SHENTEK

Biologics Quality Control Solutions

Kits & Instruments 2026

Premium Products, Consistent Quality.

For Research Use Only. Not for diagnostic or therapeutic use.

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ABOUT US

SHENTEK®, founded in 2012, is a biotechnology company with core operations in China and the United States. SHENTEK® serves global partners in the development and manufacturing of biologics, offering SHENTEK® products as high-quality quality control (QC) solutions for the biopharmaceutical industry. SHENTEK® operates across multiple centers, including Huzhou and Shanghai in China, Singapore and California, US, supporting customers throughout the development and manufacturing lifecycle of biologics.

Our standardized and customized QC products cater to diverse cell types and manufacturing processes. We have successfully supported thousands of customers—from R&D to product release—including pre-IND, IND, and BLA filings by biopharmaceutical companies, CROs/CDMOs, and research institutions. Our expertise spans cell and gene therapy, vaccines, antibodies, recombinant proteins, animal-derived medical devices, and biochemical products.

SHENTEK® is ISO 13485 certified and provides both standardized and customized solutions, including host cell DNA/protein quantitation, gene vector safety analysis, process impuritiy testing, adventitious agent detection, and cell line characterization, etc. Our solutions address QC needs across the entire workflow, from raw materials and in-process samples to final product release.

Committed to advancing technologies and innovating methods, SHENTEK® continuously makes biologics quality control simpler, faster, and more reliable. Whether you need ready-made products or tailored solutions, SHENTEK® is your trusted partner for reliable QC.

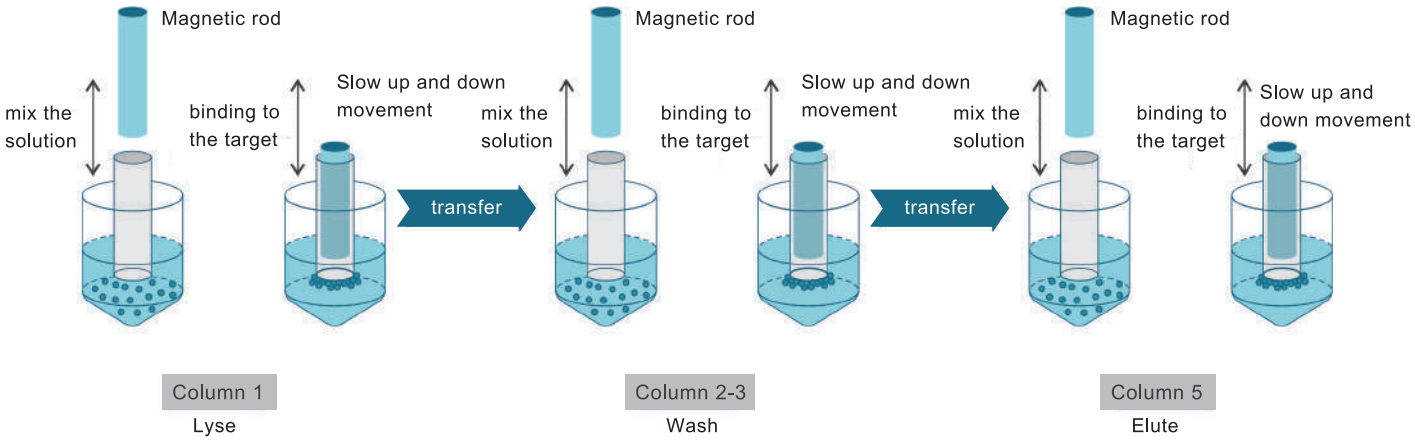
01

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® 96H Real-time PCR System

- ☑ 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® 96H real-time PCR system provides maximum performance in one-click operation mode and user-friendly wizard interface. lts exceptional temperature and optical precision ensure that assay calibration is of high accuracy; and sensitivity, lt 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 assays, and lower the risk due to manual errors, ensuring accurate and reliable quantitation.

Parameter	Performance
Sensitivity	Min. resolution of 1 copy
Range	10^0-10^{10} copies
Repeatability	CV < 1.00%
Linear Correlation Coefficient	$\|r\| \geqslant 0.9990$
Detection Channels	8 fluorescence detection channels, no crosstalk between the six channels of FAM / VIC / ROX / CY5 / QUASAR705 / ATTO425
Temperature Span	4°C - 99°C
Heating Rate	0 - 9.0°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.

SHENTEK® 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

The 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, SHENTEK® 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
1104201	SHENTEK® Residual Host Cell DNA Sample Preparation Kit (Fast)	100 Extractions
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 pastoris* , 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
1101101	SHENTEK® Residual Sf9 & AcNPV DNA Quantitation Kit	100 Reactions
1101102	SHENTEK® Residual Hi5 & AcNPV DNA Quantitation Kit	100 Reactions
1101103	SHENTEK® Residual *Saccharomyces cerevisiae* DNA Quantitation Kit	100 Reactions
1101104-1	SHENTEK® Residual HEK293 DNA Quantitation Kit (3G)	100 Reactions
1101105	SHENTEK® Residual CV-1 DNA Quantitation Kit	100 Reactions
1101109	SHENTEK® Residual E1A DNA Quantitation Kit	100 Reactions
1101110	SHENTEK® Residual E1B DNA Quantitation Kit	100 Reactions
1101116	SHENTEK® Residual BHK DNA Quantitation Kit	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
1403443	SHENTEK® Residual SV40 LTA & E1A DNA Quantitation Kit (2G)	100 Reactions
SK030222HA100	SHENTEK® Residual *Hansenula polymorpha* DNA Quantitation Kit	100 Reactions
SK030208N100	SHENTEK® Residual NS0 & SP2/0 DNA Quantitation Kit	100 Reactions
SK030227V100	SHENTEK® Residual Vero DNA-154 Quantitation Kit	100 Reactions
1101117	SHENTEK® ResHCD™ CHO DNA Quantitation Kit	100 Reactions
1101118	SHENTEK® ResHCD™ *E. coli* DNA Quantitation Kit	100 Reactions
1101119	SHENTEK® ResHCD™ Human DNA Quantitation Kit	100 Reactions
1101120	SHENTEK® ResHCD™ Plasmid DNA Quantitation Kit	100 Reactions
1101121	SHENTEK® ResHCD™ Vero DNA Quantitation Kit	100 Reactions
1101122	SHENTEK® ResHCD™ *Pichia pastoris* DNA Quantitation Kit	100 Reactions
1101127	SHENTEK® ResHCD™ MDCK DNA Quantitation Kit	100 Reactions
SK030210Q	2×qPCR 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)

SHENTEK® 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

SHENTEK® operates highly efficient animal immune pipelines for polyclonal antibody production, enabling the geretation of high-titer, highly specific antibodies with broad coverage accross HCP populations encountered throughout the bioprocess. SHENTEK® has developed a comprehensive HCP ELISA portfolio, includes solutions for major bioproduction platforms, such as E. coli BL21, E. coli K-12, and CHO. These include HCP ELISA kits specifically designed for BL21-based bioproduction, plasmid production and downstream alkaline lysis processes, as well as CHO-based bioprocesses, etc. The kits support reliable HCP quantitation across in-process samples, bulk drug substances, and final drug 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
1301305-1	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
1301311Z01	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. SHENTEK® provides specific antibodies to HCP antigens. SHENTEK® 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-Ab02	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

SHENTEK® 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)

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

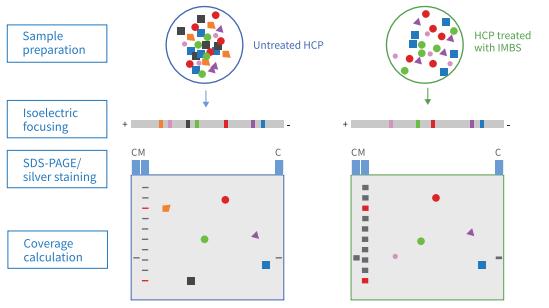
- Identification and quantitation of the individual HCP in a sample;
- Precise analysis of high-risk and process-specific HCPs for bioprocess development;
- Precise analysis of lot-to-lot HCP differences, especially for preclinical and clinical trial batches;
- Traceability system for HCP ELISA standards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

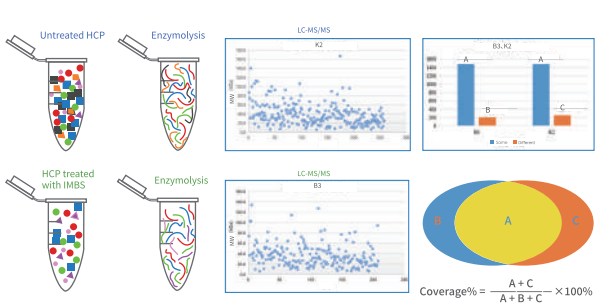
Combined with proprietary IMBS (immunomagnetic bead separation), SHENTEK® has employed two different HCP coverage assessment technology platforms - IMBS-2D and IMBS/LC-MS, to valuate the coverage of HCP recognition by antibodies, and the coverage of the high-risk HCP immunogens in both the assay standard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

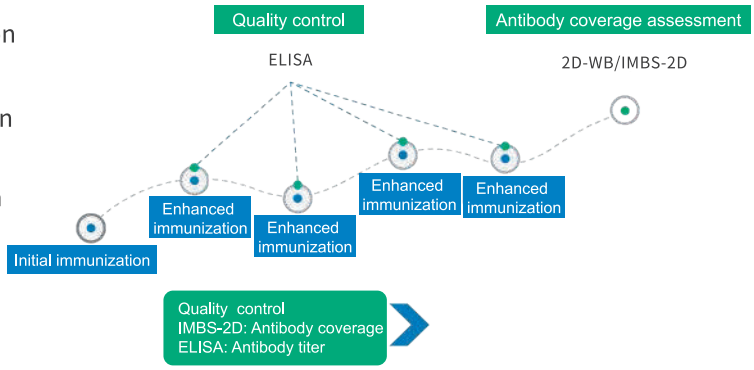
3.2.3 Anti-HCP polyclonal antibody preparation platform

1) HCP immunogen and reference standard analysis:

- HCP profile analysis and antigen generation & selection strategies
- HCP reference standards and immunogenic protein identification
- Tailored 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

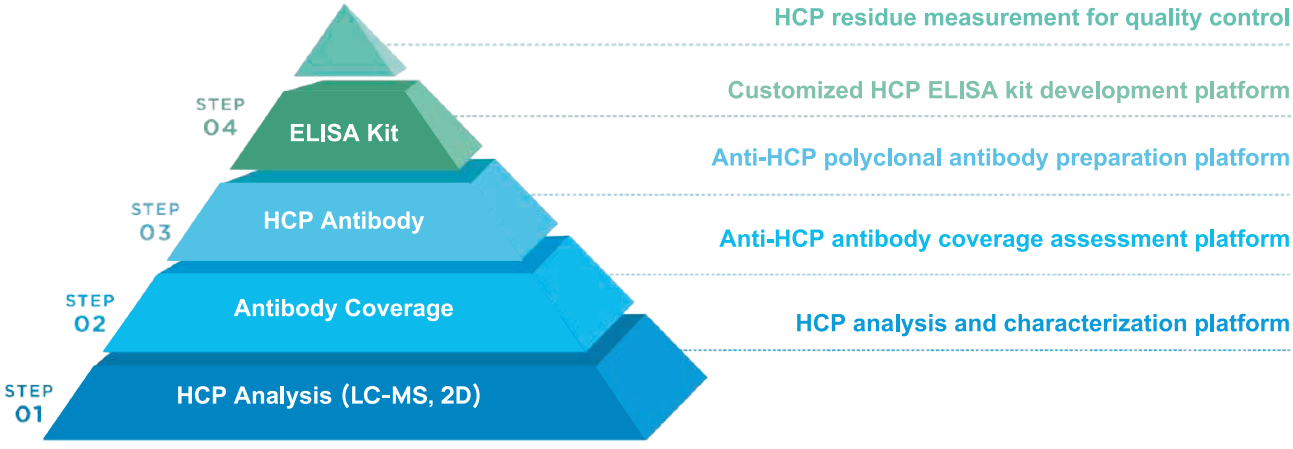


Quality control, in the multiple antibody preparation platform, comprise of using ELISA for antibody titer, and IMBS-2D/LC-MS for antibody coverage assessment, ensuring consistent quality of key components of the ELISA test kits.

3.2.4 Customized HCP ELISA kits

SHENTEK® 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. SHENTEK® 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 transgenes into cells during the development and manufacturing of cell therapy products.However, variations in vector transduction efficiency among individual cells can result in different numbers of integrated transgene copies per cell, leading to heterogeneous transgenepression and functional characteristics within the cell population.

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

A Multiplex real-time PCR assay has been developed for the detection and relative quantification of the average gene-of-interest transgene copy number by comparing the genomic DNA copies of the transgene DNA for transgene a single-copy reference gene in human cells. Quantitation reference standards are included in the kit to support accurate and consistent measurement.

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 generation is an important biosafety concern in viral vector manufacturing. Although the probability of generating replication-competent viruses is low, recombination or contamination during vector production may introduce potential safety risks. Sensitive and accurate RCV detection is therefore essential for quality control throughout the viral vector manufacturing process.

SHENTEK® provides replication-competent virus qPCR assay kits for the quality control testing of different replication-defective viral vectors. The assays support testing across multiple critical stages including 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 enables rapid and sensitive detection and quantification of replication-competent lentivirus (RCL) in lentiviral vector manufacturing and post-transduction cell and gene therapy products. It supports testing of a broad range of sample types, including master or working cell banks, end of production cells, viral vector harvest or supernatant, and CAR-T cells. The kit utilizes real-time RT-PCR to detect and quantify specific RCL sequences by comparing amplification signals between standards and samples under identical reaction conditions. An RCL quantification standard is included for accurate and consistent quantification. 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 ISO 13485 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 and quantitation of replication-competent retrovirus in retrovirus vector preparations and post-transduction cell & gene therapy products. Applicable sample type include master or working cell banks, end of production cells, viral vector harvest and supernatant, and CAR-T cells. Based on real-time RT-PCR technology, the assay quantitatively determines RCR by comparing the amplification of specific target sequences in samples and RCR standards under identical reaction conditions. An RCR quantification standard is included in the kit, enabling accurate and reliable determination of RCR copy numbers. 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 ISO 13485 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 designed for rapid and sensitive detection and quantitation of replication-competent AAV in rAAV vector preparations, and AAV-based gene therapy products. The serotype-specific qPCR assay could be performed following a cell-based amplification step to separate the replication competent AAVs from replication defective AAVs. Alternatively, it can be directly applied to viral vector products for the detection of potentially low-level rcAAv contamination. The kit includes a reference sequence and the corresponding target sequence in the same quantification standard, enabling rapid, sensitive, and serotype-specific quantification of both rAAV vectors and rcAAV in a single workflow. For rcAAV detection, the qPCR target spans the AAV ITR–rep gene junction, a critical genetic feature required for AAV replication. This target design provides high specificity for rcAAV and enables sensitive detection of potential rcAAV contamination in rAAV products. SHENTEK® 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 the efficient extraction of high-quality viral nucleic acids from different sample matrices, including cell culture with cell densities of up to 10^7 cell/mL as well as viral harvest or supernatant. The extraction efficiency has been verified across different sample types and viral concentrations, such as pseudoviruses, armored RNA viruses, bovine viruses in cell culture medium, and replication-competent viruses in viral vector samples supporting reliable performance in downstream molecular assays. 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

Flexible Sample Pretreatment for Different Viral Replication Strategies:

Sample pretreatment following cell lysis can be tailored according to the viral replication and localization characteistics.

For viruses that localize to the nucleus and may integrate into or associate with host-cell DNA during replication—including replication-competent viruses such as RCL/RCR, most DNA viruses such as rcAAV, and potentially unknown adventitious viruses—samples can be treated with Benzonase® nuclease after cell lysis to digest released host-cell genomic DNA and reduce background interference prior to viral nucleic acid extraction.

For viruses that primarily utilize host transcription and translation machinery in the cytoplasm, such as most RNA viruses, the lysate can be centrifuged after cell lysis, and the resulting supernatant can be directly subjected to viral nucleic acid extraction. This flexible pretreatment strategy helps optimize viral nucleic acid recovery while minimizing interference from host-cell nucleic acids.

05

PROCESS IMPURITY 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, SHENTEK® 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 enables sensitive and reliable quantitation of residual Serratia marcescens nonspecific endonuclease residues in downstream processing samples and product release testing. The assay performance is fully validated with high sensitivity, specificity, reproducibility and LOQ as low as down to 0.25 ng/mL. It is applicable to SMNE derived from both natural resources and recombinant protein expressed using SNME gene constructs, delivering high specificity and consistency. This kit is developed and manufactured in compliance with ISO13485 quality requirements and includes the reference standard traceable to China national standards, ensuring reliable and consistent quantitation.

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 and downstream purification. This kit is specifically designed to recognize trypsin derived from porcine pancreas as well as recombinant trypsin expressed from porcine trypsin gene constructs. With its high sensitivity, accuracy and specificity, the assay has been fully validated with a limit of quantitation (LOQ) as low as 0.040 ng/mL.

SHENTEK® also provides the Trypsin-analog ELISA Kit for the detection and quantitation of residues from ThermoFisher TrypLE™ or Sartorius Accutase™. The assay features a simple workflow and has been fully validated in accordance with applicable pharmacopeial requirements.

Both Kits use sheep antibody-coated microplates and are supported by a stable supply, ensuring consistent assay performance and reliable lot-to-lot availability.

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 derived from cows and widely used in cell culture media as a supplement to support cell growth and proliferation. However, residual BSA in biopharmaceutical products may pose potential safety and quality concerns, particularly for products intended for clinical use. 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. Its analytical performance has been fully validated in accordance with applicable pharmacopeial requirements. The kit is developed and manufactured in compliance with ISO 13485 quality management requirements and applicable regulatory standards, providing a reliable solution for residual BSA monitoring throughout bioprocess development and product quality control.

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 generally not permitted in the manufacture of biological medicinal substances and products intended for human use. therefore, the use of antibiotics should be minimized during bioprocess development. When antibiotics are necessary, antibiotics level must be monitored to control potential safety and immunogenicity risks. During downstream processing the antibiotics should be efficiently removed and removal process should be appropriately validated. Residual antibiotic levels in downstream processing samples and final products should be quantitatively determined to ensure compliance with established specifications.

SHENTEK® Kanamycin ELISA Kit is a rapid, sensitive and quantitative assay for the detection of kanamycin residue in biological samples, especially in those utilizing kanamycin- resistant plasmids for the development of gene therapies, cell-based vaccines, and other biotherapeutics. The kit is based on an indirect-competitive enzyme immunoassay. Kanamycin in the sample competes with antigen coated on the microtiter plate for binding to a specific antibody. Following the addition of enzyme conjugate and chromogenic substrate, the resulting signal is measured by a spectrophotometer. The absorbance is inversely proportional to the kanamycin concentration in the sample. Kanamycin concentration 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 SHENTEK® 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 readily evaluated following appropriate dilutions to demonstrate assay suitability for specific applications.

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

06

ADVENTITIOUS AGENT DETECTION

SHENTEK® provides rapid microbiological methods (RMM) for efficient mycoplasma, mycobacteria, bacteria, fungi and Viral 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 180 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 <63> and JP XVII requirements, and verified by third-party laboratories. The fully automated sample-to-result workflow, from DNA extraction through qPCR analysis, can be completed in less than 6 hours using the compatible Sample Preparation System and qPCR 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 up to 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
1509841-St06	MycoSHENTEK® *Acholeplasma laidlawii* Sensitivity Standard (10 CFU)	5 tubes, 10 CFU/tube
1509841-St07	MycoSHENTEK® *Mycoplasma fermentans* Sensitivity Standard (10 CFU)	5 tubes, 10 CFU/tube
1509841-St12	MycoSHENTEK® *Mycoplasma salivarium* Sensitivity Standard (10 CFU)	5 tubes, 10 CFU/tube
1509841-St13	MycoSHENTEK® *Mycoplasma hominis* Sensitivity Standard (10 CFU)	5 tubes, 10 CFU/tube
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 and ChP, all biological starting materials 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;
- Broad detection coverage for more than 100 Mycobacterium species with LOD of 10 CFU/mL;
- High specificity with no cross-reactivity observed with nearly 50 closely related microorganisms or engineered cell lines;
- Robust performance in various sample matrices, even in high-density cell cultures at up to 10 cells/mL, including CHO, HEK293T, Vero, and other cell lines;
- Broad applicability for mycobacterial testing and lot release 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

6.3 Bacteria and Fungi Fast Detection qPCR Kits

Compendial sterility testing is generally performed by membrane filtration or direct inoculation of culture medium with a product to be examined. However, conventional growth-based sterility tests have inherent limitations, including their dependence on culturable microorganisms and a lengthy incubation period of up to 14 days. These limitations can be particularly challenging for in-process control and release testing of sterile, short-shelf-life products. Regulatory guidance supports the use of alternative methods when they have been demonstrated to be equivalent to or better than compendial methods. Such approaches can enable more timely microbial detection and support effective contamination risk management, particularly in the manufacturing of advanced therapy medicinal products (ATMPs).

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 delivers robust microbial DNA recovery and sensitive detection across diverse and challenging sample matrices, including high-density cell cultures (up to 10 cells/mL of Vero, HEK293T, CHO, and other cell types), 5% human albumin, and high-titer plasmid preparations.

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 (e.g. high-Density Cell 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, using compatible instrumentation - e.g. 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 represents a critical biosafety risk. In vitro testing is an important component of viral safety assessment in accordance Multiple bovine viruses can be screened within a streamlined testing workflow, reducing testing time and eliminating the need to perform separate assays for each target. This integrated solution provides a rapid, sensitive, and reliable approach for bovine virus testing during cell bank characterization, process development, and quality control of biopharmaceutical products. with applicable ICH guidelines and pharmacopoeial requirements.
SHENTEK® provides a series of in vitro assays designed for retrovirus detection and adventitious virus screening, combining species-specific qPCR assays for targeted viral detection with next-generation sequencing (NGS) for broad, unbiased screening of unknown or unexpected viral contaminants.

6.4.1 SHENTEK® bovine virus detection kits

When establishing cell banks, bovine virus testing is essential when bovine-derived materials, such as bovine serum and bovine serum albumin, are utilized during cell culture or bioprocessing. SHENTEK® 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 of down to 50 copies/reaction with high specificity. Each kit includes an internal quality control to ensure reliable results. The bovine virus detection kits can be used in combination with the SHENTEK® Virus DNA & RNA Extraction Kit to provide an integrated sample-to-result workflow. The workflow supports efficient extraction and detection of bovine viral contaminants from diverse sample matrices, including high-density cell substrates (up to 107 cells/mL) 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. Multiple bovine viruses can be screened within a streamlined testing workflow, reducing testing time and eliminating the need to perform separate assays for each target. This integrated solution provides a rapid, sensitive, and reliable approach for bovine virus testing during cell bank characterization, process development, and quality control of biopharmaceutical products.

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

6.4.3 Specific virus detection kits for CHO cell line

CHO cell-based bioproduction carries a potential risk of viral contamination, making targeted viral testing an important component of viral safety assessment. SHENTEK® provides a portfolio of virus detection kits for key viral contaminants associated with CHO-based bioprocessing, including Mouse Minute Virus (MVM), Vesivirus 2117, Porcine Circovirus Type 1 (PCV-1), and Porcine Circovirus Type 2 (PCV-2). Based on real-time PCR (qPCR) technology, these assays enable rapid, sensitive, and specific detection of viral contaminants in CHO cell matrices. When used in combination with the SHENTEK® Virus DNA & RNA Extraction Kit, they provide an integrated workflow for efficient viral nucleic acid extraction and targeted detection, supporting viral safety testing throughout CHO-based bioprocess development and

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

6.4.4 EndoSynX™ Endotoxin Detection Kit – Recombinant Cascade Kinetic – Chromogenic Assay (rCKA)

EndoSynX™ rCKA Endotoxin Detection Kit is based on a recombinant Factor C cascade. Endotoxins activate Factor C, which sequentially activates Factor B and a proclotting enzyme. The activated enzyme cleaves a chromogenic substrate, releasing p-nitroaniline (pNA) that produces a yellow color measurable at 405 nm which the rate of absorbance increase is proportional to the endotoxin concentration.

Fully compliant with USP <85>, FDA BET guidance, and ICH Q6B, the kit aligns with the 3R (Replace Reduce, Refine in testing) principles and offers an eco-friendly alternative to traditional LAL bacterial endotoxin testing methods. It delivers proven performance equivalent to gel-clot, kinetic turbidimetric (KTA), and chromogenic assays, while recombinant production ensures outstanding lot-to-lot consistency.

Parameter	Performance
Linearity	5.0-0.005 EU/mL with correlation coefficient | r | ⩾ 0.999
LOQ	0.005 EU/mL
Precision	Upper limit of 95% confidence interval of RSD for all the samples ⩽ 30%
ACCuracy	The 95% confidence interval of recovery within 95%-115%
Robustness	Consistent results across different microplates at 406 nm absorbance
Specificity	Demonstrated detection capability for endotoxins from various bacterial

The EndoSynX™ rCKA Endotoxin Detection Kit is the ideal eco-friendly and regulatory-aligned choice for endotoxin testing in pharmaceutical, biomedical and research applications. Designed for maximum flexibility, a single kit supports two independent assay runs, allowing laboratories to maximize reagent utilization, minimize waste, and reduce testing costs. Delivering accurate and reliable endotoxin quantification over a broad dynamic range of 5–0.005 EU/mL, the kit ensures consistent performance from routine QC testing to ultra -low endotoxin analysis.

Product Number	Product Name	Quantity
1501114	SHENTEK® EndoSynX™ Recombinant Cascade Kinetic-Chromogenic Assay (rCKA) Kit	96 tests

07

CELL LINE CHARACTERIZATION

Cell line characterization is vital for confirming species identity, detecting contamination, and ensuring cell functionality. SHENTEK® 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)

The SHENTEK® 10-Species Identification Kit provides a rapid and cost-effective solution for mammalian cell authentication and cross-species contamination monitoring. The assay uses 10 species-specific primer pairs targeting conserved regions of the cytochrome c oxidase I (COI), cytochrome c oxidase II (COII), and cytochrome b (cytb) genes. Multiplex PCR generates species-specific amplicons with characteristic sizes, which are readily differentiated by 2% agarose gel electrophoresis.

The kit enables identification of 10 mammalian species, including cattle, pig, dog, cat, mouse, rat, Chinese hamster, African green monkey, rhesus monkey, and human. With analytical sensitivity equivalent to as few as 4 cells per reaction, the assay can detect cross-species contamination at levels as low as 1 contaminating cell per 1,000 cells or lower.

Compared with conventional isoenzyme-based cell authentication, the PCR-based approach offers a simpler workflow, high sensitivity, and costeffective reagent use. The included CSI Extraction Buffer enables direct PCR amplification without DNA isolation, reducing sample preparation time and hands-on steps while streamlining cell authentication and contamination monitoring.

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 can become integrated into or 'endogenized' in the genomes of various eukaryotic organisms. Some endogenous retroviral elements and exogenous retroviruses may be associated with detectable reverse transcriptase (RT) activity. A PCR-based reverse transcriptase assay provides a sensitive approach for screening biological samples for RT activity as an indicator of potential retroviral contamination. 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, the resulting cDNA is amplified by PCR and detected using a specific amplification system, following reverse transcription by active RT. A positive result indicates detectable RT activity and may suggest the presence of retrovirus or other RT-associated activity. Positive samples should be further investigated using appropriate orthogonal methods to confirm the presence and identity of viral contaminants.

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 is highly active in many stem and cancer cells and plays an important role in maintaining telomere length. Telomerase activity can be measured in vitro using the telomeric repeat amplification protocol (TRAP), a sensitive PCR-based method for detecting telomerase-mediated extension of telomeric DNA. Telomerase activity measurement can support stem cell characterization and monitoring, as well as research applications related to cancer cell characterization and tumorigenicity.

The SHENTEK® Telomerase Assay Kit enables rapid and sensitive quantitation of telomerase activity, with a limit of quantitation (LOQ) of 0.4 TPG/reaction, corresponding to telomerase activity from as few as 2 A549 cells per reaction. An internal control is incorporated into the assay to monitor potential PCR inhibition and help minimize false-negative results.

Based on a duplex real-time PCR format, the assay provides a streamlined and cost-effective alternative to conventional TRAP detection workflows. It reduces reagent and sample consumption, minimizes hands-on time and the risk of amplicon contamination, and eliminates the need for postamplification procedures such as gel electrophoresis or ELISA-based detection, thereby supporting efficient and higher-throughput telomerase activity 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 assay 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

Interleukin-6 (IL-6) is a multifunctional cytokine that can serve as a relevant biomarker for monitoring cellular responses, inflammatory activity, and cell culture conditions in bioprocessing applications. The SHENTEK® Human IL-6 (hIL-6) ELISA Kit is designed for the sensitive and quantitative determination of human IL-6 in biological samples, including cell culture supernatants and serum.

The assay is based on a sandwich ELISA format. Standards, controls, and test samples are added to a microplate pre-coated with a monoclonal anti-hIL-6 capture antibody. Human IL-6 in the samples is captured by the immobilized antibody and subsequently detected using a biotinylated monoclonal anti-hIL-6 detection antibody. Streptavidin-HRP binds to the biotinylated detection antibody, and the addition of a chromogenic substrate generates a measurable colorimetric signal. The signal intensity is proportional to the concentration of hIL-6 in the sample.

The assay has been fully validated to demonstrate reliable and consistent analytical performance, supporting quantitative IL-6 monitoring in cell culture and bioprocessing applications.

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

Note:

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