



# PharmaGenie Bioprocess ELISA Kits



Host Cell Proteins (HCPs)  
&  
Process Impurity Testing

Cell & Gene Therapy | Biologics & Biosimilars | Vaccines

## THE MISSION

Our mission is to make scientists smile through innovative products, remarkable interactions with our team and our little Genies!



**COLM RYAN PhD**  
CEO & co-founder of  
Assay Genie



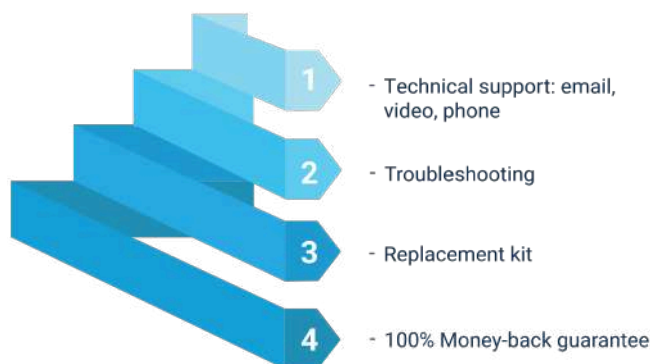
**SEÁN MAC FHEARRAIGH  
PhD** CTO & co-founder of  
Assay Genie

## Maximum Support & Guidance

Assay Genie provides excellence in support to all our customers!

Not only do we provide you with application based support before, during and after your experiments, but on those rare occasions when problems arise, we have a defined series of customer-centric steps to ensure that you are happy with our products.

So, don't worry, we also offer a 100% money-back guarantee should our products not perform as specified.



## Rapid Global Delivery

Whether you are served by one of our trusted local distributors or are part of our direct sales network, we endeavour to ship your products to you on-time, every time!

Contact us 24/7 on [www.info@assaygenie.com](mailto:www.info@assaygenie.com) to find our shipping times to your laboratory.



# PharmaGenie Bioprocess ELISA Kits

## Regulations & Guidelines

At Assay Genie, we are committed to providing high-quality ELISA kits and reagents that meet stringent regulatory and industry standards. Our products are designed for research and quality control applications in cell therapy, vaccine development and biosimilars development. Bioprocess PharmaGenie ELISA Kits are for research use only (RUO).



**ISO Quality** | Manufactured under ISO 13485:2016 quality management systems



**NIBSC/WHO (90/636) Calibration** | Reference standards supporting alignment with internationally recognized measurement and quantitation guidelines



**Pharmacopeia verification** | Including specificity, accuracy, precision, linearity, LOQ, LOD, durability, and stability assessments



**Applications** | Research use only (RUO); optimized for cell therapy, vaccine development, and biosimilar quality control



**Regulatory Guidelines** | Supports characterization of critical quality attributes (CQAs) in bioprocess and analytical workflows aligned with FDA (21 CFR 210/211), EMA, and ICH requirements

# Product Guide

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HEK293T HCP PharmaGenie ELISA Detection Kit

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# 01 Host Cell Proteins



E.coli HCP PharmaGenie ELISA Kit

HEK293T HCP PharmaGenie ELISA Detection Kit



# E.coli HCP PharmaGenie ELISA Kit

## Overview

**SKU: AEGE00001**

This kit enables the quantitative measurement of host cell proteins (HCPs) in biopharmaceuticals produced in Escherichia coli using a sandwich ELISA format.

**Applications:** Biopharmaceutical development, process optimization, and quality control to quantify residual E. coli host cell proteins during recombinant protein production.

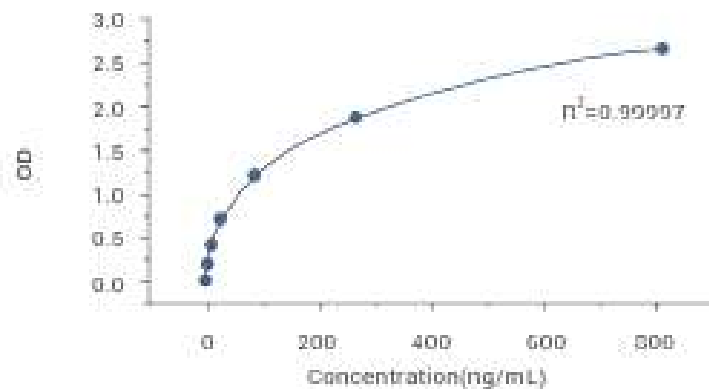
## Specification

**Assay range:** 3.3-810ng/mL

**Limit of quantitation:** 3.3ng/mL

**Precision:** CV% $\leq$ 10%, RE% $\leq$  $\pm$ 15%

## Standard curve



## Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
810	2.659	2.658	2.659
270	1.902	1.908	1.905
90	1.213	1.194	1.204
30	0.720	0.723	0.722
10	0.408	0.41	0.409
3.3	0.228	0.231	0.230
0	0.047	0.050	0.049

# HEK293T HCP PharmaGenie ELISA Detection Kit

## Overview

SKU: AEGE00003

This kit is designed for the quantitative measurement of HCP (host cell protein) content in biopharmaceuticals expressed in 293T cells by using a sandwich ELISA format.

**Applications:** Biopharmaceutical development, viral vector production, recombinant protein expression, and bioprocess monitoring in HEK293T systems.

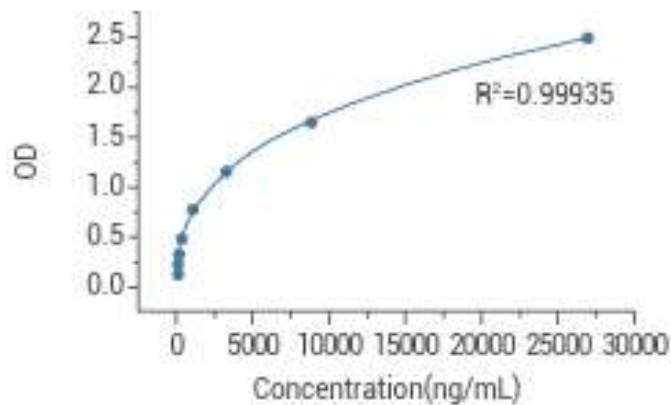
## Specification

**Assay range:** 37-27000 ng/mL

**Limit of quantitation:** 37ng/mL

**Precision:** CV% ≤ 10%, RE% ≤ ±15%

## Standard curve



## Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
27000	2.507	2.494	2.5005
9000	1.618	1.625	1.6215
3000	1.176	1.181	1.1785
1000	0.773	0.77	0.7715
333	0.496	0.475	0.4855
111	0.289	0.285	0.287
37	0.205	0.195	0.2
0	0.14	0.137	0.1385

# 02 Residual Contaminants

Benzonase Nuclease PharmaGenie ELISA Kit

BSA Residual Contamination PharmaGenie ELISA Kit

HIV-1 p24 Residual Contamination PharmaGenie ELISA Kit

T7 RNA Polymerase PharmaGenie ELISA Kit

dsRNA Residual Contamination PharmaGenie ELISA Kit



# Benzonase Nuclease PharmaGenie ELISA Kit

## Overview

**SKU: AEGE00004**

This kit is designed for the quantitative measurement of residual nuclease in intermediates, semi-finished products, and final biological products using a sandwich ELISA format.

**Applications:** Biopharmaceutical manufacturing, viral vector and vaccine production, downstream purification monitoring, and process impurity testing.

## Specification

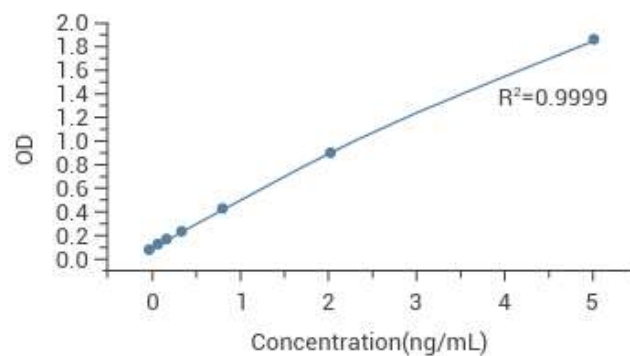
**Assay range:** 0.05-5ng/mL

**Limit of quantitation:** 0.05ng/mL

**Limit of detection:** 0.05ng/mL

**Precision:** CV%  $\leq$  10%, RE%  $\leq$   $\pm$ 15%

## Standard curve



## Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
5	1.925	1.774	1.849
2	0.917	0.865	0.891
0.8	0.447	0.441	0.444
0.32	0.228	0.209	0.218
0.128	0.146	0.137	0.141
0.0512	0.114	0.107	0.110
0	0.090	0.091	0.091

# BSA Residual Contamination PharmaGenie ELISA Kit

## Overview

**SKU: AEGE00005**

This kit is designed for the quantitative measurement of residual BSA in intermediates, semi-finished products, and final biological products using a sandwich ELISA format.

**Application:** Biopharmaceutical development, cell culture and recombinant protein production, downstream purification monitoring, and process impurity quality control.

## Specification

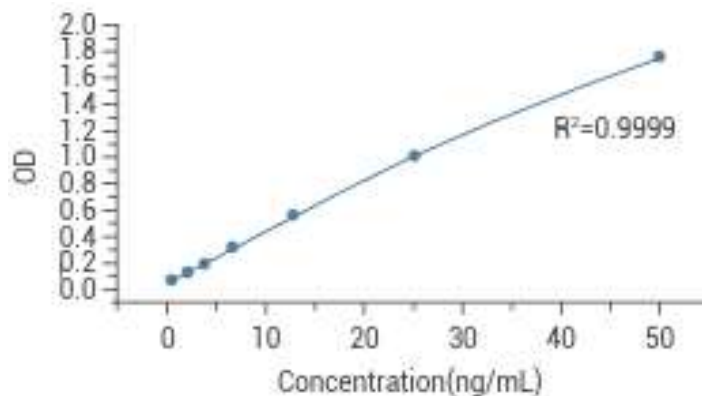
**Assay range:** 1.56-50 ng/mL

**Limit of quantitation:** 1.56 ng/mL

**Limit of detection:** 0.5ng/mL

**Precision:** CV% ≤ 10%, RE% ≤ ±15%

## Standard curve



## Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
50	1.775	1.803	1.789
25	1.091	0.995	1.043
12.5	0.571	0.591	0.581
6.25	0.324	0.308	0.316
3.125	0.193	0.179	0.186
1.56	0.132	0.127	0.130
0	0.072	0.088	0.080

# HIV-1 p24 Residual Contamination PharmaGenie ELISA Kit

## Overview

**SKU: AEGE0008**

This kit utilizes a sandwich ELISA format for the quantitative measurement of HIV-1 p24 antigen in biological samples.

**Applications:** Viral safety testing, viral clearance validation, and quality control in biopharmaceutical manufacturing

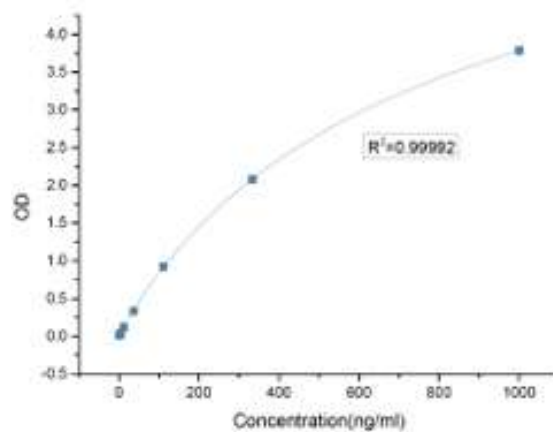
### Specification

**Assay range:** 1.37-1000 ng/mL

**Detection sensitivity:** 0.35 ng/mL

**Precision:** CV% ≤ 10%, RE% ≤ ±15%

### Standard curve



### Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
1000.00	3.8020	3.7780	3.790
333.33	2.1020	2.0660	2.084
111.11	0.9526	0.9072	0.930
37.04	0.3212	0.3512	0.336
12.35	0.1222	0.1243	0.123
4.12	0.0403	0.0459	0.043
1.37	0.0174	0.0177	0.018
0.00	0.0059	0.0058	0.006

# T7 RNA Polymerase PharmaGenie ELISA Kit

## Overview

SKU: AEGE00011

This kit is designed for the quantitative measurement of residual T7 RNA polymerase used in RNA pharmaceutical production processes, utilizing a sandwich ELISA format.

**Applications:** mRNA vaccine development, in vitro transcription workflows, recombinant protein expression, and bioprocess impurity monitoring.

## Specification

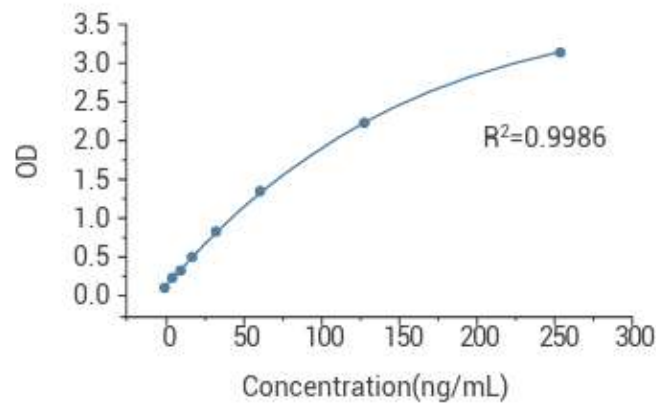
**Assay range:** 4-256 ng/mL

**Limit of quantitation:** 4 ng/mL

**Limit of detection:** 2 ng/mL

**Precision:** CV% ≤ 10%, RE% ≤ ±15%

## Standard curve



## Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
50	1.775	1.803	1.789
25	1.091	0.995	1.043
12.5	0.571	0.591	0.581
6.25	0.324	0.308	0.316
3.125	0.193	0.179	0.186
1.56	0.132	0.127	0.130
0	0.072	0.088	0.080

# dsRNA Residual Contamination PharmaGenie ELISA Kit

## Overview

**SKU: AEGE00012**

The dsRNA Residual Contamination PharmaGenie ELISA Kit uses a sandwich ELISA format to quantitatively measure double-stranded RNA (dsRNA) in samples.

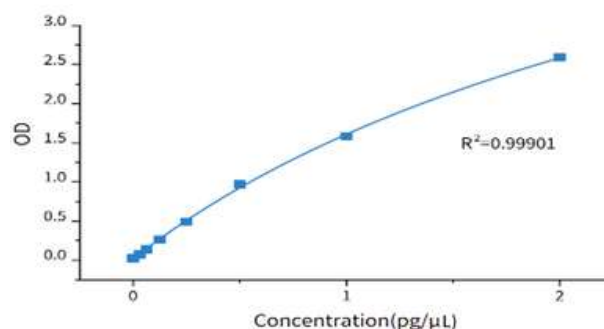
**Applications:** mRNA vaccine development, RNA therapeutics manufacturing, in vitro transcription workflows, and nucleic acid impurity monitoring.

## Specification

Standard type	Assay range (pg/ $\mu$ L)	Limit of quantitation (pg/ $\mu$ L)	Limit of detection (pg/ $\mu$ L)	Recovery rate	CV%
No modification	0.0156-0.5	0.0156	0.001	80-120%	$\leq 10\%$
N1-Me-pUTP modified	0.0312-1	0.0312	0.001	80-120%	$\leq 10\%$
pUTP modified	0.0156-0.5	0.0156	0.001	80-120%	$\leq 10\%$
5-OMe-UTP modified	0.0625-1	0.0625	0.01	80-120%	$\leq 10\%$

\*Range of linearity: Coefficient of determination  $> 0.99$

## Standard curve



## Datasheet

Concentration of standard (pg/ $\mu$ L)	OD value1	OD value2	Mean value
2	2.8412	2.7362	2.7887
1	1.8725	1.9135	1.8930
0.5	1.0863	1.1207	1.1035
0.25	0.623	0.6055	0.6143
0.125	0.3388	0.3292	0.3340
0.0625	0.1947	0.1885	0.1916
0.0312	0.1192	0.1247	0.1220
0	0.0567	0.0518	0.0543

# 03 Lentivirus



Lentivirus Titer p24 PharmaGenie ELISA Kit



# Lentivirus Titer p24 PharmaGenie ELISA Kit

## Overview

SKU: AEGE00002

This assay utilizes a sandwich ELISA format for the sensitive detection of HIV-1 p24 protein in biological samples.

**Applications:** Gene therapy research, lentiviral vector production, viral vector quantification, and cell and gene therapy development.

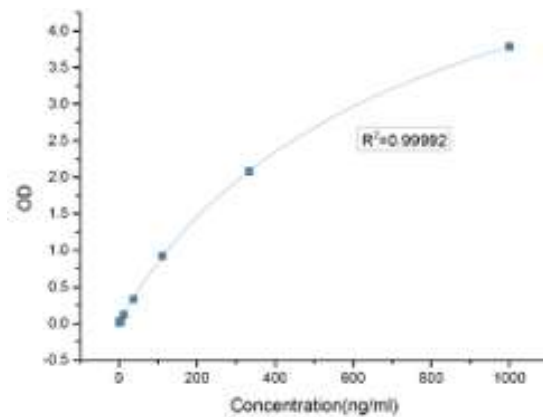
## Specification

**Assay range:** 1.37-1000 ng/mL

**Detection sensitivity:** 0.35 ng/mL

**Precision:** CV% ≤ 10%, RE% ≤ ±15%

## Standard curve



## Datasheet

Concentration of standard (ng/mL)	OD value1	OD value2	Mean value
1000.00	3.8020	3.7780	3.790
333.33	2.1020	2.0660	2.084
111.11	0.9526	0.9072	0.930
37.04	0.3212	0.3512	0.336
12.35	0.1222	0.1243	0.123
4.12	0.0403	0.0459	0.043
1.37	0.0174	0.0177	0.018
0.00	0.0059	0.0058	0.006

# 04 Cellular Markers & Cytokines



Cytokine Multiplex PharmaGenie ELISA Kit



# Cytokine Multiplex PharmaGenie ELISA Kit

## Overview

**SKU: AEGE00007**

The kit is an ELISA kit for the semi-quantification of Human CAR-T / CRS (Cytokine Release Syndrome) Cytokine (IL2, IL6, IL10, IFN gamma) in serum, plasma and cell culture supernatants.

**Applications:** Cell culture optimization, process development, and cytokine profiling in biomanufacturing workflows

## Specification

### Assay range:

**IL2:** 15.625-500 pg/mL

**IL6:** 31.25-1000 pg/mL

**IL10:** 15.625-500 pg/mL

**IFN- $\gamma$ :** 15.625-500 pg/mL

### Limit of quantitation:

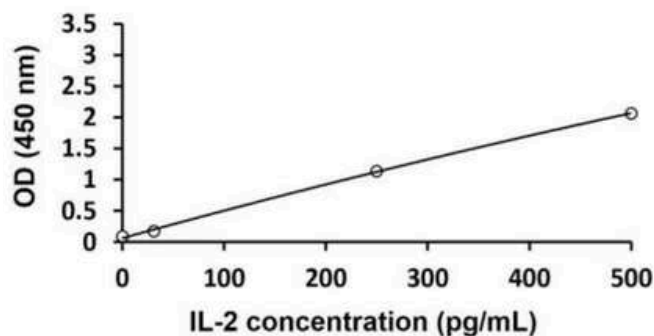
**IL2:** 15.625 pg/mL

**IL6:** 31.25 pg/mL

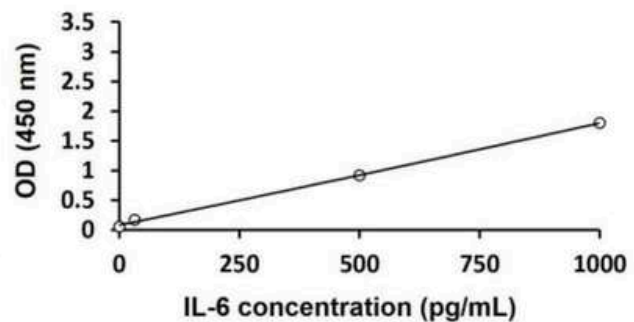
**IL10:** 15.625 pg/mL

**IFN- $\gamma$ :** 15.625 pg/mL

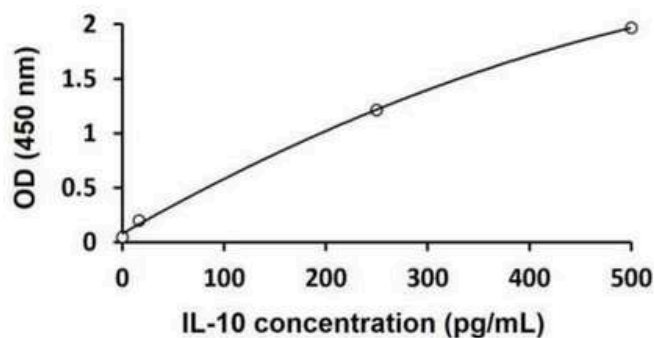
## Standard curve



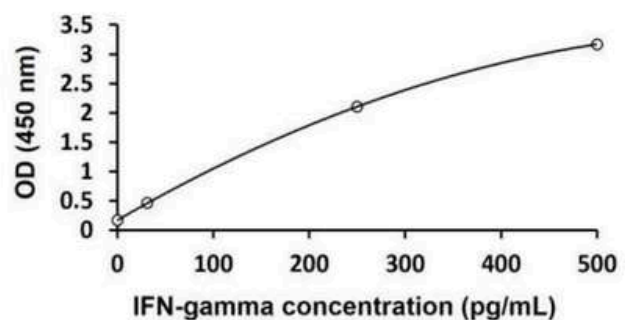
Example of Human IL-2 standard curve



Example of Human IL-6 standard curve



Example of Human IL-10 standard curve



Example of Human IFN-gamma standard curve

## PharmaGenie Bioprocess ELISA Kits

Codes	Product Names	Size	Sample Type
AEGE00001	E.coli HCP PharmaGenie ELISA Kit	96T	E.coli engineered cells
AEGE00002	Lentivirus Titer p24 PharmaGenie ELISA Kit	96T	CHO, E. coli, Vero cell cultures
AEGE00003	HEK293T HCP PharmaGenie ELISA Detection Kit	96T	293T cell cultures
AEGE00004	Benzonase Nuclease PharmaGenie ELISA Kit	96T	Biological samples
AEGE00005	BSA Residual Contamination PharmaGenie ELISA Kit	96T	Serum, plasma & cell supernatants
AEGE00006	Trypsin Residual Contamination PharmaGenie ELISA Kit	96T	Serum, plasma & cell supernatants
AEGE00007	Cytokine Multiplex PharmaGenie ELISA Kit	96T	Serum, plasma & cell supernatants
AEGE00008	HIV-1 p24 Residual Contamination PharmaGenie ELISA Kit	96T	Biological samples
AEGE00009	DNase I Residual Contamination PharmaGenie ELISA Kit	96T	Biological samples
AEGE00010	RNase Inhibitor Residual Contamination PharmaGenie ELISA Kit	96T	Biological samples
AEGE00011	T7 RNA Polymerase PharmaGenie ELISA Kit	96T	Biological samples
AEGE00012	dsRNA Residual Contamination PharmaGenie ELISA Kit	96T	Biological samples

## Other Bioprocess ELISA Kits

Codes	Product Names	Size	Sample Type
AEKE03565	HCP (L.lactis Host Cell Proteins) ELISA Kit	96T	E.coli engineered cells supernatants
AEFI00401	HEK293 Host Cell Protein (HCP) ELISA Kit	96T	293T cell cultures
AEFI00494	VERO Host Cell Protein (HCP) ELISA Kit	96T	Biological samples
AEFI01007	Pseudomonas Exotoxin A ELISA Kit	96T	Serum, plasma & cell supernatants
AEFI01012	Ovalbumin (OVA) ELISA Kit	96T	Serum, plasma & cell supernatants
AEFI01016	FLAG-Tag (DYKDDDDK-Tag) ELISA Kit	96T	Serum, plasma & cell supernatants
AEFI01040	CHO Host Cell Protein (HCP) ELISA Kit	96T	CHO cell supernatants
AEFI01041	E.coli Host Cell Protein (HCP) ELISA Kit	96T	Serum, plasma & cell supernatants
AEFI03788	CHO HCPs (Chinese Hamster Ovary host cell proteins) ELISA Kit	96T	CHO cell supernatants
BOFI00128	BSA ELISA Kit	96T	Serum, plasma & cell supernatants
HUFI03402	Human Cell-Free DNA (cfDNA) Autoantibodies ELISA Kit	96T	Serum, plasma & cell supernatants
PRFI00229	Porcine Trypsin ELISA Kit	96T	Serum, plasma & cell supernatants
UNFI0091	Lipopolysaccharides (LPS) ELISA Kit	96T	Serum, plasma & cell supernatants
HDES0122	CHO HCP ELISA Kit	96T	CHO cell supernatants
HDES0124	Pichia HCP ELISA Kit	96T	Pichia cells supernatants

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Dublin, Ireland | London, UK