



# Biomaterials Catalog

Antigens & Antibodies Supply

werfen

Werfen is a global, family-owned, diagnostics company focused in providing innovative specialized diagnostic solutions to improve patient healthcare, founded in 1966 in Barcelona, Spain.

Our Immunoassay Technology Center has consolidated experience in research, development and manufacturing of customized assays and biomaterials.

We offer end-to-end solutions for the IVD industry with the most innovative capabilities to enhance competitiveness and time-to-market.

Our mission is to become your partner of choice as a center of excellence in providing innovative end-to-end solutions (products & services) to IVD companies.



## Innovation

Our Immunoassay Technology Center ranks among the top centers of excellence for immunoassay and biomaterial development and manufacturing in the industry. Our focus on technological advances ensures our customers access to state-of-the-art R&D and manufacturing capabilities. Werfen's innovative nature is strengthened through close relationships with prestigious universities and biotechnology research centers around the world.

## Operational Excellence

Our key strength is the combination of the ongoing effort to improve our organizational processes, products and services with the Werfen mindset that embraces principles and tools to create a sustainable partnership with our customers and employees. Our Quality System is certified to ISO 13485:2016 / EN ISO 13485:2016 as well as MDSAP.

## Commitment

Customers and patients benefit from the efficiency of a talented global team of qualified and specialized professionals who lend their enthusiasm, dedication and energy on a daily basis in order to provide high quality products & services.



# Biomaterials for the IVD Industry

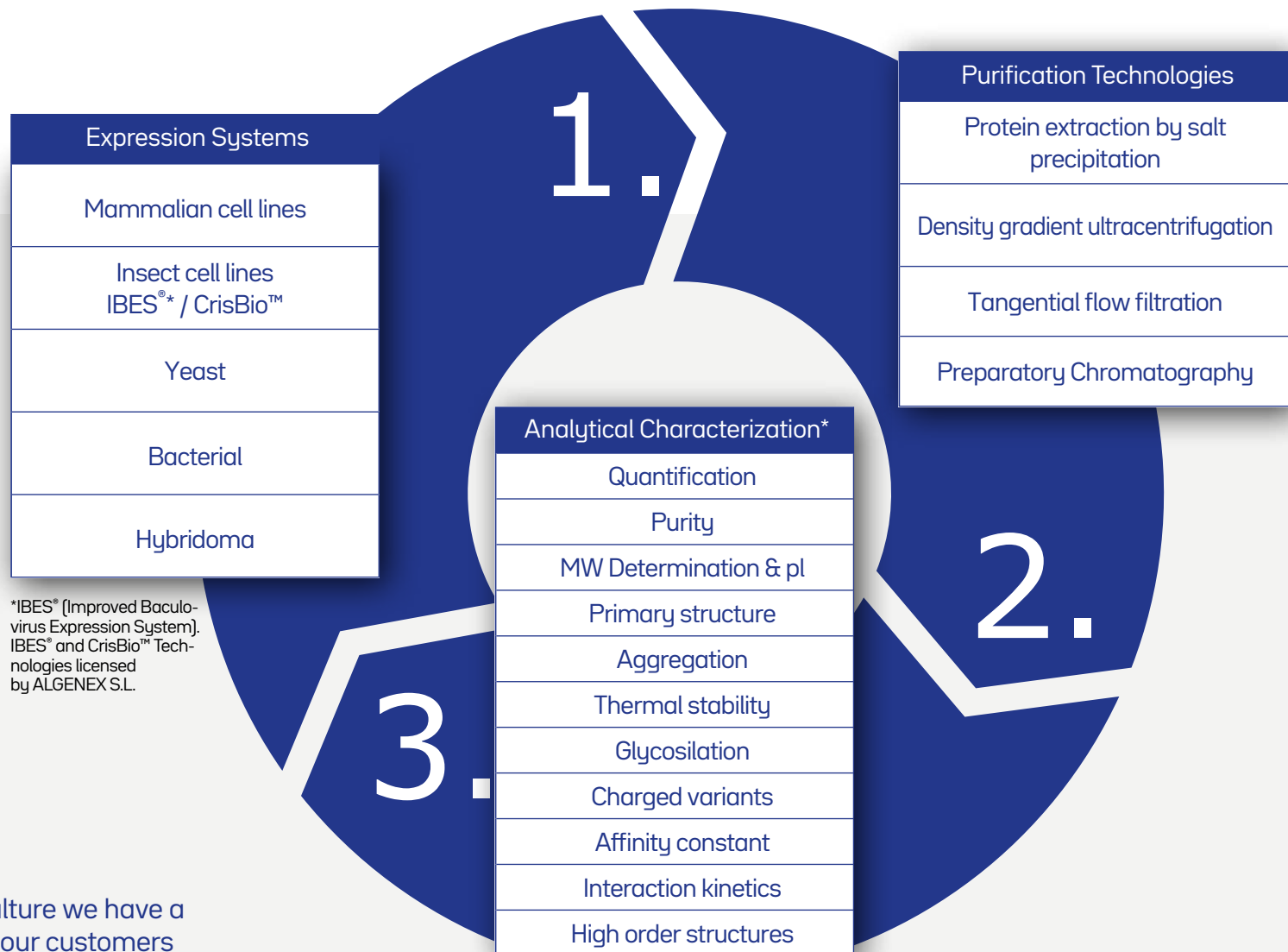
Werfen offers a broad range of biomaterials, including antigens, antibodies, obtained by following validated standards of quality procedures. Those procedures ensure the traceability, reproducibility and robustness of every single product. Our expertise is attested to by more than 200 biomaterials that are being used in diagnostic technologies.

Our know-how in biomaterials is focused on their application in commercial diagnostic assays that provides a low-risk, reliable and highly successful option for our customers to reduce time to market in their developments and secure their operations.

## Acronym List

<b>A<sub>280</sub></b>	Absorbance at 280 nm	<b>HEV</b>	Hepatitis E Virus
<b>Ab</b>	Antibody	<b>HPLC</b>	High Performance Liquid Chromatography
<b>Ag</b>	Antigen	<b>HTLV</b>	Human T-lymphotropic Virus
<b>αHBs</b>	Anti-Hepatitis B Surface	<b>IBES</b>	Improved Baculovirus Expression System
<b>ASO</b>	Anti-Streptolysin O	<b>IVD</b>	In Vitro Diagnostics
<b>CHO</b>	Chinese Hamster Ovary	<b>mAb</b>	Monoclonal Antibody
<b>CL</b>	Chemiluminescence	<b>MES</b>	2-[N-morpholino]ethanesulfonic acid
<b>ELISA</b>	Enzyme-Linked ImmunoSorbent Assay	<b>NTE</b>	NaCl-Tris-EDTA buffer
<b>GMP</b>	Good Manufacturing Practices	<b>pAb</b>	Polyclonal Antibody
<b>HBV</b>	Hepatitis B Virus	<b>PBS</b>	Phosphate-Buffered Saline
<b>HCV</b>	Hepatitis C Virus	<b>PlGF</b>	Placental Growth Factor
<b>HEPES</b>	N-2-hydroxyethylpiperazine-N-2-ethane sulfonic acid	<b>Rec</b>	Recombinant
		<b>sFlt-1</b>	Soluble fms-like tyrosine kinase-1

# Biomaterials Manufacturing Capabilities



\*IBES<sup>®</sup> (Improved Baculovirus Expression System).  
IBES<sup>®</sup> and CrisBio<sup>™</sup> Technologies licensed by ALGENEX S.L.

Thanks to our partnering culture we have a vast experience of meeting our customers needs and their regulatory requirements in order to commercialize their products worldwide.

\*This table compiles all the available analytical characterization methodologies. Depending on the biomaterial, there are methodologies applied on routine or upon request



Werfen is your partner with state-of-the-art manufacturing capabilities to have the supply of critical biomaterials that cover market needs in a continuous, reliable and low-risk manner securing your operations.

## CAPABILITIES

- 38,000 m<sup>2</sup> [409,028 ft<sup>2</sup>] facilities of which 10,000 m<sup>2</sup> [107,639 ft<sup>2</sup>] are dedicated to production activities
- Extensive manufacturing scale-up capabilities
- Biosafety level 2 laboratories
- Positive and negative pressurized laboratories
- State-of-the-art equipment: Bioreactors, AKTA Systems among others
- ISO 8 classified areas for production and filling
- Production under GMP's procedures
- Production under Lean Manufacturing
- 5S methodology implemented in all the production areas
- Final QC functional and physicochemical analysis





Chagas	
Recombinant Antigens	p. 19
Recombinant TcF Antigen	

●			

*\*Please note that this table is merely indicative. Other uses may be applicable depending on customer needs. For further technical information or requests please contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com).*



# Fertility

The following products have been tested in the following applications. This information derives from use in commercial diagnostic assays and/or testing within our laboratories.

Fertility	Chemiluminescence	ELISA	Turbidimetry	Rapid Test
<b>Monoclonal Antibodies</b>				
Anti-Placental Growth Factor mAb (PGF16M)	●			
Anti-Placental Growth Factor mAb (PGF03m)	●			
Anti-sFlt-1 mAb (SFT10m)	●			
Anti-sFlt-1 mAb (SFT18)	●			

Other uses may be applicable depending on customer needs. For further technical information or requests please contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com).

## Monoclonal Antibodies

The following products have been tested in the following applications. This information derives from use in commercial diagnostic assays and/or testing within our laboratories.

Product Description	Presentation	Reference	Storage
Anti-Placental Growth Factor mAb (PGF16M)	1 mg/vial	3000-5330	-70°C*
Anti-Placental Growth Factor mAb (PGF16M)	mg/custom size	3000-5329	-70°C*

The information contained in this catalogue is for informational purposes. Contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com) for further technical information and product availability.  
\*Avoid repeated freezing and thawing.

### Details

<b>Source</b>	Hybridoma cell line
<b>Storage Buffer</b>	50 mM MES, 150 mM NaCl, pH 6
<b>Purification Method</b>	Protein A
<b>Protein Concentration</b>	≥ 1.00 mg/mL [ $A_{280}$ ]
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Anti-Placental Growth Factor mAb (PGF03m)	1 mg/vial	3000-5332	-70°C*
Anti-Placental Growth Factor mAb (PGF03m)	mg/custom size	3000-5331	-70°C*

The information contained in this catalogue is for informational purposes. Contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com) for further technical information and product availability.

\*Avoid repeated freezing and thawing.

## Details

<b>Source</b>	Hybridoma cell line
<b>Storage Buffer</b>	50 mM MES, 150 mM, NaCl, pH 6
<b>Purification Method</b>	Protein A
<b>Protein Concentration</b>	≥ 1.00 mg/mL ( $A_{280}$ )
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Anti-sFtl-1 mAb (SFT10m)	1 mg/vial	3000-5334	-70°C*
Anti-sFlt-1 mAb (SFT10m)	mg/custom size	3000-5333	-70°C*

The information contained in this catalogue is for informational purposes. Contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com) for further technical information and product availability.

\*Avoid repeated freezing and thawing.

## Details

<b>Source</b>	Hybridoma cell line
<b>Storage Buffer</b>	50 mM MES, 150 mM, NaCl, pH 6
<b>Purification Method</b>	Protein A
<b>Protein Concentration</b>	≥ 1.00 mg/mL ( $A_{280}$ )
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Anti-sFlt-1 mAb (SFT18)	1 mg/vial	3000-5336	-70°C*
Anti-sFlt-1 mAb (SFT18)	mg/custom size	3000-5335	-70°C*

The information contained in this catalogue is for informational purposes. Contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com) for further technical information and product availability.

\*Avoid repeated freezing and thawing.

## Details

<b>Source</b>	Hybridoma cell line
<b>Storage Buffer</b>	PBS, pH 7.4
<b>Purification Method</b>	Protein G
<b>Protein Concentration</b>	≥ 1.00 mg/mL ( $A_{280}$ )
<b>Preservative</b>	No Preservative Added

# Inflammation

The following products have been tested in the following applications. This information derives from use in commercial diagnostic assays and/or testing within our laboratories.

Inflammation	Chemiluminescence	ELISA	Turbidimetry	Rapid Test
ASO				
Recombinant Antigens				
Recombinant Streptolysin O			●	●
Recombinant Streptolysin O Stabilized			●	●

Other uses may be applicable depending on customer needs. For further technical information or requests please contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com).



# ASO

## Recombinant Antigens

Product Description	Presentation	Reference	Storage
Recombinant Streptolysin O	mg/custom size*	3000-5258	-70°C**

\*For large quantities, packaging available upon request - minimum size 5 mg/vial. \*\*Avoid repeated freezing and thawing.

### Specifications

<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	Tris-HCl, pH 8.5
<b>Purification Method</b>	Metal Affinity Chromatography
<b>Protein Concentration</b>	2.00 - 4.00 mg/mL ( $A_{280} \times 0.79$ )
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Recombinant Streptolysin O stabilized	1mg/mL	3000-5311	-70°C**
Recombinant Streptolysin O stabilized	mg/custom size*	3000-5259	-70°C**

\*For large quantities, packaging available upon request - minimum size 5 mg/vial. \*\*Avoid repeated freezing and thawing.

### Specifications

<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	Tris-HCl, pH 8.2
<b>Purification Method</b>	Metal Affinity Chromatography
<b>Protein Concentration</b>	1.00 - 2.00 mg/mL [Lowry Method]
<b>Preservative</b>	No Preservative Added

# Infectious Diseases

## Hepatitis B

The following products have been tested in the following applications. This information derives from use in commercial diagnostic assays and/or testing within our laboratories.

Hepatitis B	Chemiluminescence	ELISA	Turbidimetry	Rapid Test
<b>Native Antigens</b>				
Hepatitis B Surface Antigen (ad Subtype)	●	●		
Hepatitis B Surface Antigen (ay Subtype)	●	●		
<b>Recombinant Antigens</b>				
Recombinant HBc Antigen	●	●		
Recombinant HBsAg Ay	●			

Other uses may be applicable depending on customer needs. For further technical information or requests please contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com).

## Native Antigens

Product Description	Presentation	Reference	Storage
Hepatitis B Surface Antigen (ad Subtype)	1 mg/vial	3000-5201	-20°C**
Hepatitis B Surface Antigen (ad Subtype)	mg/custom size*	3000-5200	-20°C**

\*For large quantities, packaging available upon request - minimum size 5 mg/vial. \*\*Avoid repeated freezing and thawing.

### Specifications

<b>Source</b>	Human plasma
<b>Storage Buffer</b>	PBS, pH 7.4
<b>Purification Method</b>	Ultracentrifugation
<b>Protein Concentration</b>	2.00 - 3.00 mg/mL ( $A_{280} / 3.726$ )
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Hepatitis B Surface Antigen (ay Subtype)	1 mg/vial	3000-5199	-20°C**
Hepatitis B Surface Antigen (ay Subtype)	mg/custom size*	3000-5198	-20°C**

\*For large quantities, packaging available upon request - minimum size 5 mg/vial. \*\*Avoid repeated freezing and thawing.

### Specifications

<b>Source</b>	Human plasma
<b>Storage Buffer</b>	PBS, pH 7.4
<b>Purification Method</b>	Ultracentrifugation
<b>Protein Concentration</b>	2.00 - 3.00 mg/mL (A <sub>280</sub> / 3.726)
<b>Preservative</b>	No Preservative Added

## Recombinant Antigens

Product Description	Presentation	Reference	Storage
Recombinant HBc Antigen	1 mg/vial	3000-5100	-20°C**
Recombinant HBc Antigen	mg/custom size*	3000-5102	-20°C**

\*For large quantities, packaging available upon request - minimum size 5 mg/vial. \*\*Avoid repeated freezing and thawing.

### Specifications

<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	PBS, pH 7.4
<b>Purification Method</b>	Ultracentrifugation
<b>Protein Concentration</b>	0.20 - 1.00 mg/mL (Lowry Method)
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Recombinant HBsAg ay	mg/custom size	3000-7069	-20°C**

\*These products are in R&D Stage and are for "Investigation / Research Use Only". The information contained in this catalogue is for informational purposes. Contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com) for further technical information and product availability.

### Specifications

<b>Source</b>	CHO Cells
<b>Storage Buffer</b>	Phosphate Buffer , Sodium Chloride
<b>Purification Method</b>	Immunoaffinity
<b>Protein Concentration</b>	0.5 to 2.0 mg/mL
<b>Preservative</b>	No Preservative added

# Hepatitis C

The following products have been tested in the following applications. This information derives from use in commercial diagnostic assays and/or testing within our laboratories.

Hepatitis C	Chemiluminescence	ELISA	Turbidimetry	Rapid Test
<b>Recombinant Antigens</b>				
Recombinant HCV Capsid Polypeptide	●	●		
Recombinant HCV NS3 Polypeptide	●	●		

Other uses may be applicable depending on customer use. For further technical information or requests please contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com).

## Recombinant Antigens

Product Description	Presentation	Reference	Storage
Recombinant HCV Capsid Polypeptide	mg/custom size*	3000-5103	-70°C**
Recombinant HCV Capsid Polypeptide	1mg/vial	3000-5314	-70°C**

\*For large quantities, packaging available upon request - minimum size 1 mg/vial. \*\*Avoid repeated freezing and thawing.

### Specifications

<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	Acetate, NaCl, pH 5.5
<b>Purification Method</b>	Ion Exchange Chromatography
<b>Protein Concentration</b>	0.50 - 2.00 mg/mL [ $A_{280}$ ]
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Recombinant HCV NS3 Polypeptide	mg/custom size*	3000-5104	-70°C**
Recombinant HCV NS3 Polypeptide	1mg/vial	3000-5105	-70°C**

\*For large quantities, packaging available upon request - minimum size 1 mg/vial. \*\*Avoid repeated freezing and thawing.

### Specifications

<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	Tris-HCl, NaCl, pH 8.6
<b>Purification Method</b>	Affinity Chromatography
<b>Protein Concentration</b>	0.50 - 2.00 mg/mL [ $A_{280}$ ]
<b>Preservative</b>	No Preservative Added

# Syphilis

The following products have been tested in the following applications. This information derives from use in commercial diagnostic assays and/or testing within our laboratories.

Syphilis	Chemiluminescence	ELISA	Turbidimetry	Rapid Test
<b>Recombinant Antigens</b>				
Recombinant p15 (II) <i>Treponema pallidum</i> Ag	●	●		
Recombinant p17 <i>Treponema pallidum</i> Ag	●	●		
Recombinant p47 <i>Treponema pallidum</i> Ag	●	●		
Recombinant H-p17 <i>Treponema pallidum</i> Ag	●	●		
Recombinant H-p47 <i>Treponema pallidum</i> Ag	●	●		

Other uses may be applicable depending on customer needs. For further technical information or requests please contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com).

## Recombinant Antigens

Product Description	Presentation	Reference	Storage
Recombinant p15 (II) <i>Treponema pallidum</i> Ag	mg/custom size*	3000-5289	-70°C**
Recombinant p15 (II) <i>Treponema pallidum</i> Ag	1mg/vial	3000-5306	-70°C**

\*For large quantities, packaging available upon request - minimum size 1 mg/vial. \*\*Avoid repeated freezing and thawing.

### Specifications

<b>Tag</b>	GST
<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	Tris-HCl, NaCl, pH 8.0
<b>Purification Method</b>	Affinity Chromatography
<b>Protein Concentration</b>	3.00 - 7.00 mg/mL [ $A_{280} \times 0.74$ ]
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Recombinant p17 <i>Treponema pallidum</i> Ag	mg/custom size*	3000-5280	-70°C**
Recombinant p17 <i>Treponema pallidum</i> Ag	2mg/vial	3000-5305	-70°C**

\*For large quantities, packaging available upon request - minimum size 2 mg/vial. \*\*Avoid repeated freezing and thawing.

### Specifications

<b>Tag</b>	GST
<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	Tris-HCl, NaCl, pH 8.0
<b>Purification Method</b>	Affinity Chromatography
<b>Protein Concentration</b>	8.00 - 12.00 mg/mL [ $A_{280} \times 0.78$ ]
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Recombinant p47 <i>Treponema pallidum</i> Ag	mg/custom size*	3000-5284	-70°C**
Recombinant p47 <i>Treponema pallidum</i> Ag	1mg/vial	3000-5307	-70°C**

\*For large quantities, packaging available upon request - minimum size 1 mg/vial. \*\*Avoid repeated freezing and thawing.

### Specifications

<b>Tag</b>	GST
<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	Tris-HCl, NaCl, pH 8.0
<b>Purification Method</b>	Affinity Chromatography
<b>Protein Concentration</b>	4.00 - 6.00 mg/mL [ $A_{280} \times 0.8$ ]
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Recombinant H-p17 <i>Treponema pallidum</i> Ag	mg/custom size*	3000-5254	-70°C**
Recombinant H-p17 <i>Treponema pallidum</i> Ag	1mg/vial	3000-5308	-70°C**

\*For large quantities, packaging available upon request - minimum size 1 mg/vial. \*\*Avoid repeated freezing and thawing.

## Specifications

<b>Tag</b>	HIS
<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	Tris-HCl, NaCl, pH 8.0
<b>Purification Method</b>	Metal Affinity Chromatography
<b>Protein Concentration</b>	2.00 - 5.00 mg/mL [ $A_{280} \times 1.38$ ]
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Recombinant H-p47 <i>Treponema pallidum</i> Ag	mg/custom size*	3000-5263	-70°C**
Recombinant H-p47 <i>Treponema pallidum</i> Ag	1mg/vial	3000-5309	-70°C**

\*For large quantities, packaging available upon request - minimum size 1 mg/vial. \*\*Avoid repeated freezing and thawing.

## Specifications

<b>Tag</b>	HIS
<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	Tris-HCl, NaCl, pH 8.0
<b>Purification Method</b>	Metal Affinity Chromatography
<b>Protein Concentration</b>	2.00 - 5.00 mg/mL [ $A_{280} \times 0.91$ ]
<b>Preservative</b>	No Preservative Added

# Herpes

The following products have been reported to work in the following applications. This information derives from use in commercial diagnostic assays and/or testing within our laboratories.

Herpes	Chemiluminescence	ELISA	Turbidimetry	Rapid Test
<b>Recombinant Antigens</b>				
Recombinant gG1 Protein HSV-1	●	●		
Recombinant gG2 Protein HSV-2	●	●		

Other uses may be applicable depending on customer needs. For further technical information or requests please contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com).

## Recombinant Antigens

Product Description	Presentation	Reference	Storage
Recombinant gG1 Protein HSV-1*	0.5 mg/vial	3000-5288	-70°C**
Recombinant gG1 Protein HSV-1*	mg/custom size*	3000-5279	-70°C**

\*For large quantities, packaging available upon request - minimum size 5 mg/vial. \*\*Avoid repeated freezing and thawing.

#This product is manufactured using CrisBio™ technology from ALGENEX S.L.

### Specifications

<b>Source</b>	<i>Trichoplusia ni</i> .
<b>Storage Buffer</b>	HEPES, NaCl, pH 7.5
<b>Purification Method</b>	Ion Exchange and Affinity Chromatography
<b>Protein Concentration</b>	0.50 - 2.00 mg/mL [ $A_{280} \times 6.95$ ]
<b>Preservative</b>	No Preservative Added

Product Description	Presentation	Reference	Storage
Recombinant gG2 Protein HSV-2*	0.5 mg/vial	3000-5282	-70°C**
Recombinant gG2 Protein HSV-2*	mg/custom size*	3000-5283	-70°C**

\*For large quantities, packaging available upon request - minimum size 5 mg/vial. \*\*Avoid repeated freezing and thawing.

#This product is manufactured using CrisBio™ technology from ALGENEX S.L.

### Specifications

<b>Source</b>	<i>Trichoplusia ni</i> .
<b>Storage Buffer</b>	HEPES, NaCl, pH 8.2
<b>Purification Method</b>	Ion Exchange and Affinity Chromatography
<b>Protein Concentration</b>	0.80 - 1.50 mg/mL [ $A_{280} \times 5.45$ ]
<b>Preservative</b>	No Preservative Added

# Chagas

The following products have been tested in the following applications. This information derives from use in commercial diagnostic assays and/or testing within our laboratories.

Chagas		Chemiluminescence	ELISA	Turbidimetry	Rapid Test
<b>Recombinant Antigens</b>					
Recombinant TcF Antigen		●			

Other uses may be applicable depending on customer needs. For further technical information or requests please contact [Immunoassay@werfen.com](mailto:Immunoassay@werfen.com).

## Recombinant Antigens

Product Description	Presentation	Reference	Storage
Recombinant TcF Ag	mg/custom size*	3000-5321	-70°C**
Recombinant TcF Ag	4mg/vial	3000-5322	-70°C**

\*For large quantities, packaging available upon request - minimum size 1 mg/vial. \*\*Avoid repeated freezing and thawing.

### Details

<b>Source</b>	<i>Escherichia coli</i>
<b>Storage Buffer</b>	Tris, NaCL, pH 8.0
<b>Purification Method</b>	Chromatography
<b>Protein Concentration</b>	1.00 - 4.00 mg/mL [BCA method]
<b>Preservative</b>	No Preservative Added



# Powering Patient Care

**werfen**

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