EXCELL BIO

Biological Product Quality
Safety and Risk Control



Quality Control Solutions for Biological Products

Characterization Reagents Product Brochure

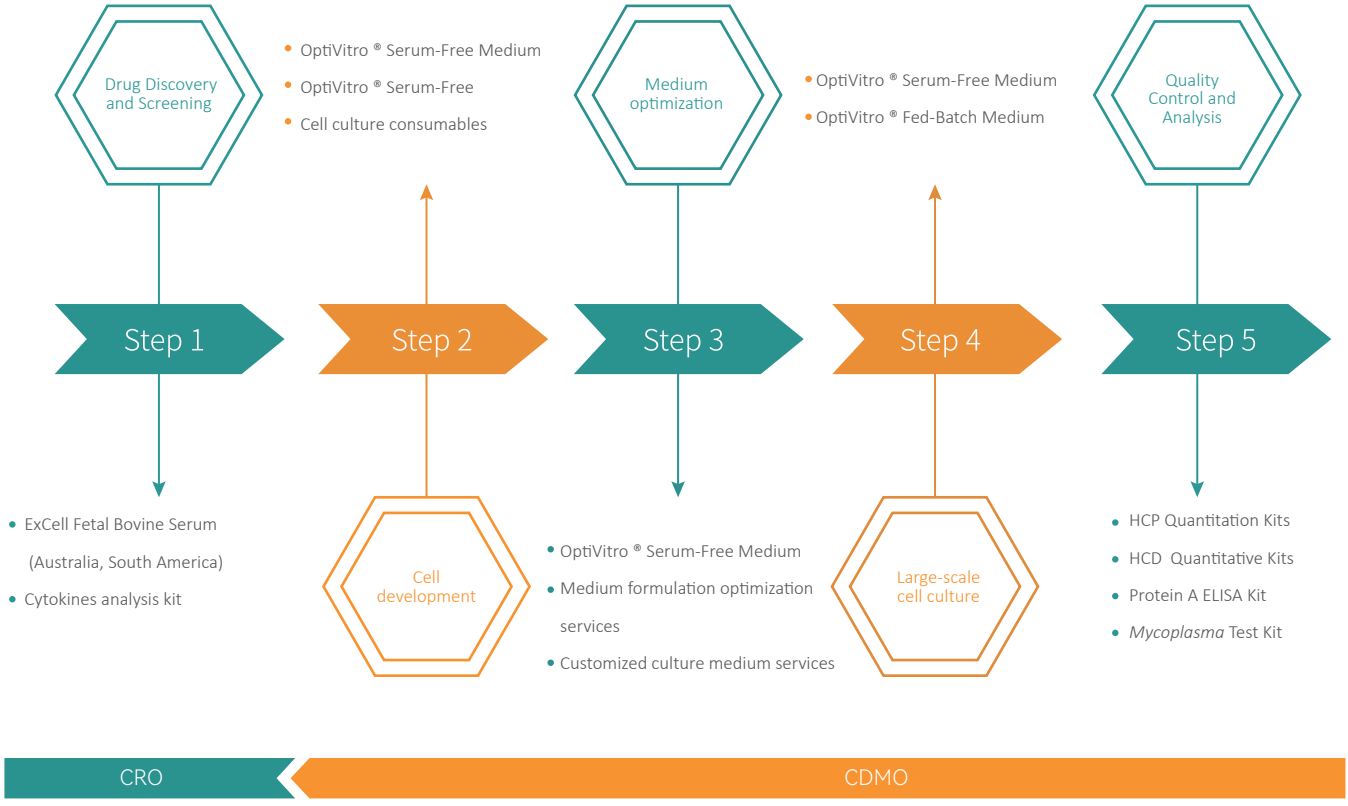
ExCell



ABOUT US

Founded in 2013, ExCell Bio, with the mission of "accelerating the application of life science and technology for the benefit of people's health". At present, the company focuses on three major product sectors, namely, serum-free culture medium, fetal bovine serum and identification reagents, to provide international quality products and services for customers of biopharmaceuticals, cell and gene therapy, and basic scientific research.Relying on the international and professional R & D technical team, quality and production team and commercialization team, the company continues to innovate, pursue excellence, continuously optimize product performance, ensure reliable quality and stable supply, fully enable the rapid and healthy development of the biomedical industry.

EXCELL BIO PROVIDES ONE-STOP SERVICE FOR BIOPHARMACEUTICALS





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Host Cell Protein Quantitation

ResiQuant ® HCP Quantitation Kit

ResiQuant® HCP Quantitative Kit is used for quantltative detection of host cell protein impurities in the biologicals produced with CHO、*E.coli* or HEK293 cell line etc as host cells, so as to fullfil the quanlity control of HCP impurities.

Product Performance

Methodological performance		CHO HCP ELISA kit	E. *Coli* HCP ELISA kit	HEK 293 HCP ELISA kit
Linearity	Quantitative range	1.0~250 ng/mL	1.0~250 ng/mL	10.2~1000 ng/mL
	(Four-parameter fit) R2	> 0.99	> 0.99	> 0.99
Accuracy	Relative Deviation	RSD≤20%	RSD≤20%	RSD≤20%
Recovery rate	recovery rate	70%~130%	70%~130%	70%~130%
Precision	Inter-batch	CV≤15%	CV≤15%	CV≤20%
	Inter-batch	CV≤20%	CV≤20%	CV≤25%
Specificity		No cross-reaction to 1 μg/mL HEK 293T, E. Coli, Vero and other host proteins.	No cross-reaction to 1 μ g/mL CHO, HEK 293, Vero HCP	No cross-reaction to1 μg/mL CHO, E. Coli, the detection value of Vero HCP
Matrix effects		5mg/mL human IgG without interference	No interference with 2.5 × TE buffer	1 mg/mL, 5 mg/mL HSA (plant source) did not interfere
LLOQ		1.0 ng/mL	1.0 ng/mL	10.2 ng/mL
ULOQ		250 ng/mL	250 ng/mL	1000 ng/mL
Robustness	Instrument suitability	MD SpectraMax i3x/BioTek ELx800/Thermo Fish Multiskan TM SkyHigh		
Expiration		Stored at 2-8 ℃ for 12 months		

Product Features

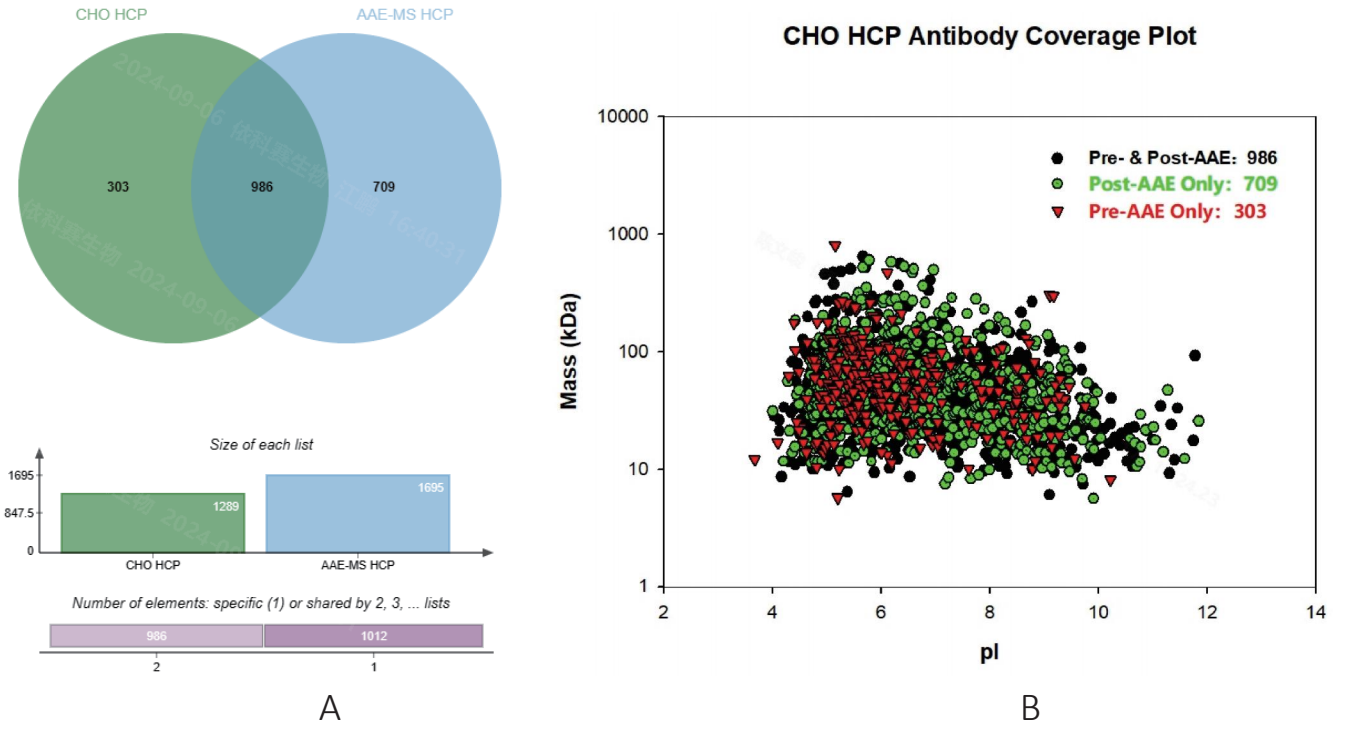
Excellent performance

Sample	OD			Back-calculating concentration (ng/mL)			Recovery rate
	OD1	OD2	Mean	1	2	Mean	
TS1	1.375	1.340	1.358	29.1	27.8	28.5	/
TS1 Spiked(32.5 ng/mL)	1.887	1.881	1.884	55.4	54.9	55.2	80%
TS2	0.676	0.665	0.671	10.4	10.2	10.3	/
TS2 Spiked(11.1ng/mL)	1.158	1.101	1.130	22	20.4	21.2	98%
TS3	0.197	0.198	0.198	2.1	2.2	2.1	/
TS3 Spiked(3.7ng/mL)	0.390	0.385	0.388	5.2	5.2	5.2	83%

Recovery rate using CHO HCP ELISA kit

High Antibody Coverage

No less than 80% coverage rate of all HCP test antibodies



A B

Figure 1. Antibody coverage of ResiQuant® CHO HCP ELISA kit

A: CHO HCP pre-AAE and post-AAE Wayne chart

B: CHO HCP Virtual 2D-PAGE based on mass spectrometry identification (MW vs. pI)

Recognized High-risk Proteins

AAE-MS analysis revealed that the CHO HCP impurities captured by the corresponding antibodies included 69 widely existing host cell protein groups, among which 22 groups were identified as highly risk impurities.

Name	Impact	Type of Impact
Phospholipase B-like 2 (PLBL2)	Immunogenicity	immunogenic response
Glutathione-S-Transferase (GST)*	Immunogenicity	immunogenic response
Lipoprotein Lipase (LPL)	Formulation	degradation of polysorbates
Lysosomal Acid Lipase (LAL)	Formulation	degradation of polysorbates
Matrix Metalloproteinase (MMP)*	Drug Quality	degradation of drug
Peptidyl-prolyl cis-trans isomerase A (PPIA)	Drug Quality	aggregation of drugs
Peroxiredoxin (PRDX)*	Immunogenicity	immunogenic response
Cathepsins D	Drug Qaulity	fragmentation of Drug
Protein S100*	Immunogenicity	immunogenic response
Serine Protease (HTRA1)	Drug Qaulity	modification of drug
Protein disulfide isomerase (PDI)	Drug Qaulity	aggregation of drugs

High-risk HCPs recognized by the antibodies of CHO HCP ELISA kit (partially)

Product Information

Item No.	Product	Size
CRH00-3031/3032	ResiQuant® Ready-to-use CHO HCP ELISA Kit 2G	48T/96T
CRH00-3051/3052	ResiQuant® CHO HCP ELISA Kit -FAST	48T/96T
CRH00-3041/3042	ResiQuant® E.coli HCP ELISA Kit-Plasmid	48T/96T
CRH00-3061/3062	ResiQuant® HEK 293 HCP ELISA kit	48T/96T

Host Cell DNA Quantitation

ResiQuant® Universal DNA Residual Sample Pretreatment Kit

ResiQuant® Universal DNA Residual Sample Pretreatment kit is used to extract residual host cell DNA from biopharmaceutical raw materials, finished products, semi-finished products and intermediates products generated by different cell lines such as CHO, E.coli, Human, Vero, Pichia, NS0 and MDCK etc.

The pretreatment kit uses chemical lysis and magnetic beads to extract residual DNA fragments from different types of samples, including samples with extremely high protein concentration.

Product Features

- Good compatibility: compatible with other residual DNA detection kits;
- Magnetic bead extraction: meet high-throughput requirements;
- High recovery rate: the sample recovery rate reaches 70-130%;

Recovery rate analysis of simulated samples

Simulated samples		Spike concentration (fg/uL)	Sample determination mean(fg/uL)	CV (%)	Recovery Rate(%)
DLB(NEG)	high	150000	121233	3%	81%
	medium	1500	1379	6%	92%
	low	15	16	10%	105%
Matrix: BSA (10mg/mL)	high	150000	145733	3%	97%
	medium	1500	1696	7%	113%
	low	15	18	4%	117%
Matrix: BSA (100mg/mL)	high	150000	119800	11%	80%
	medium	1500	1045	11%	70%
	low	15	13	8%	91%

Product Information

Item No.	Product	Size
CRB00-0011/0012	ResiQuant® Universal DNA Residual Sample Pretreatment Kit	50 T/100 T

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ResiQuant ® DNA Quantitative Kit

ResiQuant® DNA Quantitative Kit can quickly detect the residual host cell DNA in the intermediate products, semi-finished products and finished products of various biological products and pharmaceuticals.

(Recommended to use with ResiQuant® Universal DNA Residual Sample Pretreatment kit)*

Product Performance

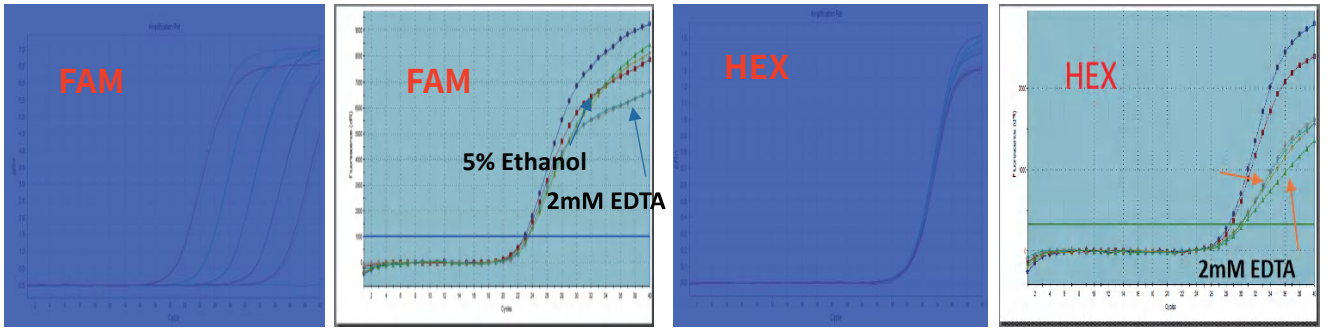
Methodological performance		CHO	*E.coli*	Vero	HEK293
Linearity	Quantitative range	3fg/μL~300pg/μL	30fg/μL~300pg/μL	3fg/μL~300pg/μL	30fg/μL~300pg/μL
	R^2	> 0.99	> 0.99	> 0.99	> 0.99
	Amplification efficiency	90%~110%	90%~110%	90%~110%	90%~110%
Accuracy	Deviation	CV≤15%	CV≤15%	CV≤15%	CV≤15%
Recovery rate		70%~130%	70%~130%	70%~130%	70%~130%
Precision	Repeatability	CV≤15%	CV≤15%	CV≤15%	CV≤15%
	Intermediate precision	CV≤15%	CV≤30%	CV≤30%	CV≤30%
Specificity		No cross-react to other DNA			

Product Features

- Ready-to-use: Ready-to-use of calibrator needs no more run to run calibrator preparation and improves the assay stability;
- High accuracy: DNA calibrators have a complete traceability chain, traceable to national standards;
- Exclusive: specific detection of residual DNA in host cells;
- High precision: high intra-batch repeatability;
- Anti-interference: *UNG System* can effectively remove residual pollution of PCR products;

  Internal Control (IC) improves the assay quality by helping indentification of PCR inhibition possibly introduced by sample preparation.

IC: improve the assay reliablity by ruling out the possible PCR inhibition introduced by the sample



qPCR Standard Curve

Well	Well Name	Dye	Ct (dR)	ΔCt
A1	control	FAM	22.9	-
B1	control	FAM	23.1	
C1	5% Ethanol	FAM	23.3	0.2-0.6
D1	5% Ethanol	FAM	23.5	
C4	2mM EDTA	FAM	23.5	0.4-0.7
D4	2mM EDTA	FAM	23.6	

Well	Well Name	Dye	Ct (dR)	ΔCt
A1	control	HEX	28.3	-
B1	control	HEX	28.7	
C1	5% Ethanol	HEX	30.3	1.2-2.0
D1	5% Ethanol	HEX	29.9	
C4	2 mM EDTA	HEX	29.9	1.2-1.7
D4	2 mM EDTA	HEX	30.0	

* When |ΔCt|>1 at HEX channel, the reaction was not uniform or there was interference, it is recommended to redo the test

Product Information

Item No.	Product	Size
CRH00-1091/1092	ResiQuant® Ready-to-use Quantitative CHO DNA Kit(Taqman)	50 T/100 T
CRH00-1101/1102	ResiQuant® Ready-to-use Quantitative E.coli DNA Kit(Taqman)	50 T/100 T
CRH00-1081/1082	ResiQuant® Ready-to-use Quantitative HEK293 DNA Kit(Taqman)	50 T/100 T
CRH00-1031/1032	ResiQuant® Quantitative Vero DNA Kit(Taqman)	50 T/100 T

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Process-related impurities Quantitation

ResiQuant® Protein A ELISA Kit

In the production and purification process of antibody products, Protein A affinity chromatography is a common tool for separating and purifying antibodies, but Protein A leakage happens during the purification process, which will affect the purity and potency of the products.

ResiQuant® Protein A Elisa Kit utilizes sandwich ELISA two-step method, which can quickly detect the Protein A residue in the products or intermediates.

Product Performance

Performance		Recombinant protein A	Alkali-resistant protein A	Alkali-resistant protein A 2G
Quantitative range		41-10000 pg/mL	41-10000pg/mL	4.9-1200 pg/mL
Limit of Quantitation (LOQ)		41pg/mL（CV＜20%）	41pg/mL（CV＜20%）	4.9pg/mL（CV＜20%）
PRECISION	Intra-batch	CV≤20%	CV ≤ 20% (upper and lower limits of quantification ≤ 25%)	CV≤20%
	Inter-batch	CV≤25%	CV≤20%	CV≤20%
Recovery rate		70%~130%		

Product Features

- Easy to operate: use boiling water bath or dry bath to process samples;
- Less operating time: sample processing only takes 10 minutes, and detection experiment takes 2.5 hours;
- High sensitivity: the detection sensitivity of Alkali-Resistant Protein A ELISA Kit 2G is as low as 2.5 pg/mL;

  Recombinant Protein A Elisa kit is as low as 13.7 pg/mL;

Product Information

Item No.	Product	Size
CRP00-3011/3012	ResiQuant® Recobinant Protein A Elisa Kit	48 T/96 T
CRP00-3021/3022	ResiQuant® Alkali-Resistant Protein A ELISA Kit	48 T/96 T
CRP00-3031/3032	ResiQuant® Alkali-Resistant Protein A ELISA Kit 2G	48 T/96 T

Mycoplasma Test

ResiQuant® *Mycoplasma* DNA Isolation Kit
ResiQuant® *Mycoplasma* Detection Kit(Taqman)

ResiQuant® *Mycoplasma* DNA Isolation Kit and ResiQuant® *Mycoplasma* Detection Kit(Taqman) provide a one-stop solution for *mycoplasma* test. It is used for detection of *mycoplasma* contamination in master cell bank, working cell bank, virus seed lot and cell products.

Product Performance

validation	Approval standard	Result
Detection limit	Tested as positive for at least 23/24 10 CFU/mL mycoplasma-spiked CHO cell samples	PASS
Specificity	Negative to 9 EP specified bacterial and 4 species cell genomic DNA widely used industrial mammalian	PASS
The species of *mycoplasma*	Mollicutes species	174 species
Stability	10 CFU/mL *Mycoplasma* spiked samples can be detected after 15 times of Freeze-Thaw cycles	PASS
Instrument suitability	ABI7500/Bio-Rad CFX96/ LightCycler 480/qTOWER3G/QIAquant 96	PASS
Matrix	Cell sample (1E7 cells/mL); cell culture supernatant; serum ; serum-free medium ; cell cryopreservation solution;	PASS
Comparability	Equivalent to the official cell culture method	PASS

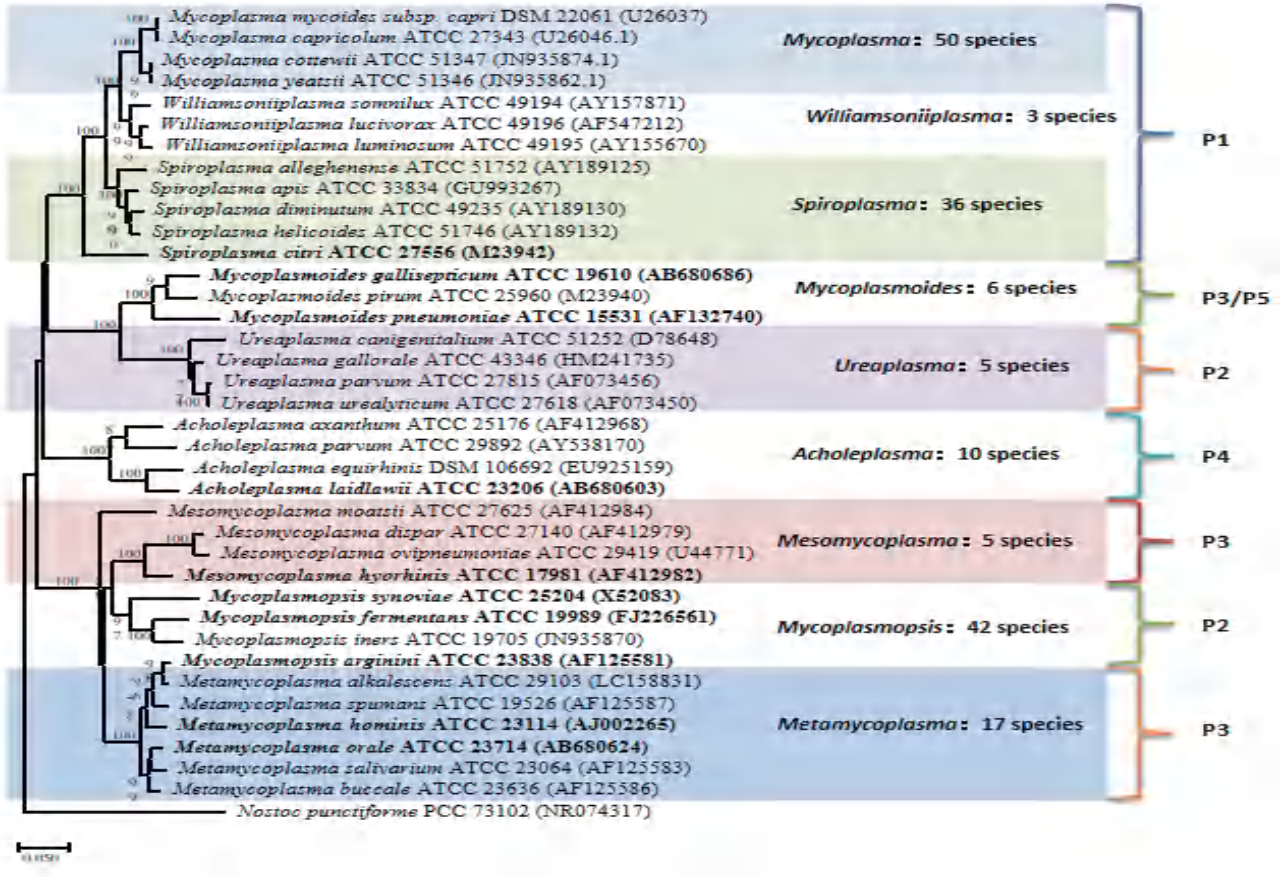
Product Features

- High sensitivity: Equivalent to the official cell culture method through parallel comparison and verification.
- Comply with Pharmacopoeia Regulations:

  Validation in accordance with European Pharmacopoeia EP 2.6.7 and Japanese Pharmacopoeia JP G3

▶ Wide Coverage:

174 species of mycoplasma from 9 genera of Phyllobacteriae could be detected with multiple probes.



▶ False Positive Control:

The touch-down qPCR technology is used to reduce non-specific amplification, and the UNG anti-contamination system is introduced, to effectively minimize false positive.

▶ False Negative Control:

A dual-channel detection method, including PC (positive control) and RC (recovery control), is used to monitor sample recovery and matrix interference to reduce the risk o false negative.

Product Information

Item No.	Product	Size
CRB00-0031/0032	ResiQuant® *Mycoplasma* DNA Isolation Kit	15T/30T
CRB00-1011/1012	ResiQuant® *Mycoplasma* Detection Kit(Taqman)	50T/100T

Cytokines Analysis Kits

ExCell Bio Elisa Kit

The ExCell Bio ELISA kits use sandwich method to detect macromolecular antigens including commonly used cytokines. The ELISA kit products have been used widely in academic and industrial reseaches for over 20 years, and gained good reputation in many well-known universities and research institutions.

Product Features

- Excellent performance:
  highly senstive as to pg/mL level;
  inter-batch deviation is small (CV≤10%);
- Wide applicability:
  suitable for samples like cultured medium,serum and properly prepared extracts etc.

Cytokines analysis kit

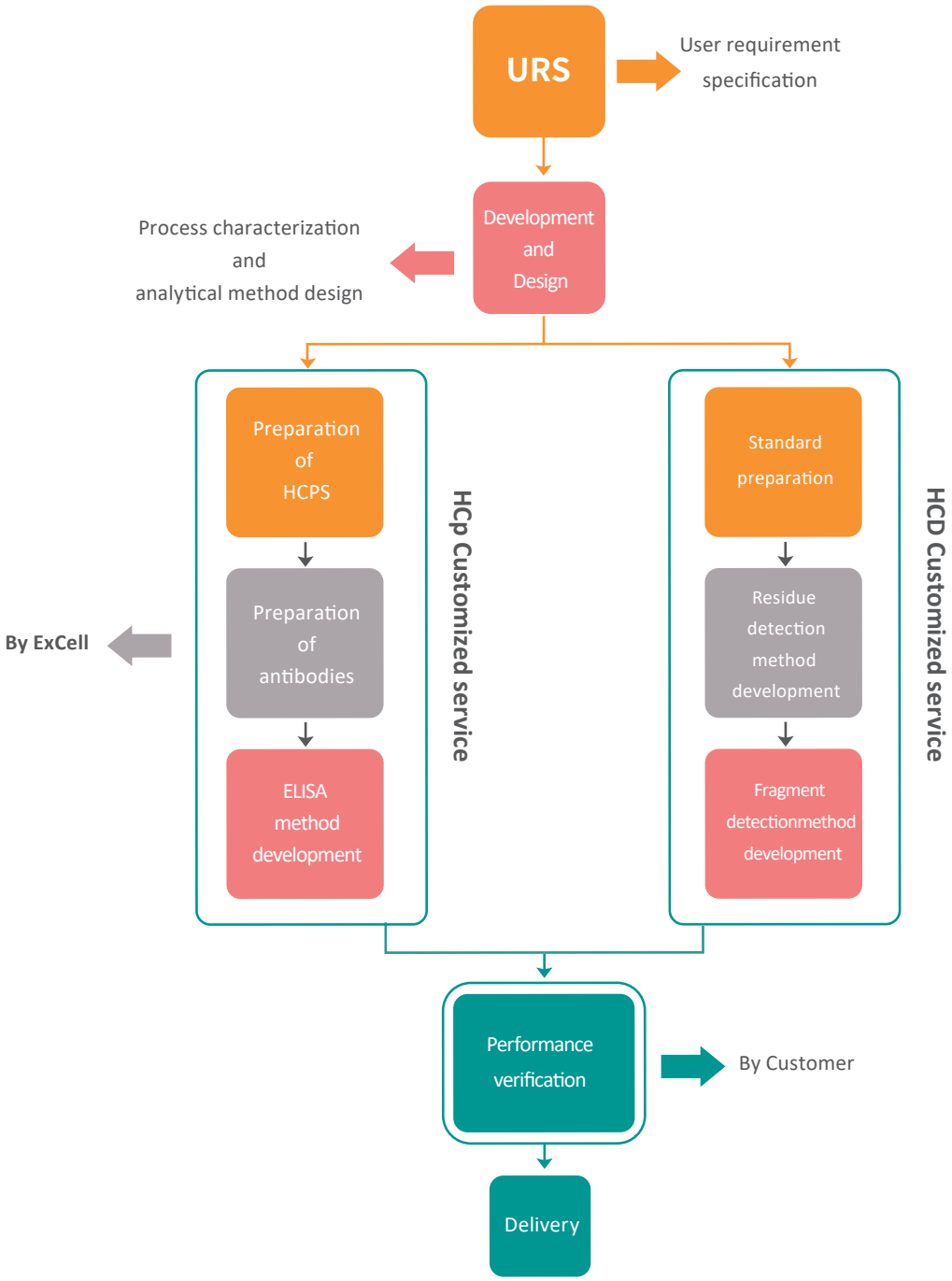
Species include Human, Mouse, Rat, etc., including factors for various disease research.

Tumor markers	Cardiovascular diseases related	Metabolic related	Diabetes related
G-CSF、DDK-1、FGF、HGF、IFN-γ、IL-10L、IL-12p70、IL-12/IL-23 p40、IL-13、IL-17、IL-18、IL-2、IL-4、IL-5、Leptin、MMP-2、MMP-3、MMP-9、TGF-β1、TMP-1	MCP-1、MIP1α、CCLS/Rantes、CRP、GMCSF、G-CSF、FGF、IL-1α、IL-1β、IFN-γ、IL-10、IL-15、IL-18、IL-2、IL-5、IL-6、IL8、TGF-β1、TNF-α、VEGF	Adiponectin、DDK -1、HGF、IL-1β、IL-6、Lipocalin-2/NGAL、Leptin、Restsin	Adiponectin、MCP-1、MIPIα、CRP、ICAM1、IFN-γ、.L-10、1L-1β、IL-6、IL-8、Insulin、Leptin、Resistin、TGF-β1、TNF-α
Rheumatoid arthritis related	**Growth and differentiation related**	**Inflammation related**	**Sepsis related**
IL-1β、IL-2、IL-4、IL-6、IL-7、IL-10、IL-12p70、IL-13、IL-15、IL-17、IL-18、TNF-α、TGF-β1、VEGF	MCP-1、G-CSF、IFN-γ、IL-10、IL-12p70、IL-13、IL-1β、IL-2、IL-23、IL-4、IL-6、IL-8、TNF-α	MCP-1、MIP1α、G-CSF、ICAM-1、IFN-γ、IL-10、IL-12p70、IL-13、IL-17、IL-1β、IL-23、IL-4、IL-6、IL-8、TNF-α	MCP-1、MIP1α、CRP、IL-10、IL-12p70、IL-1β、IL-4、IL-6、IL-8、TNF-α、VCAM-1

Customized service

ExCell Bio has professional R&D teams with rich experience in kit development, providing customized services for specific host cells and production processes. and creates exclusive kits for you for clinical declaration.

Customized Development Services



Antibody coverage testing service

AAE-LC-MS：

Antibody development → Br-agarose conjugated antibody IgG → Affinity Purified CHO HCP → LC-MS

- AAE can enrich and detect a variety of low concentration HCP
- The result of antigen detection is more accurate
- Combined with LC-MS to identify the HCP species in the sample, and provide protein content, molecular weight, isoelectric point and other information

Characteriazation Reagents

Regulatory Compliant, Robust Quality

- Compliance with regulations
- GMP-like quality Control
- Stable and Reliable

Professional R&D team and laboratory





ExCell

Empowering Cell Culture,
Advancing Excellent Innovation.

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