



Customized Assay Development & Manufacturing

Living Immunoassay
Excellence

OUR CUSTOMIZED ASSAY SOLUTIONS



CUSTOMIZED 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



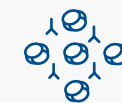
TIME TO MARKET IS KEY

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 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

Design

Feasibility Studies

Development

Clinical Studies

Manufacturing

Fill & Pack

Worldwide Registration



Make use of our expertise for the complete development of your 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

Werfen,
your OEM
partner
of choice

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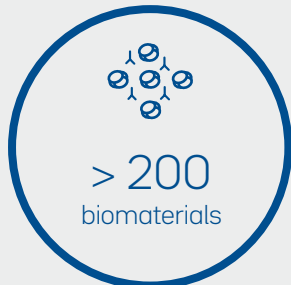
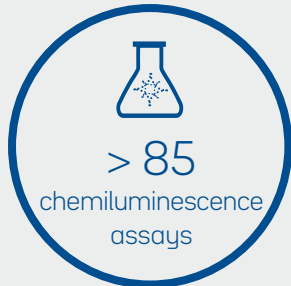
Consistently rated as a top-quality partner for OEM solutions

Werfen 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 diagnostic Assays and Biomaterials

Werfen 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.

Our development achievements



Operational Excellence - continuous improvement of processes, products and services

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

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werfen

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