ratio of 10:1 (limit of quantification, or LOQ) and can be reliably quantified by the Dynabeads beads–based automated ELISA.

Challenges of conventional SARS-CoV-2 spike ELISA kits

- Long incubation times of 2–4 hours
- Many washing steps
- Long protocols with a lot of manual handling

Advantages of Dynabeads SARS-CoV-2 spike ELISA kits

- Increased kinetics and binding capacity—reduces incubation time to 45 minutes
- High reproducibility and sensitivity
- Enables automation—helps reduce hands-on time and manual errors

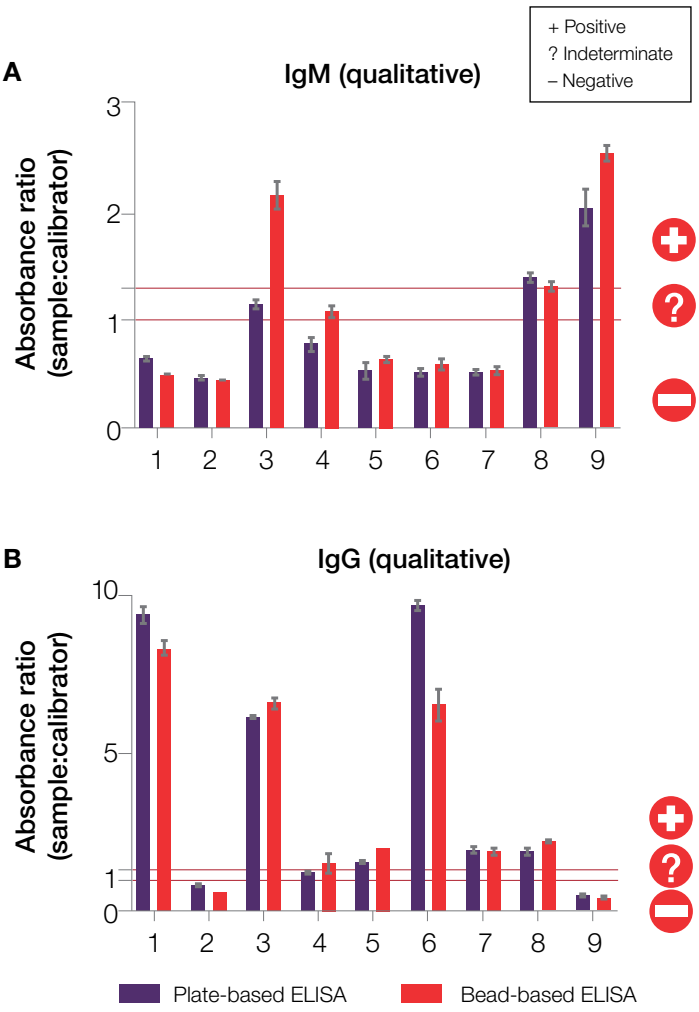


Figure 5. Clinical research samples show good correlation between bead-based and plate-based ELISA assays in detecting SARS-CoV-2 IgM and IgG antibodies. A qualitative assay is used to detect IgM and IgG in clinical research samples using the Dynabeads beads–based automated ELISA. The data are presented as a ratio between absorbance values from the sample over absorbance values obtained by the calibrator (medium). For comparison, a plate-based method is included. A ratio of <1 shows that the target is absent while a ratio of >1.3 indicates that the target is present. A ratio between 1 and 1.3 is indeterminate. (**A**) Clinical research samples 3 and 9 are classified as IgM-positive when using the Dynabeads beads–based automated ELISA, while clinical research samples 4 and 8 are identified as indeterminate. (**B**) In contrast, clinical samples 1, 3, 4, 5, 6, 7, and 8 are classified as IgG-positive using the same method.

Dynabeads SARS-CoV-2 spike beads

Aiding your research needs, Invitrogen™ Dynabeads™ SARS-CoV-2 spike beads are also available as a separate stand-alone product if you want to optimize your own conditions or create your own assay. As the SARS-CoV-2 spike protein binds to angiotensin-converting enzyme 2 (ACE2) expressed on the surface of the endothelial host cells, the spike-conjugated Dynabeads beads may also be used for ACE2 protein purification or ACE2-positive cell enrichment.

- Optimization of kit
- Creation of own SARS-CoV-2 ELISA assay
- Isolation of ACE2-positive cells (data currently not available)
- ACE2 protein purification (data currently not available)

Ordering information

Product	Product size	Cat. No.
Dynabeads SARS-CoV-2 Spike IgG ELISA Kit	96 rxns	18000D
Dynabeads SARS-CoV-2 Spike IgM ELISA Kit	96 rxns	18010D
Dynabeads SARS-CoV-2 Spike Ig Total ELISA Kit	96 rxns	18020D
Dynabeads SARS-CoV-2 Spike Beads	3 mL	18100D

Find out more at
thermofisher.com/dynabeadssarscov2antibodydetection

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