SHENTEK™

Biologics Quality Control Solutions

Kits & Instruments 2025

Premium Products, Consistent Quality.

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ABOUT US

Huzhou Shenke Biotechnology Co., Ltd. (HZSKBIO®), established in 2012, is a biotechnology company based in Huzhou and Shanghai cities, China. For more than 10 years, HZSKBIO® has successfully supported thousands of customers in the development and manufacturing of biologics. Our expertise encompasses the entire product cycle, including product design, development, launch, and application, to guarantee the delivery of high-quality QC products for clients.

HZSKBIO® focuses on the development and industrial standardization of key general analytical technologies for quality control solutions of biological products. HZSKBIO® provides products and related services that are of high quality and performance, for biopharmaceutical companies, CRO/CDMO, and research institutions. We comprise of R&D, production, QA, sales and service departments, to serve the customers in various biopharmaceutical segments, such as cell & gene therapy, vaccines, antibodies, recombinant proteins, animal-derived medical devices, and biochemical medicines, etc. HZSKBIO® meets the QC needs from starting and raw materials to in-process samples and final products.

HZSKBIO® is IS013485 certified, and compliant in quality for providing fully integrated solutions of both standardized and customized products, for example, residual host cell nucleic acid/protein quantitation, gene vector safety analysis, process-related residue assay, adventitious agent detection, cell line characterization, and so on.

HZSKBIO® is committed to becoming a pioneer of new technologies for quality analysis, a leader of novel testing methods, an advocate of standardization of QC tests, and dedicated to providing tools that empowers innovations and development of biologics.

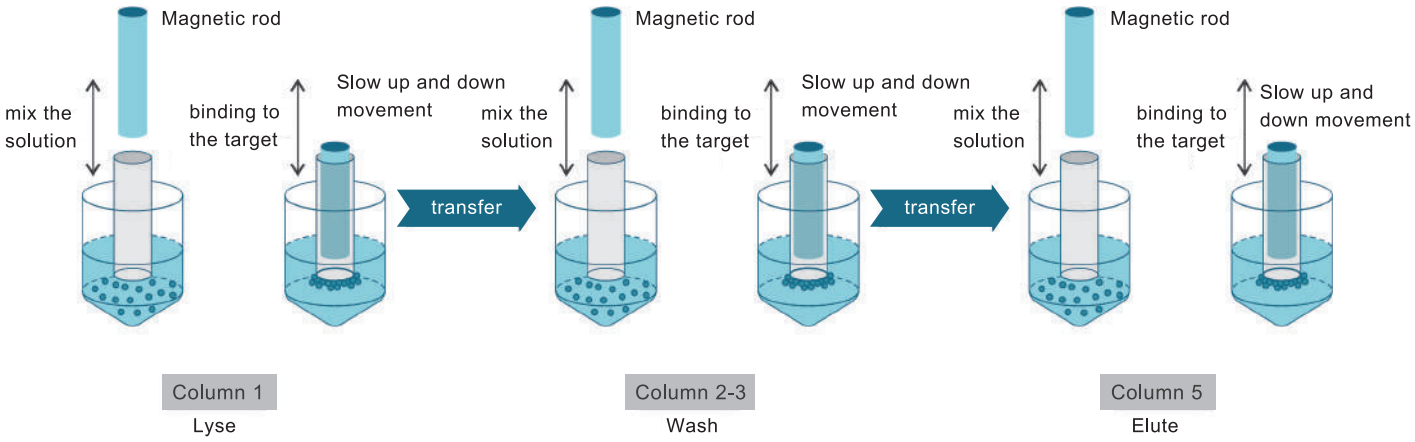
01

Quality Control Tools for Biological Products — Nucleic Acid Detection System

qPCR technology is highly sensitive and the sensitivity could be impacted by different factors such as equipment, consumables, reagents, personnel and environment. Discrepancies can come possibly from sample preparation to data analysis. Therefore, a consistent real-time PCR assay performance is established based on lab capability, sample preparation process, qPCR reagents, equipment system and qualified personnel.

1.1 rHCDpurify® Sample Preparation System

- ☑ Barcode scanning capable: Ensuring accuracy and efficiency;
- ☑ Ergonomic design: Ultra-large display screen for ease of use;
- ☑ Temperature control: Precise setting for lysis and extraction efficiency enhancement;
- ☑ Extraction performance: Validated efficient recovery of trace residual DNA from various sample matrix;
- ☑ Compatible products: SHENTEK® sample preparation kits with built-in programs;
- ☑ Programmable mode: Customize your protocol for sample preparation with appropriate kits.



The rHCDpurify® sample preparation system is an automated nucleic acid extraction platform for biological products. The built-in optimized and validated procedures are compatible with SHENTEK® DNA Sample preparation kits for residual host cell, mycoplasma, and mycobacteria, etc. It has one-click operation mode of trace DNA extraction and purification from various species of host cells, microorganisms, virus, animal-origin biomaterials, etc. in different sample matrices. All of these procedures are fully validated to ensure accurate and reproducible recovery results.

Product Number	Product Name	Contents
1609850	rHCDpurify® Preparation System	SKRDP-32Pro
1104192	rHCDpurify® Preparation Consumable Kit	Plastic sleeve (×100)
		96 deep-well plate (×48)
		Negative quality control (100 mL × 1 bottle)

1.2 SHENTEK® 96S Real-time PCR System

Validated test procedures:

- ☑ SHENTEK® host cell DNA/RNA residue detection procedures
- ☑ SHENTEK® host cell DNA size analysis procedures
- ☑ SHENTEK® reverse transcriptase activity test procedure
- ☑ SHENTEK® replication-competent virus test procedures
- ☑ MycoSHENTEK® mycoplasma and mycobacteria detection procedures
- ☑ MicroSHENTEK® bacteria and fungi detection procedures
- ☑ AdvSHENTEK™ endogenous and exogenous virus detection procedures

The SHENTEK® 96S real-time PCR system provides maximum performance in one-click operation mode and user-friendly wizard interface. Its exceptional temperature and optical precision ensures that assay calibration is of high accuracy; and sensitivity. It is an ideal and economic platform with flexibility in reagents and consumables. All SHENTEK® nucleic acid detection kits will achieve stable quality results for QC tests of biological products. Together with rHCDpurify® Sample Preparation System, we offer a complete system from automated nucleic acid extraction to detection, and lower the risk due to manual errors, ensuring accurate and reliable quantitation.

Parameter	Performance
Sensitivity	Min. resolution of 1 copy
Range	1–10^{10} copies
Repeatability	CV < 1.00%
Linear Correlation Coefficient	$\|r\| \geqslant 0.9990$
Detection Channels	6 fluorescence detection channels, no cross-talk between the four channels of FAM/VIC/ROX/CY5
Temperature Span	4–99 °C
Heating Rate	0–4.0 °C/s
Temperature Accuracy	± 0.1 °C
Ancillary Equipment	SHENTEK rHCDpurify® Sample Preparation System
Compliance	GMP grade
	FDA 21 CFR Part 11

02

RESIDUAL HOST CELL NUCLEIC ACID QUANTITATION

Most of the recombinant proteins, antibodies, vaccines, gene therapies and other biological products are generated from complex systems of bioengineered cell substrates (e.g. bacterial, yeast, animal or human-derived cells). Residual host cell DNA and RNA in a complex arrays of varying fragment sizes and composition, may remain in the final manufactured product with potential immunogenicity risk, and sometimes a case-by-case risk-based assessment is recommended. Pharmaceutical regulatory agencies and organizations defined the acceptable levels of residual host cell DNA for the single doses of biological products, mostly no more than 10 ng/dose, with the fragment size limit less than 200 bp.

HZSKBIO® rHCD & rHCR quantitation and rDNA size analysis kits provide specific, sensitive and reliable detection by qPCR assay for different host cell lines. Customized kits for some specific cell lines can also be developed and manufactured to meet the quantitative assay needs.

2.1 SHENTEK® Sample Preparation Kits

2.1.1 Residual host cell DNA & RNA sample preparation kits

Manual and automated sample preparations are used for residual DNA or RNA recovery in a broad range of biological products from various manufacturing steps and types, such as in-process samples, bulk harvest, and final product. The rHCDpurify® sample preparation system, with SHENTEK® sample preparation kits, offer stable and efficient automated extraction of trace amounts of host cell DNA or RNA. The efficient and reproducible recovery have been validated in multiple complex sample mixture (high protein, high salt, low pH, etc.). DNA or RNA extraction compatible with SHENTEK® downstream analysis platform provides an integrated solution from sample preparation to PCR assay for host cell residual DNA or RNA quantitation and DNA size analysis.

2.1.2 Residual host cell DNA sample preparation kit for vaccines

This kit is specific for residual host cell DNA extraction from vaccine dosages, compatible with the rHCDpurify® system for automated sample preparation. If the vaccine sample contains aluminum adjuvant, HZSKBIO® can provide aluminum adjuvant dissociation buffer along with the sample preparation kit.

2.1.3 Animal-origin residual DNA sample preparation kits

Animal-origin residual DNA level is one of the evaluation indicators for decellularization process of biologic scaffold materials. Since the extracellular matrix in biomedical materials contain a large quantity of structural proteins, the DNA residue assay method for biological products listed in the pharmacopoeias cannot be applied directly for biological scaffold materials. Therefore, an effective sample pre-treatment is required for biomedical materials: nucleic acids are released after matrix digestion, then extraction and purification performed before quantitative testing. The rHCDpurify® automation system for nucleic acid extraction ensure rapid purification and high recovery of trace animal-origin residual DNA from various biomedical materials.

Product Number	Product Name	Quantity
1104191	SHENTEK® Residual Host Cell DNA Sample Preparation Kit	100 Extractions
SK030206DM50	SHENTEK® Residual Host Cell DNA Sample Preparation Kit For Vaccines	50 Extractions
1104193	SHENTEK® Animal-origin Residual DNA Sample Preparation Kit	50 Extractions
1201205	SHENTEK® Residual Host Cell RNA Sample Preparation Kit	100 Extractions

2.2 SHENTEK® Residual Host Cell DNA Quantitation Kits

Residual host cell DNA is quantitated by qPCR methods, covering the following species of cells and vectors:

1) Bacteria, such as E. coli, etc.
2) Yeasts, such as Pichia pastoria, etc.
3) Insect cells, such as Hi5, etc.
4) Animal cells, such as CHO, Vero, MDCK, etc.
5) Human cells, such as HEK293, etc.
6) Genetic vectors, such as plasmids, etc.

The SHENTEK® Residual Host Cell DNA Quantitation Kits is based on a highly efficient hot-start PCR reaction system and are tolerant to common PCR inhibitors or interferences, ensuring reliable, specific and sensitive quantitation, with the lowest end of quantitation at fg/μL DNA level. These kits are compatible with highly efficient DNA recovery using SHENTEK® Residual Host Cell DNA Sample Preparation Kits. Internal Positive Control (IPC, VIC assay) is provided for either kits, respectively for optional use (please consult technical support for use if needed). The development and production of the kits comply with ISO13485 quality standard. Full validation reports, for quantitative assays are available, and which meet requirements of pharmacopeia regulations. These kits have been applied successfully to QC tests for regulatory filings in US and Europe.

Product Number	Product Name	Quantity
1101107-1	SHENTEK® Residual E. coli DNA Quantitation Kit (2G)	100 Reactions
SK030205P100	SHENTEK® Residual Pichia pastoris DNA Quantitation Kit	100 Reactions
SK030222HA100	SHENTEK® Residual Hansenula polymorpha DNA Quantitation Kit	100 Reactions
1101103	SHENTEK® Residual Saccharomyces cerevisiae DNA Quantitation Kit	100 Reactions
1101100-1	SHENTEK® Residual CHO DNA Quantitation Kit (2G)	100 Reactions
SK030208N100	SHENTEK® Residual NS0 & SP2/0 DNA Quantitation Kit	100 Reactions
SK030204V100	SHENTEK® Residual Vero DNA Quantitation Kit	100 Reactions
SK030227V100	SHENTEK® Residual Vero DNA-154 Quantitation Kit	100 Reactions
1101105	SHENTEK® Residual CV-1 DNA Quantitation Kit	100 Reactions
SK030209M100	SHENTEK® Residual MDCK DNA Quantitation Kit	100 Reactions
1101101	SHENTEK® Residual Sf9 & AcNPV DNA Quantitation Kit	100 Reactions
1101102	SHENTEK® Residual Hi5 & AcNPV DNA Quantitation Kit	100 Reactions
1101108	SHENTEK® Residual Human DNA Quantitation Kit (2G)	100 Reactions
1101104-1	SHENTEK® Residual HEK293 DNA Quantitation Kit (3G)	100 Reactions
1101116	SHENTEK® Residual BHK DNA Quantitation Kit	100 Reactions
1403443	SHENTEK® Residual SV40 LTA/E1A DNA Quantitation Kit (2G)	100 Reactions
1101109	SHENTEK® Residual E1A DNA Quantitation Kit	100 Reactions
1101110	SHENTEK® Residual E1B DNA Quantitation Kit	100 Reactions
1101111-1	SHENTEK® Residual Plasmid DNA Quantitation Kit (3G)	100 Reactions
1101123	SHENTEK® Residual PG13 DNA Quantitation Kit	100 Reactions
1101124	SHENTEK® Residual MRC-5 DNA Quantitation Kit	100 Reactions
1101125	SHENTEK® Residual RDF21 DNA Quantitation Kit	100 Reactions
SK030210Q	2xqPCR SHENmix (MasterMix for qPCR reaction)	500 Reactions
SK030215D	DNA Dilution Buffer(For PCR)	16 tubes, 1.5 mL/tube

2.3 SHENTEK® Residual Host Cell DNA Size Analysis Kits

Residual DNA fragment size distribution assessment, based on quantitative PCR (qPCR) system for various host cells, are able for detecting the sizes of DNA fragments from < 100 bp, 100–200 bp, 200–500 bp, to > 500 bp. The kits are used in parallel with species/sequence-specific quantitation of residual host cell DNA on different qPCR systems with sample preparation from SHENTEK® Residual Host Cell DNA Sample Preparation Kits. The assay performance have been validated by multiple parties. The linear range, precision, limit of quantitation and specificity all comply with the requirements of pharmacopoeia regulations.

Product Number	Product Name	Quantity	DNA Fragment Size (bp)
1103170-2	SHENTEK® Residual CHO DNA Size Analysis Kit (2G)	4 × 100 Reactions	<100/100+/200+/500+
1103171-2	SHENTEK® Residual E. coli DNA Size Analysis Kit (2G)	4 × 100 Reactions	<100/100+/200+/500+
1103172	SHENTEK® Residual Pichia Pastoris DNA Size Analysis Kit	3 × 100 Reactions	100+/200+/500+
1103173	SHENTEK® Residual Human DNA Size Analysis Kit (2G)	4 × 100 Reactions	<100/100+/200+/500+
1103174	SHENTEK® Residual Vero DNA Size Analysis Kit (2G)	4 × 100 Reactions	<100/100+/200+/500+
1103175	SHENTEK® Residual MDCK DNA Size Analysis Kit	4 × 100 Reactions	<100/100+/200+/500+
1103176	SHENTEK® Residual HEK293 DNA Size Analysis Kit	4 × 100 Reactions	<100/100+/200+/500+
1103177	SHENTEK® Residual Sf9 DNA Size Analysis Kit	4 × 100 Reactions	<100/100+/200+/500+
1103178	SHENTEK® Residual PG13 DNA Size Analysis Kit	3 × 100 Reactions	100+/200+/500+
1103179	SHENTEK® Residual BHK DNA Size Analysis Kit	4 × 100 Reactions	<100/100+/200+/500+
SK030307S-P	SHENTEK® Residual HPV18 E6/E7 DNA Size Analysis Kit	4 × 100 Reactions	E6:100+/200+, E7:100+/200+

2.4 SHENTEK® Residual Host Cell RNA Quantitation Kits

The kits are used to quantitate host cell RNA residues in cell and gene therapy products, covering E. coli cell lines for plasmid production and HEK293T for recombinant vector generation. The kits are prepared with specific pre-designed primers and probes, enable one-step RNA reverse transcription to avoid the contamination risk during reaction.

SHENTEK® Residual Host Cell RNA Quantitation Kits have been fully validated on different qPCR instruments. These kits are generally used with SHENTEK® Residual Host Cell RNA Sample Preparation Kit for highly efficient RNA recovery.

Product Number	Product Name	Quantity
1201201-1	SHENTEK® Residual E.coli RNA Quantitation Kit (2G)	100 Reactions
1201202	SHENTEK® Residual 293T RNA Quantitation Kit	100 Reactions

2.5 Animal-derived Residual DNA Quantitation Kits For Biomedical Materials

The Animal-derived Residual DNA Quantitation Kits are used to quantitate residual DNA of animal origin (such as bovine and porcine origins) in biomedical samples. The kits provide rapid, specific, and reliable assays, and high sensitivity up to fg/μL level. Bovine/Porcine control DNA as quantitation standards are included in the kits and the assay validation meet the requirements of pharmacopeia regulations. The product development and manufacturing comply with ISO13485 quality standard.

Product Number	Product Name	Quantity
1101112	SHENTEK® Residual Bovine DNA Quantitation Kit	100 Reactions
1101113	SHENTEK® Residual Porcine DNA Quantitation Kit	100 Reactions

03

RESIDUAL HOST CELL PROTEIN QUANTIFICATION (rHCP)

HZSKBIO® developed various process or platform-specific host cell protein (HCPs) ELISA kits and performed coverage assessment of how complete an antibody population recognize reference and sample HCP population, using orthogonal technologies of 2D-silver stain and LC-MS/MS. The kit development and production complies with ISO13485 quality standard, and the assay performance have been fully validated in compliance with pharmacopoeia requirements. To help achieve effective CPP (critical process parameters) and CQA (critical quality attributes) of biologics development pipelines, the following characteristerics of HCP assay are critical:

1) High Sensitivity: Low level of residual HCP is detectable in high concentration of product proteins;
2) High Coverage: Immunoassays employed to cover the vast majority of different protein groups;
3) Process relevance: High resolution and sensitivity to the HCP change in the process development.

3.1 SHENTEK® Residual Host Cell Protein ELISA Kits

HZSKBIO® operates highly efficient animal immune pipelines for polyclonal antibody production that guarantees reliable antibodies with high titer and high recognition across all of the bioprocess HCP populations. HZSKBIO® developed E.coli (Expression Strain BL21) HCP ELISA kits specialized for E.coli BL21 bioproduction HCP detection, E.coli (Cloning Strain K-12 & Alkaline Lysis) HCP ELISA kit specific for the HCP detection in the plasmid production and downstream alkaline lysis, as well as CHO HCP ELISA kit, etc., which are applicable for HCP quantitation for in-process samples, bulk and final products.

Product Number	Product Name	Quantity
1301301	SHENTEK® E.coli (Protein Expression Strains) HCP ELISA Kit	96 Tests
1301301-1	SHENTEK® E.coli (Protein Expression Strains) HCP ELISA Kit (One-step ELISA)	96 Tests
1301302	SHENTEK® E.coli (K-12 & Alkaline Lysis) HCP ELISA Kit	96 Tests
1301304-1	SHENTEK® CHO HCP ELISA Kit (One-step ELISA)	96 Tests
1301305	SHENTEK® CHO-K1 HCP ELISA Kit (One-step ELISA)	96 Tests
1301305-1	SHENTEK® CHO-K1 HCP ELISA Kit (One-step ELISA)	96 Tests
1301315	SHENTEK® CHO PLBL-2 HCP ELISA Kit	96 Tests
1301308	SHENTEK® MDCK HCP ELISA Kit (One-step ELISA)	96 Tests
1301309	SHENTEK® Vero HCP ELISA Kit (One-step ELISA)	96 Tests
1301312	SHENTEK® Sf9 HCP ELISA Kit (One-step ELISA)	96 Tests
1301311	SHENTEK® HEK293 HCP ELISA Kit (One-step ELISA)	96 Tests
1301313	SHENTEK® P. pastoris HCP ELISA Kit (One-step ELISA)	96 Tests

To ensure the accuracy of ELISA assay for HCP quantitation, coverage of the HCP population should be assessed. HZSKBIO® provides specific antibodies to HCP antigens. HZSKBIO® also provides negative controls from animal sera, as well as 2D QC standards and 2D Clean-up kits to reduce the high levels of interference (due to detergents, salts, lipids, phenols, and nucleic acid plasma contaminants) in protein samples, improving the performance of 2D electrophoresis.

Product Number	Product Name	Quantity
1301301-Ab01	SHENTEK® Anti-E.coli (Protein Expression Strains) HCP Antibody	1mg
1301302-Ab01	SHENTEK® Anti-E.coli (K-12 & Alkaline Lysis) HCP Antibody	1mg
1301304-Ab01	SHENTEK® Anti-CHO HCP Antibody	1mg
1301305-1-Ab01	SHENTEK® Anti-CHO-K1 HCP Antibody	1mg
1301308-Ab01	SHENTEK® Anti-MDCK HCP Antibody	1mg
1301309-Ab01	SHENTEK® Anti-Vero HCP Antibody	1mg
1301312-Ab01	SHENTEK® Anti-Sf9 HCP Antibody	1mg
1301311-Ab01	SHENTEK® Anti-HEK293 HCP Antibody	1mg
1301313-Ab01	SHENTEK® Anti-P.pastoris HCP Antibody	1mg

3.2 Customized Residual Host Cell Protein (rHCP) Analysis Services

HZSKBIO® established and is offering a multi-level HCP analysis technology platform:

- HCP quantitation and analysis technology platform: ELISA, LC-MS, 2D (fluorescent staining & silver staining)
- HCP coverage assessment platform: IMBS-2D, IMBS/LC-MS
- Anti-HCP polyclonal antibody preparation platform: Multi-model approach
- Customized HCP ELISA kit development platform

3.2.1 HCP assay and analysis services (ELISA, LC-MS and 2D electrophoresis technology platforms)

HZSKBIO® LC-MS and 2D electrophoresis technology platforms provide the followings services besides HCP-ELISA method:

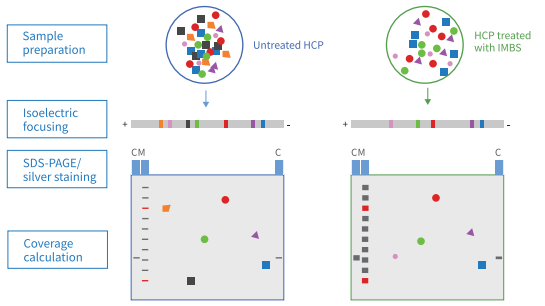
- Identification and quantitation of the individual HCP in a sample;
- Precise analysis of high-risk and process-specific HCPs for bioprocess development;
- Precise analysis of lot-to-lot HCP differences, especially for preclinical and clinical trial batches;
- Traceability system for HCP ELISA standards to ensure assay accuracy and reliability.

HCP analysis instruments—ELISA/2D/LC-MS

3.2.2 HCP coverage assessment platform (IMBS-2D, IMBS/LC-MS)

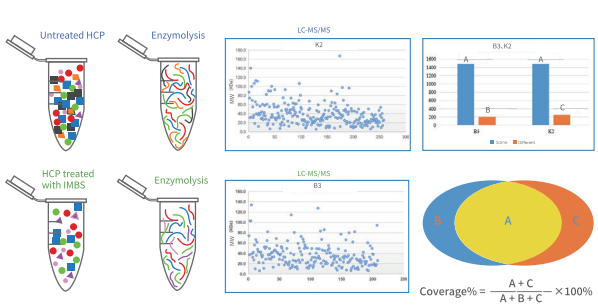
Combined with proprietary IMBS (immunomagnetic bead separation), HZSKBIO® has employed two different HCP coverage assessment technology platforms - IMBS-2D and IMBS/LC-MS, to valuate the coverage of HCP recognition by antibodies, and the coverage of the high-risk HCP immunogens in both the assay standard and the characterizing HCP antibodies.

2D electrophoresis process (Coverage assessment)



Coverage assessment (IMBS+2D-silver stain)

LC-MS process (Coverage assessment)



Coverage assessment (IMBS+LC-MS/MS)

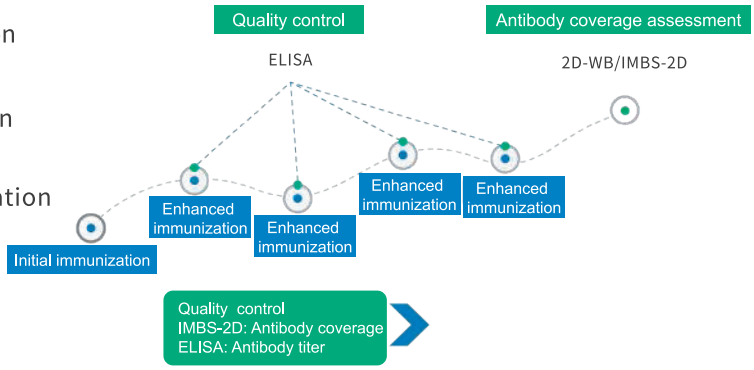
3.2.3 Anti-HCP polyclonal antibody preparation platform

1) HCP immunogen and reference standard analysis:

- HCP profile analysis and antigen generation & selection strategies
- HCP reference standards and immunogenic protein identification
- Different animal immunization & antibody preparation strategies for different antigen groups

2) Anti-HCP polyclonal antibody preparation:

- Development of animal immunization programs
- Comprehensive quality monitoring throughout the preparation process
- Scaled-up preparation platform of anti-HCP polyclonal antibodies

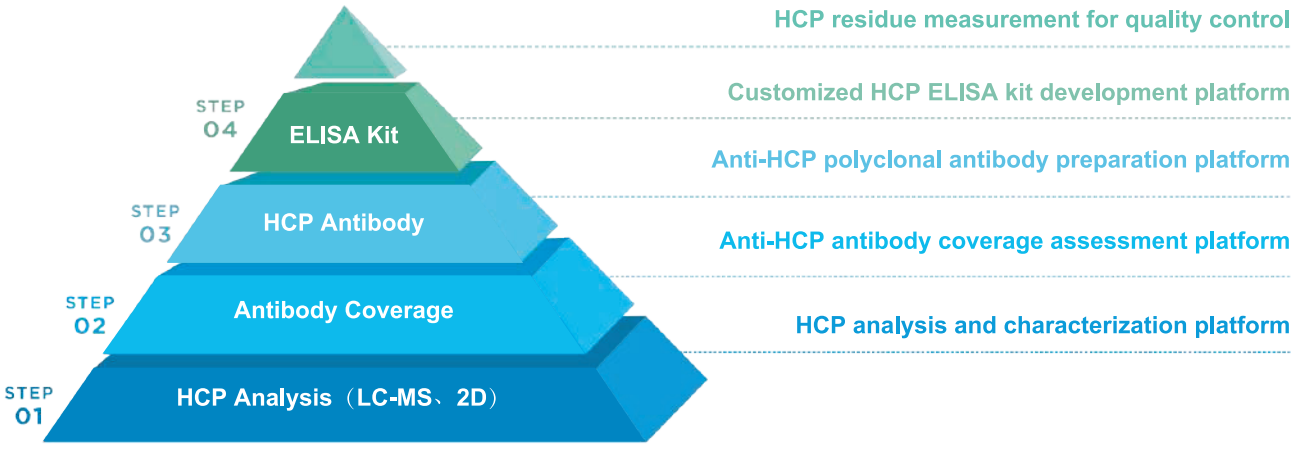


Quality control, in the multiple antibody preparation platform, comprise of using ELISA for antibody titer, and IMBS-2D/LC-MS for antibody coverage assessment, ensuring consistent quality of key components of the ELISA test kits.

3.2.4 Customized HCP ELISA kits

HZSKBIO® has established a highly efficient HCP immunogen and anti-HCP antibody preparation and analysis platform, which provides customized process- or product-specific HCP reference standard and diverse antibodies, ensuring the efficient development and consistent supply of high-quality HCP ELISA kits. Also the comprehensive performance validation of ELISA assays are in compliance with pharmacopeia regulations and regulatory filing requirements.

- Characterization, preparation and stability studies of immunogen/rHCP standards, turn-around time (TAT) around 3–4 months
- Preparation and characterization of anti-HCP polyclonal antibody, TAT around 4–8 months
- Process development and production of ELISA kits, TAT around 4–6 months
- HCP ELISA kit performance validation, TAT around 1–2 months



HCP analysis “Pyramid”

04

VECTOR SAFETY ANALYSIS

The design rationality, process development and quality control of both viral and non-viral vector-based in-vitro gene modification systems directly impact the clinical safety and efficacy of the final products. Biosafety study and risk assessment should be investigated for the gene-delivery vector design, processing and release. HZSKBIO® provides quality control testing via identification of gene copy number, detection of replication-competent viruses, and examination of genetic stability, for the biosafety assessment of the gene delivery vectors.

4.1 SHENTEK® CAR/TCR Gene Copy Number Quantification Kit

Since the exogenous gene insertion site and relative copy numbers of insertion sites determines the gene expression levels of target cells, the copy number of the inserted gene in the target product should be assayed as controls for transduction/transfection efficiencies, subsequent to the introduction of the gene construct into cells. High sensitivity and throughput real-time PCR has been used to analyze transgene copy number in genetically modified target cells, and digital PCR methods are also used to determine the absolute copy number.

Lentivirus vector are used to introduce CAR or TCR genetic sequence into cell therapy products. However, due to the variations among different individuals' genomes, there may be variable copy numbers of the lentivirus-specific TCR gene transferred into peripheral T cells, resulting in different cytotoxicity in heterogeneous CAR-T cell populations.

SHENTEK® CAR/TCR Gene Copy Number Quantification Kit is a reliable and accurate quality control test for the detection of transgene copy number in CAR-T cells that are transfected with rHIV-1 lentiviral vectors.

Multiplex real-time PCR assay has been developed for detection and relative quantification of average gene-of-interest copy number by comparing the number of the genomic DNA for transgene expression to the single-copy gene in a human cell population. Quantitation reference standards are included in the kit.

Product Number	Product Name	Quantity
SK030221CA100	SHENTEK® CAR/TCR Transgene Copy Number Quantitation Kit	100 Reactions

4.2 SHENTEK® Replication-Competent Virus Quantification Kits

The replication-competent virus risk is an important biosafety concern for usage of viral vectors. Through recombination with host sequences or contamination, replication competent virus may be generated, although low in probability, may increase with each successive replication. Therefore a sensitive and accurate assay, for detection of replication-competent viruses in large vector populations, is required for quality control at multiple stages of vector production process, to avoid any potential risks, including immunogenicity risks.

HZSKBIO® provides replication-competent virus qPCR assay kits for the quality control testing of different replication-defective viral vectors. The tests are designed for master cell banks, working cell banks, end of production cells, bulk harvest, supernatant, and post-transduction cell products.

4.2.1 SHENTEK® replication-competent lentivirus (RCL) quantitation kit

SHENTEK® RCL quantification kit is suitable for the quick and sensitive detection of replication-competent lentivirus in the lentivirus vector preparation and cell & gene therapy post-transduction products, for example, master or working cell banks, end of production cells, viral vector harvest or supernatant, and CAR-T cells. This assay uses real-time RT-PCR to evaluate PC amplification of specific sequences in both standards and samples under identical reaction conditions to accurately quantify the copy number of RCL. The RCL quantification standard is included in the kit. The assay is highly specific and is fully validated in compliance with requirements of pharmacopeia regulations. It is developed and manufactured in compliance with IS013485 quality standard and regulatory requirements.

Product Number	Product Name	Quantity
1403441	SHENTEK® Replication-Competent Lentivirus (RCL) Quantitation Kit	100 Reactions

4.2.2 SHENTEK® replication-competent retrovirus (RCR) quantitation kit

SHENTEK® RCR quantification kit is suitable for the quick and sensitive detection of replication-competent retrovirus in retrovirus vector preparation and cell & gene therapy post-transduction products. For example, the master or working cell banks, end of production cells, viral vectors harvest and supernatant, and CAR-T cells. Based on real-time RT-PCR technology, the assay evaluates amplification of specific sequences in samples and standards under identical reaction conditions to accurately quantify the copy number of RCR. The RCR quantification standard is included in the kit. The assay is highly specific and has been fully validated in compliance with pharmacopeia requirements. It is developed and manufactured in compliance with ISO13485 quality standard and regulatory requirements.

Product Number	Product Name	Quantity
1403442	SHENTEK® Replication-Competent Retrovirus (RCR) Quantitation Kit	100 Reactions

4.2.3 SHENTEK® replication-competent adeno-associated virus (rcAAV) quantitation kits

SHENTEK® rcAAV quantification kit is suitable for quick and sensitive and replication-competent AAV detection in rAAV vector preparation, as well as AAV-based gene therapy products. The serotype-specific qPCR assay could be performed after a cell-based amplification portion to separate the truly replication competent AAVs and replication defective AAVs. In addition, it can be directly applied to detect for potentially low-level rcAAV in viral vector products. The reference sequence and the target sequence designed for qPCR assay are prepared in the same standard, allowing for rapid, sensitive and serotype-specific quantification of both rAAV vectors and rcAAV simultaneously. The target DNA sequence selected for rcAAV detection spans an AAV ITR-rep gene junction, which is the requisite feature for AAV replication, achieving a maximum detection of potential contamination level for rcAAV. HZSKBIO® provides two serotype-specific qPCR assays to detect rcAAV serotype 2/N & 5/N (N indicates all capsid proteins) for a broad range of samples, from rAAV bulk to final products and post-transduction cell samples.

Product Number	Product Name	Quantity
1403444	SHENTEK® rcAAV-2/N Quantitation Kit	100 Reactions
1403445	SHENTEK® rcAAV-5/N Quantitation Kit	100 Reactions

4.3 SHENTEK® Virus DNA & RNA Extraction Kit

SHENTEK® Viral DNA & RNA Extraction Kit is designed for high-quality viral nucleic acid extraction from different sample matrices, including cell culture not higher than 10^7 cell/mL and viral harvest or supernatant. The extraction efficiency has been verified for reliable downstream performance with the aforesaid samples spiked with different concentrations of viruses, such as pseudoviruses, armor RNA viruses, bovine viruses in cell culture medium, and replication-competent viruses in viral vector samples. This kit is compatible with the rHCDpurify® pretreatment system for automated extraction. The extracted virus DNA/RNA can be used directly for downstream applications such as PCR, RT-PCR, qPCR and qRT-PCR experiments.

Product Number	Product Name	Quantity
1506730	SHENTEK® Virus DNA & RNA Extraction Kit	50 Extractions

Before nucleic acid extraction, sample pretreatment methods of cell lysate vary slightly depending on viral replication pathways. If a virus localizes to the nucleus and integrates with the DNA of the host cell for replication, such as replication-competent viruses - RCL/RCR and most DNA viruses (e.g. rcAAV) or unknown adventitious viruses, the sample can be treated with benzonase nuclease after cell lysis to dissolve the released host cell genome. For viruses that utilize host transcription and translation in the cytoplasm, such as most RNA viruses, samples can be centrifuged after cell lysis and the supernatant is used for nucleic acid extraction directly.

05

PROCESS-RELATED RESIDUE ASSAY

Process-related impurities introduced into the manufacturing process originate from a variety of stages, including cell-derived impurities, media components, antibiotics, buffer substances, anti-foaming agents, process-enhancing agents, enzymes, or leachable compounds from contact materials, etc. These process residuals can impact product safety and critical quality attributes at low concentrations, and require highly specific, sensitive, and robust detection and quantification to validate effective removal in process development or validation. Therefore, HZSKBIO® provides the corresponding quality control solutions for these process residuals, to support process development, monitor batch to batch variations and ensure product release meeting specification limits.

5.1 SHENTEK® Nonspecific Endonuclease (SMNE) ELISA Kit

The SHENTEK® Nonspecific Endonuclease (SMNE) ELISA Kit quantitates Serratia marcescens nonspecific endonuclease residues in downstream processing samples and product release. The assay performance is fully validated with high sensitivity, specificity, reproducibility and LOQ limit down to 0.25 ng/mL. It is suitable for the detection of Serratia marcescens non-specific endonuclease, from natural resources or recombinant protein from SNME gene construct expression, with high specificity and consistency. This kit is developed and manufactured in compliance with ISO13485 quality requirements and the reference standard in this kit is traceable to China national standards.

Product Number	Product Name	Quantity
1402421	SHENTEK® Nonspecific Endonuclease (SMNE) ELISA Kit	96 tests

5.2 SHENTEK® Porcine Trypsin & Trypsin-analog ELISA Kits

The SHENTEK® Porcine Trypsin ELISA Kit is a reliable and efficient solution for detecting and quantifying trypsin residues during the bioprocessing purification process. This kit is specifically designed to recognize trypsin derived from porcine pancreas or recombinant protein expression of the porcine trypsin gene construct. With its high sensitivity, accuracy, specificity, and a low limit of quantitation at 0.040 ng/mL, the assay performance has been fully validated.

HZSKBIO® also provides the Trypsin-analog ELISA Kit suitable for the detection and quantitation of ThermoFisher TrypLE™ or Sartorius Accutase residues. This kit follows a simple workflow and is fully validated in compliance with pharmacopeia requirements.

Both kits that have been pre-coated with sheep antibodies are available in a highly stable supply and ensure exceptional performance.

Product Number	Product Name	Quantity
1402422	SHENTEK® Porcine Trypsin ELISA Kit	96 tests
1402424	SHENTEK® Trypsin-analog ELISA Kit	96 tests

5.3 SHENTEK® Bovine Serum Albumin (BSA) ELISA Kit

Bovine serum albumin (BSA) is a serum albumin protein from cows and serves in cell culture media as a supplement to feed cells and promote cell growth. Residual bovine serum albumin in some formulations has occasionally caused adverse effects. The SHENTEK® BSA ELISA Kit is a solid-phase sandwich ELISA assay for quantitative measurement with high sensitivity, excellent specificity, and batch-to-batch consistency. The assay performance is fully validated in compliance with requirements of the pharmacopoeia regulations. This kit is developed and manufactured in compliance with the ISO13485 quality standard and regulatory requirements.

Product Number	Product Name	Quantity
1401401	SHENTEK® Bovine Serum Albumin (BSA) ELISA Kit	96 tests

5.4 SHENTEK® Kanamycin ELISA Kit

Penicillin or other β-lactam antibiotics are not tolerated in the manufacture of biological medicinal substance and products for human use. Therefore, the use of antibiotics should be avoided as much as possible in the bioprocess development. When they must be used, antibiotics level must be monitored to avoid potential immunogenicity risk. In the downstream purification process, the antibiotics should be efficiently removed and removal validated. The concentration of antibiotics residues in the downstream processing samples and in the product release should be analyzed to meet specification limit.

SHENTEK® Kanamycin ELISA Kit is a rapid, sensitive and quantitative analysis of kanamycin residue in biological samples, especially in those utilizing kanamycin-resistant plasmids for the development of gene therapies, cell-based vaccines, and similar biotherapeutics. The kit is based on an indirect-competitive enzyme immunoassay. Kanamycin in the sample competes with antigen coated on the microtiter plate for the antibody. After the addition of enzyme conjugate, chromogenic substrate is used and the signal is measured by a spectrophotometer. The absorbance value is inversely proportional to the kanamycin concentration in the sample. The total amount of kanamycin in the sample is obtained by comparison with the standard curve and adjusted by the sample dilution factor. The assay performance is fully validated in compliance with the requirements of pharmacopeia regulations. This kit is developed and manufactured under ISO13485 quality standard and regulatory compliance.

Product Number	Product Name	Quantity
1401402	SHENTEK® Kanamycin ELISA Kit	96 tests

5.5 SHENTEK® Deoxyribonuclease I (DNase I) ELISA Kit

The DNase I Residual Detection Kit is specifically designed for the quantitative detection of DNase I residues during in-process monitoring and final release testing of mRNA vaccines, gene therapies, and other biologics. It plays a critical role in minimizing the risk of unintended nucleic acid degradation, ensuring the integrity and safety of the final product. This kit is fully validated to meet pharmacopoeia standards, offering reliable performance for regulatory compliance. Samples can be easily tested through appropriate dilutions to confirm the its suitability for the specific application.

Product Number	Product Name	Quantity
1402428	SHENTEK® Deoxyribonuclease Ⅰ (DNase Ⅰ) ELISA Kit	96 Tests

06

ADVENTITIOUS AGENT DETECTION

HZSKBIO® provides rapid microbiological methods (RM) for efficient mycoplasma, mycobacteria, bacteria, fungi control of raw materials, in-process samples, conventional pharmaceuticals, biotech & short shelf life products and environmental samples. Through systematic validation in suitability, linearity, specificity, sensitivity, limit of detection, robustness (instrument suitability & matrix effect), and ruggedness, the methods have been demonstrated as equivalent to conventional compendial test methods, and are suitable for a variety of samples as alternative analytical methods in regulatory filing.

6.1 Mycoplasma Fast Detection qPCR Kits

6.1.1 MycoSHENTEK® mycoplasma DNA extraction and detection kits

The MycoSHENTEK® mycoplasma DNA detection kit determines the presence or absence of mycoplasma DNA contamination (over 170 species of mycoplasma, spiroplasma and acholeplasma) in a broad range of samples, such as cell banks, virus seeds, cell culture derived biologicals like cell & gene therapy products, and biopharmaceuticals. It is a multiplex qPCR assay, with internal positive control, that offers high sensitivity, specificity and robustness, as alternative to compendial culture method (10 CFU/mL detection limit) and indicator cell culture method (100 CFU/mL detection limit). This nucleic acid amplification technique (NAT) method for mycoplasma limit test has been fully validated in compliance with EP 2.6.7, USP <77> and JP XVII requirements, and verified by third-party laboratories. The automated workflow from DNA extraction to assay analysis is less than 6 hours, based on the dedicated programs and compatible instrumentation - the rHCDpurify sample preparation system and the SHENTEK® 96S real-time PCR instrument.

MycoSHENTEK® mycoplasma DNA extraction and detection kits (2G) improve DNA extraction efficiency in complex matrices, for example, biological samples with 5% human albumin or 10^7 cells/mL cell culture, etc. The sensitivity meets 10 CFU/mL detection limit, with optimal performance from DNA extraction and PCR amplification efficiencies.

Product Number	Product Name	Quantity
1509840	MycoSHENTEK® Mycoplasma DNA Extraction Kit (2G)	50 Extractions
1509841	MycoSHENTEK® Mycoplasma DNA Detection Kit (2G)	50 Reactions

6.1.2 MycoSHENTEK® mycoplasma standards

1) MycoSHENTEK® Mycoplasma sensitivity standard

Each tube of sensitivity standard contains 10 CFU or 100 CFU of inactivated mycoplasma, which can be used safely and reliably in NAT methods. The colony forming unit (CFU) determined by the culture method and the genomic copy (GC) number by dPCR quantitation, are provided in the Certificate of Analysis for each lot. It cannot be used for culture method due to mycoplasma inactivation.

2) MycoSHENTEK® Mycoplasma DNA reference standard

Mycoplasma DNA reference standard with GC (Genome copy) calibrated at 1×10^8 copies/μL concentration can be used safely and reliably as quantitative controls. The desired concentration is obtained by serial dilution with DNA dilution buffer. They are intended for quantitation, calibration and specificity assessment if added with genomes of other species.

Product Number	Product Name	Quantity
1501501	MycoSHENTEK® Mycoplasma orale Sensitivity Standard (10 CFU)	5 tubes, 10 CFU/tube
1501503	MycoSHENTEK® Mycoplasma pneumoniae Sensitivity Standard (10 CFU)	5 tubes, 10 CFU/tube
1501505	MycoSHENTEK® Mycoplasma hyorhinis Sensitivity Standard (10 CFU)	5 tubes, 10 CFU/tube
1502550	MycoSHENTEK® Mycoplasma orale DNA Standard (1×10^8 copies/μL)	1 tube, 100 μL/tube
1502551	MycoSHENTEK® Mycoplasma pneumoniae DNA Standard (1×10^8 copies/μL)	1 tube, 100 μL/tube
1502552	MycoSHENTEK® Mycoplasma hyorhinis DNA Standard (1×10^8 copies/μL)	1 tube, 100 μL/tube

6.2 Mycobacteria Fast Detection qPCR Kits

6.2.1 MycoSHENTEK® mycobacteria DNA extraction and detection kits

According to the requirements of EP, FDA, USP and ChP, all biological starting materials should be should be examined for evidence of mycobacterial colonies. If alternative tests are used, including PCR assays, they should be shown to be sufficiently sensitive to test for the presence of mycobacteria.

MycoSHENTEK® mycobacteria DNA extraction and detection kits for qPCR assay:

- Fully automatic extraction using rHCDpurify® Sample Preparation System, and sensitive detection assay using SHENTEK® 96S Real-time PCR Instrument;
- Sensitive detection of more than 100 Mycobacterium species with LOD of 10 CFU/mL;
- High specificity with no cross-reactivity to nearly 50 species of closely related microorganisms or engineered cell lines;
- Effective detection in various sample matrices, even low copies in high-density cell cultures (10^7 cell/mL of CHO, HEK293T and Vero and other cell cultures);
- Suitable for mycobacteria lot-release test of master cell banks, working cell banks, virus seeds, cell therapy products, and vaccine products, etc. in a variety of biologics production platforms and modalities.

Product Number	Product Name	Quantity
1503601	MycoSHENTEK® Mycobacteria DNA Extraction Kit	50 Extractions
1503602	MycoSHENTEK® Mycobacteria DNA Detection Kit	50 Reactions

6.2.2 MycoSHENTEK® mycobacteria standards

MycoSHENTEK® Mycoplasma sensitivity standard:

Each tube of sensitivity standard contains 10 CFU or 100 CFU of inactivated mycobacteria, which can be used safely and reliably in NAT methods. The colony forming unit (CFU) determined by the culture method and the genomic copy (GC) number by dPCR quantitation, are provided in the Certificate of Analysis for each lot. It cannot be used for culture method due to inactivated mycobacteria. The standard solution or the matrix spike are intended for validating sensitivity, specificity, robustness, as well as the correlation check between the CT values and the log number of mycoplasma standard concentration.

Product Number	Product Name	Quantity
1503603	MycoSHENTEK® Mycobacterium phlei Sensitivity Standard (10 CFU)	3 tubes, 10 CFU/tube
1503604	MycoSHENTEK® Mycobacterium phlei Sensitivity Standard (100 CFU)	3 tubes, 100 CFU/tube
1503605	MycoSHENTEK® Mycobacterium neoaurum Sensitivity Standard (10 CFU)	3 tubes, 10 CFU/tube
1503606	MycoSHENTEK® Mycobacterium neoaurum Sensitivity Standard (100 CFU)	3 tubes, 100 CFU/tube

6.3 Bacteria and Fungi Fast Detection qPCR Kits

Compendial test for sterility is generally carried out by membrane filtration or direct inoculation of culture medium with a product to be examined. The test method and conditions should be exactly the same as method suitability test. Application of traditional growth-based methods is restricted because the methods require organisms to be culturable, and a 14-days long incubation time. Consequently, other suitable microbial tests (e.g., rapid methods) are considered for in-process control, and release testing of sterile short-life products. As recommended by regulatory bodies, alternative methods, that have been demonstrated as equivalent or better than conventional methods, are appropriate for rapid microbial detection, as well as for risk management in advanced therapy medicinal products (ATMPs) manufacturing.

6.3.1 MicroSHENTEK ® bacteria and fungi DNA extraction and detection

MicroSHENTEK® bacteria and fungi DNA extraction kit is optimized uniquely for DNA extractionfrom cell banks (master cell banks & working cell banks), and cell-culture derived biologics (vaccines & cell therapy products, etc.), using an efficient combination of zirconia beads for mechanical disruption and magnetic beads for nucleic acid extraction. MicroSHENTEK® bacteria and fungi DNA detection kit utilizes real-time PCR method for rapid and sensitive determination of bacterial and fungal contamination.

This microbial DNA extraction and detection system can effectively isolate and test for the presence or absence of microbial DNA across a variety of complex sample matrices, including high cell density cultures (10^6 cells/mL of Vero/293T/CHO or other cell types), 5% human albumin, high titer plasmid preparation, etc.

MicroSHENTEK® bacteria and fungi DNA extraction and detection kits:

◆ Capable of detecting more than 92% known bacterial and fungal species, covering nearly 5,000 speicies of fungi and 60,000 species (or subspecies) of bacteria, with LOD below 100CFU/mL;
◆ High specificity without cross-reactivity between fungi and bacteria; high specificity was verified against nearly 30 species of non-fungal and bacterial microorganisms, such as actinomycetes, mycobacteria, mycoplasma, or engineered cell lines.
◆ Positive, negative and internal controls are employed as references to prove the functionality of the reaction mix for amplification of the target(s), and rule out any inhibition.
◆ Effective detection in various sample matrices (except for bacterial detection in plasmid samples), especially for high cell density cultures (10^6 cells/mL of Vero/293T/CHO or other cell types), 5% human albumin, high plasmid titer preparation, etc.
◆ The reaction system contains dUTP/UNG to effectively eliminate carry-over contamination, and avoid generation of false positives.
◆ Automated workflow, from DNA extraction to assay analysis, is less than 6 hours, that is based on dedicated programs and compatible instrumentation - the rHCDpurify® sample preparation system and the SHENTEK® 96S real-time PCR instrument.
◆ Fully validated assay, as alternative microbial detection method, in compliance with USP <1071>, EP <5.1.6> and ChP <9201>.

Product Number	Product Name	Quantity
1504633	MicroSHENTEK® Fungi & Bacteria DNA Extraction Kit	50 Extractions
1504631	MicroSHENTEK® Fungi DNA Detection Kit	50 Reactions
1504632	MicroSHENTEK® Bacteria DNA Detection Kit	50 Reactions

6.4 Adventitious Virus Detection Kits

For cell culture-derived therapeutics, adventitious viral contamination is a key biosafety concern and in vitro test is required according to ICH guidelines and pharmacopoeial regulations.
HZSKBIO® provides a series of in vitro assays designed for retrovirus detection and adventitious virus screening, such as species-specific viral qPCR assays and NGS for unknown species, that can be used to screen cell banks, seed banks, raw materials and final products.

6.4.1 SHENTEK® bovine virus detection kits

When constructing cell banks, it is essential to conduct bovine virus detection if any bovine-derived materials, such as bovine serum and bovine serum albumin, are utilized. HZSKBIO® offers the bovine virus detection kits (BVDV, PI-3, REO-3, BAV-3, BPV) in accordance with pharmacopoeia requirements. The kits employ real-time PCR technology for rapid virus detection, achieving a sensitivity level as low as 50 copies/reaction with high specificity. Each kit includes an internal quality control to ensure reliable results. The kits are used together with the SHENTEK® Virus DNA & RNA Extraction Kit, which allows for the extraction of bovine virus contamination in various samples, such as 10^7 cell/mL substrates and bovine serum.

Product Number	Product Name	Quantity
1506731	SHENTEK® BVDV Detection Kit	50 Reactions
1506736	BVDV Positive Control	100μL × 3 tubes
1506732	SHENTEK® PI-3 Detection Kit	50 Reactions
1506738	PI-3 Positive Control	100μL × 3 tubes
1506733	SHENTEK® REO-3 Detection Kit	50 Reactions
1506737	REO-3 Positive Control	100μL × 3 tubes
1506734	SHENTEK® BAV-3 Detection Kit	50 Reactions
1506739	BAV-3 Positive Control	100μL × 3 tubes
1506735	SHENTEK® BPV-1 Detection Kit	50 Reactions
1506740	BPV-1 Positive Control	100μL × 3 tubes

6.4.2 SHENTEK® bovine virus detection kits

The bovine virus detection kit utilizes qPCR technology to simultaneously identify Bovine Viral Diarrhea Virus (BVDV), Reovirus Type 3 (REO-3), Parainfluenza Virus Type 3 (PI-3), Bovine Adenovirus Type 3 (BAV-3), and Bovine Parvovirus Type 3 (BPV-3) in a single test. This saves time and eliminates the need for separate qPCR assays for each virus. When combined with the SHENTEK® Virus DNA & RNA Extraction Kit and rHCDpurify® sample preparation system, the kit enables rapid and sensitive detection across various samples, including cell substrates and bovine serum. The kit also includes positive controls and internal quality controls, and the assay has been fully validated to ensure reliable and effective results.

Product Number	Product Name	Quantity
1506741	SHENTEK® Bovine Virus Detection Kit (BVDV/REO-3/PI-3/BPV-3/BAV-3)	50 Reactions
1506736	BVDV Positive Control	100μL × 3 tubes
1506737	REO-3 Positive Control	100μL × 3 tubes
1506738	PI-3 Positive Control	100μL × 3 tubes
1506739	BAV-3 Positive Control	100μL × 3 tubes
1506746	BPV-3 Positive Control	100μL × 3 tubes

6.4.4 Specific virus detection kits for CHO cell line

There is a potential risk of viral contamination in the bioproduction when using CHO cell line. HZSKBIO® has developed the following virus detection kits - Mouse Minute Virus (MVM), Vesivirus 2117, Porcine Circovirus Type 1 (PCV-1), and Porcine Circovirus Type 2 (PCV-2).

These kits employ qPCR technology, and are used with SHENTEK® Virus DNA & RNA Extraction Kit for rapid, specific, and sensitive detection of potential virus contamination in the CHO cell matrix.

Product Number	Product Name	Quantity
1506742	SHENTEK® MVM Detection Kit	50 Reactions
1506747	MVM Positive Control	100μL × 3 tubes
1506743	SHENTEK® Vesivirus 2117 Detection Kit	50 Reactions
1506743-R01	Vesivirus 2117 Positive Control	100μL × 3 tubes
1506744	SHENTEK® Porcine Circovirus (PCV-1) Detection Kit	50 Reactions
1506744-R01	PCV-1 Positive Control	100μL × 3 tubes
1506745	SHENTEK® Porcine Circovirus (PCV-2) Detection Kit	50 Reactions
1506745-R01	PCV-2 Positive Control	100μL × 3 tubes

07

CELL LINE CHARACTERIZATION

Cell line characterization is vital for confirming species identity, detecting contamination, and ensuring cell functionality. HZSKBIO offers an efficient solution for effective cell line monitoring and genomic integrity assessment. Our extraction-free method provides rapid species identification and sensitive cross-contamination detection using a multiplex PCR-based assay. SHENTEK® Telomerase Assay Kit, utilizing real-time PCR, quantifies telomerase activity - a key indicator of cellular immortality, proliferation, and aging. The reverse transcriptase activity assay reliably detects RNA viruses, safeguarding cell line integrity. For immune response analysis, the Human IL-6 ELISA Kit and Human IFN-γ ELISA Kit are ideal for assessing cell health and functionality in bioprocess monitoring.

7.1 SHENTEK® 10-Species Identification Kit (Multiplex qPCR method)

HZSKBIO® designed 10 species-specific primer pairs, targeted at conserved sequences of the cytochrome Coxidase I and II genes and the cytochrome b gene, that function in a multiplex PCR-based assay and generate a size specific amplicon for each of the species detected. The amplified fragments were analyzed according to their sizes by electrophoresis on 2% agarose gels. This method provides a rapid, simple, highly sensitive and cost-effective method for identification of ten species (Cattle, Pig, Dog, Cat, Mouse, Rat, Chinese Hamster, African Green Monkey, Rhesus Monkey and Human), and cross-contamination detection. The sensitivity was determined as equivalent to an amount of DNA as 4 cells/reaction, and the detection limit of interspecies cross-contamination was verified to 1 alien cell/1000 cell concentration or even lower. Compared to isoenzyme biochemical analysis, the application of PCR technique to the cell line authentication requires only a single amplification assay with sufficient cross-contamination sensitvity and inexpensive reagents. The kit includes CSI extraction buffer, resulting in an extraction-free sample preparation that does away with DNA isolation, and that can be used for direct amplification. Consequently, time is reduced compared to DNA isolation-based approaches, as well as traditional culture-based approaches.

Product Number	Product Name	Quantity
1801940	SHENTEK® 10-Species Cell Line Identification Kit	50 Reactions

7.2 SHENTEK® Reverse Transcriptase Assay Kits

Recent studies showed many viral sequences are integrated or 'endogenized' in the genomes of various eukaryotes.Retroviruses and other endogenous viruses can be detected via a PCR-based reverse transcriptase assay. The SHENTEK® Reverse Transcriptase Assay Kit is a convenient and efficient method for quantitative determination of reverse transcriptase activity in cell cultures and other biological samples. It uses MS2 RNA as the template, for detection of the specific PCR amplification, after active reverse transcription. A positive result would suggest employing other methods for further confirmation of the retrovirus contamination.

Positive assay control of the reverse transcriptase assay, are prepared according to the Chinese Pharmacopoeia 2020 and supplied separately.

Product Number	Product Name	Quantity
1505700	SHENTEK® Reverse Transcriptase Assay Kit	50 Reactions
1505701	SHENTEK® Reverse Transcriptase Assay Control	25 µL × 1 tube

7.3 SHENTEK® Telomerase Assay Kit

Telomerase activity is exhibited in stem or tumor cells. It can be measured in vitro by a sensitive and efficient polymerase chain reaction (PCR)-based detection method, also known as telomeric repeat amplification protocol (TRAP). This assay can be used to monitor the stem cell growth and viability, also used for the tumorigenicity assessment in cells. SHENTEK® Telomerase Assay Kit performs rapid and accurate quantitation of telomerase activity with the limit of quantitation at 0.4 TPG/reaction or 2 A549 cells/reaction or below. The assay employs the internal control to rule out inhibition and avoid false negative results. This duplex qPCR method is a time and cost effective approach by reducing reagent and sample usage, enhancing throughput, preventing sample contamination, and eliminating the need for additional procedures such as gel electrophoresis or ELISA analysis.

Product Number	Product Name	Quantity
1802950	SHENTEK® Telomerase Assay Kit	200 Reactions

7.4 SHENTEK® Human IFN-γ ELISA Kit

This kit is specifically designed for the quantitative detection of Human Interferon-γ in biologics, including applications such as CAR-T cell potency evaluation. The assay involves adding standards, controls, and samples to the pre-coated microplate wells, followed by the addition of a detection antibody to form a double-antibody sandwich complex. This complex generates a measurable signal for accurate quantification. The kit's performance has been fully validated, ensuring sensitivity, specificity, precision, and lot-to-lot consistency, in compliance with pharmacopoeial standards.

Product Number	Product Name	Quantity
1402430	SHENTEK® Human IFN-γ ELISA Kit	96 Tests

7.5 SHENTEK® Human IL-6 ELISA Kit

In biomanufacturing and cell culture monitoring, IL-6 testing is essential for evaluating the cell health and the effectiveness of culture conditions. This kit provides quantitative detection of Human IL-6 (hIL-6) in biologics, such as cell culture supernatants and serum. The assay begins by adding standards, controls, and test samples to a pre-coated microplate with monoclonal anti-hIL-6 antibody. A sandwich complex is formed through the addition of biotinylated monoclonal anti-hIL-6 antibody, which generates a measurable signal upon reaction with the substrate. This assay has been full validated to ensure the stable, reliable performance for effective bioprocess monitoring.

Product Number	Product Name	Quantity
1402431	SHENTEK® Human IL-6 ELISA Kit	96 Tests

SHENTEK

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