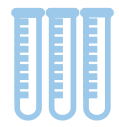


# Customized IVD Assay Development & Manufacturing



Living Immunoassay Excellence

# OUR CUSTOMIZED IVD ASSAY SOLUTIONS



## CUSTOMIZED IN VITRO DIAGNOSTIC ASSAY SOLUTIONS FOR YOUR AUTOMATED PLATFORMS

Extensive and proven experience on immunoassays, most notably using chemiluminescence and turbidimetry technologies, for a variety of automated platforms



## END-TO-END ASSAY LIFECYCLE SERVICES IN ONE PLACE

Providing solutions from the early stages of product development right through to product manufacturing, including high value-added services such as clinical studies, worldwide registration and on-market product support



## TIME TO MARKET IS KEY

Bringing your assay to market rapidly thanks to integrated project management for optimized development time and dedicated product transfer from R&D to manufacturing to ensure speed, efficiency and reliability



## LONG-TERM PARTNERSHIP

Fully committed to building mutually beneficial long-term relationships with our partners in the IVD Industry



## THE MOST SUITABLE BIOMATERIAL FOR YOUR ASSAY

Design, development and manufacture of the biomaterial that perfectly suits your final in vitro diagnostic assay



## DESIGN, FEASIBILITY AND DEVELOPMENT OF ASSAYS

Customized assay development solutions, comprising the design of the assay, feasibility studies with the reagent formulation and full development



## CONTRACT MANUFACTURING

Manufacturing adapted to your specific needs, from supplying bulk reagents to tailor-made kit assembly and packaging services



## GLOBAL PRESENCE

Extensive experience in clinical studies and regulatory affairs, with an in-depth knowledge of the requirements of each market

## OUR OFFER

### Continuous Quality Control Process



Make use of our expertise for the complete development of your in vitro diagnostic assays

1

*De novo*: Design, Development, Production, Fill & Pack and Registration



Use our prototypes and proof-of-concept (evaluation to verify biomaterials and reagent formulation) or a comprehensive range of pre-developed chemiluminescent reagents

2

Proof of Concept: Development, Production, Fill & Pack and Registration



Benefit from our offer in bulk, ready-made solutions for turbidimetric (latex or antiserum-based) and chemiluminescent reagents

3

Bulk: Production and Fill & Pack

Biokit, your OEM partner of choice

# Biokit, your OEM partner of choice

## Consistently rated as a top-quality partner for OEM solutions

Biokit can assure IVD companies the development and supply of assays that cover their demand needs continuously and reliably, securing their operations, through our state-of-the-art development and manufacturing capabilities.

## Center of Excellence for IVD Immunoassays and Biomaterials

Biokit strive to meet the highest standards of innovation and quality in the research, development and manufacturing of assay and biomaterial solutions for the IVD industry, with the ultimate goal of promoting greater laboratory efficiency and better clinical outcomes for patients.



## Operational Excellence - continuous improvement of processes, products and services

- Development of products with a comprehensive process management approach in order to offer **competitive solutions** in terms of time to market, critical chain project management and efficiency.
- Production under **GMP procedures** and **lean manufacturing**
- **ISO 8 classified areas** for production and filling
- **5S methodology** implemented in all production areas
- Extensive manufacturing **scale-up** capabilities

Our Manufacturing figures	Our Filling & Packaging capabilities	
+600 References in manufacturing	10 automated liquid filling lines	+30 types of vials in use
+150 Million IVD tests manufactured every year	3 lyophilizers and +50,000 lyophilized vials per batch	+8 million vials filled per year
+160 Liters of chemiluminescent microparticles per batch	Labelling automated vision inspection system	+15,000 kits packed per batch
+300 Liters of latex reagents per batch		+1.4 million kits packed per year
+500 Liters of buffer per batch		

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