

Werfen, your partner of choice

Consistently rated as a top-quality partner for Immunoassay Components

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



> 93
chemiluminescence
assays



> 50
latex
assays



> 200
biomaterials



Experience with
> 110
analyzers

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
>500 References in manufacturing	10 automated liquid filling lines
>150 Million diagnostic tests manufactured every year	4 lyophilizers and >50,000 lyophilized vials per batch
>Up to 120 liters of chemiluminescent microparticles per batch	Labelling automated vision inspection system
>Up to 440 liters of latex reagents per batch	>13 million vials filled per year
>Up to 4500 liters of buffer per batch	>1.8 million kits packed per year

3100-9769 R06 MARCH-2025

werfen

Av. Can Montcau 7
08186 Lliçà d'Amunt
Barcelona, Spain
Phone: +34-93-860-9000
werfen.com/immunoassay

Customized Assay Development & Manufacturing

werfen

OUR CUSTOMIZED ASSAY SOLUTIONS



CUSTOMIZED DIAGNOSTIC ASSAY SOLUTIONS FOR YOUR AUTOMATED PLATFORMS

Extensive and proven experience on
Immunoassays, most notably using chemilu-
minescence 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 biomate-
rial 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
partner
of choice