Overview
Bio-Layer is an Australian company that develops and commercializes novel materials for the biotechnology, diagnostics, and pharmaceutical industries. Its current focus is the provision of material science–based solutions for surfaces that improve the way immunoassays are developed and manufactured. The global immunoassay market is worth US$6–7 billion, and is growing at approximately 11%–12% per annum.

Bio-Layer’s materials address critical challenges for life science research and diagnostic products, including increasing sensitivity, improving specificity and reproducibility, and saving costs. The combination of rational design, combinatorial chemistry, and surface science has resulted in the creation of a process that can simultaneously develop and test thousands of surface coatings, which can be screened to identify the optimal composition for a particular type of diagnostic test surface.

Bio-Layer–developed surfaces are currently incorporated in four commercial immunoassays used in academic and research applications, and are distributed by a major global life sciences company.

Technology
Existing industry practices for developing immunoassays involve using standard solid-phase materials (plastic, glass, etc.) and customizing the biological components. Bio-Layer understands that the surface to which a molecule is attached affects the performance of that molecule in an assay; and the company’s approach is to engineer the solid-phase materials, providing the opportunity for a paradigm shift in immunoassay development.

The Bio-Layer technology platform combines patented rational design, combinatorial chemistry methods, and surface modification processes to generate thousands of diverse surface coatings that display a spectrum of predetermined molecular characteristics. These surface coatings can be rapidly screened to identify candidates with superior characteristics for a specific application. Existing surface companies only manufacture and test a dozen or so “nonintelligent” surfaces a year, not thousands like Bio-Layer.

A fully integrated informatics system built around Bio-Layer’s proprietary structure–property database supports the high-speed optimization of “lead” candidates to products. The concept is analogous to modern high-throughput drug discovery screening.

Bio-Layer can layer these surface coatings onto existing microplates, microarrays, beads, and membranes that are routinely used in immunoassays. The ability to deliver predictable biomolecular control regardless of solid-support materials or formats is unique in the life sciences industry.
Bio-Layer Offering

Currently, within the pharmaceutical and diagnostic industries, plastic, glass, organic polymers, and silicon are used extensively as solid-phase supports for biological studies (e.g. protein and gene biochips, multiwell plates and beads for high-throughput screening, columns and membranes for purification). The inability to modify and control the surface properties of these materials in a predictable manner is significantly hindering these companies from increasing the sensitivity of existing assays and enabling new assays that currently cannot be performed with existing protocols.

Using its material discovery technology, Bio-Layer can provide to the immunoassay market surface coatings that bind, present, and protect proteins for optimized use, thus giving more sensitive and robust assays, simplifying assay protocols, and enabling new assays.

The current product development program of Bio-Layer addresses the recognized problems of immunoassays, which have suboptimal sensitivity and reproducibility due to unpredictable and random immobilization of the capture antibody to a test surface, e.g. plastic or glass (Fig. 1a). Compared to existing methods, current Bio-Layer products (Fig. 1b) can make immunoassays more sensitive (up to 70-fold) and cheaper (90% faster to produce with 50% less reagents). These characteristics are highly desired by manufacturers of diagnostic kits and immunoassays. Bio-Layer’s first generation of Mix&Go products have already been incorporated into commercial diagnostic assays used in research, and are being distributed by a major life sciences company.

![Fig. 1. (a) Random immobilization and denaturation on standard surfaces. (b) Surfaces that orient, support, and optimize antibody binding for Immunoassays.](image-url)