

SHENTEK® Residual Host Cell DNA & RNA Quantitation



Product introduction

The SHENTEK® host cell residual DNA & RNA quantitation systems offer integrated solutions from sample preparation to qPCR assay for specific, rapid and reliable quantitation of residual Host Cell DNA (rHCD) and RNA (rHCR), covering production cell expression systems such as bacteria, yeast, insect, and mammalian cells, with sensitivity down to the fg DNA/ μ L level. The assays are compatible with SHENTEK® residual host cell DNA sample preparation kit, ensuring highly efficient DNA recovery. The system provides an easy workflow to deliver results in 5 hours. Internal Positive Control (IPC, VIC assay) is provided for optional use in every qPCR assay to exclude false negative results. The assay performance has been fully validated and complies with regulatory requirements. These kits have been applied successfully to QC tests for regulatory filings in USA, Europe, and other countries.

In addition, SHENTEK provides integrated solutions for the development and validation of customized assays for the species- or sequence-specific residual DNA/RNA quantitation, together with optimized sample pretreatment protocols for complex biological matrices. These assays are tailored to the specific detection requirements of different host cells and target sequences, supporting regulatory submissions and reliable batch release testing across a wide range of biologics.



info@shentekbio.com

☎ US Mobile: +1-908-822-3199

☎ US Office: +1-800-960-3004 ext 720

For Research Use Only.

Not for diagnostic or therapeutic use.

SHENTEK® Residual Host Cell DNA Sample Preparation Kits

1. Residual DNA sample preparation kits

The SHENTEK® Residual Host Cell DNA Sample Preparation Kit (Fast) is specifically designed for rapid and efficient pretreatment of residual host cell DNA (HCD) samples from biological products and process intermediates. Leveraging advanced magnetic particle technology with an optimized lysis system, the kit enables high-efficiency isolation and purification of trace levels of residual host cell DNA across a broad range of sample matrices, including challenging samples containing potential interfering substances such as chondroitin sulfate and heparin. The purified DNA is optimized for downstream quantitative residual DNA analysis, delivering reliable, consistent, and reproducible assay performance.

2. Residual RNA sample preparation kit

The kit enables efficient and reproducible extraction of residual host cell RNA from a broad range of biological products. Its optimized extraction chemistry enables robust RNA recovery while effectively removing potential inhibitors, providing purified RNA suitable for downstream RT-qPCR and other molecular assays. Consistent and reliable RNA recovery has been validated across diverse sample matrices.

Product Number	Product Name	Quantity
1104201	SHENTEK® Residual Host Cell DNA Sample Preparation Kit (Fast)	100 Extracts
1201205	SHENTEK® Residual Host Cell RNA Sample Preparation Kit	100 Extracts

SHENTEK® Residual Host Cell RNA Quantitation Kits

Based on real-time PCR technology, the SHENTEK® Residual Host Cell RNA Quantitation System is designed for the sensitive and specific quantification of residual host cell RNA in cell and gene therapy products derived from *E. coli* and HEK293T cells.

The kits use pre-designed specific primers and probes for one-step reverse transcription and amplification, providing high efficiency, specificity, and sensitivity. The kits have been validated on multiple qPCR platforms and are compatible with the SHENTEK® Residual Host Cell RNA Sample Preparation Kit for efficient RNA extraction.

Product Number	Product Name	Quantity
1201201-1	SHENTEK® Residual <i>E. coli</i> RNA Quantitation Kit (2G)	100 Reactions
1201202	SHENTEK® Residual 293T RNA Quantitation Kit	100 Reactions
1201203	RT-PCR Grade Water	16 tubes, 1.5 mL/tube

Validation of Residual Host Cell RNA Quantitation Assays

The qPCR assay performance validation was carried out with reference to USP (Chapter 1225), EP (Chapter 2.6.21), ChP (Chapter 9101) and ICH guideline Q2.

Parameters		Acceptance Criteria
Linear Range		Correlation coefficient: $R^2 > 0.990$; Efficiency: $90\% \leq E \leq 110\%$; The %CV should be within 15% of nominal concentration, 20% of nominal concentration at LLOQ and ULOQ.
Accuracy		The intra-assay values met: %CV: $\leq 30\%$; Recovery: 50% – 150%.
Precision	Repeatability	The values of 10 technical replicates of the same sample meets $CV \leq 15\%$.
	Intermediate precision	The %CV of 9 inter-assay values at each concentration level (total 3 concentrations) were less than 15% at nominal concentration levels, and 20% at LOQ level.
LOQ		The %CV of all replicates at the LOQ level are less than 20%.
Specificity		No cross-reactivity with nontarget DNA or RNA of the commonly used production cells, engineered bacteria and fungi, plasmid DNA, etc.
Robustness	Freeze-thaw stability	Stable assay performance for at least 5 freeze-thaw cycles.
	Instrument suitability	Good consistency of the assay performance on different qPCR instruments (e.g. SHENTEK-96S, ThermoFisher ABI 7500, Bio-Rad CFX-96, Bioer FQD-96A, etc.)

SHENTEK® Residual Host Cell DNA Quantitation Kits

The SHENTEK® Residual Host Cell DNA Quantitation Kit series provides a reliable solution for quantifying residual host cell DNA in biopharmaceutical products and drug substances. With optimized primers and advanced qPCR chemistry, the kits enable rapid, specific, and sensitive detection of trace residual DNA with femtogram-level sensitivity. High-quality DNA standards enable robust standard curve generation with excellent linearity across broad dynamic range, supporting accurate quantitation of residual Host Cell DNA from complex process intermediates to highly purified final biopharmaceutical products. Optimized primer design provides exceptional specificity toward target cell genomic DNA with no detectable cross-reactivity, ensuring reliable and accurate residual DNA quantitation across diverse sample matrices.

The SHENTEK® ResHCD™ Host Cell DNA Quantitation Kit series contains optimized enzyme formulations and proprietary stabilizing components to enhance reagent stability and tolerance against temperature fluctuations, enabling reliable transportation and extended storage. The assay demonstrated consistent performance following storage at 2–8°C for up to two months, with no significant impact on assay performance observed.

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® E1A Residual DNA Quantitation Kit	100 Reactions
1101110	SHENTEK® E1B Residual 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™ <i>E. coli</i> 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™ <i>Pichia pastoris</i> DNA Quantitation Kit	100 Reactions
1101127	SHENTEK® ResHCD™ MDCK DNA Quantitation Kit	100 Reactions

Validation of Residual Host Cell DNA Quantitation Assays

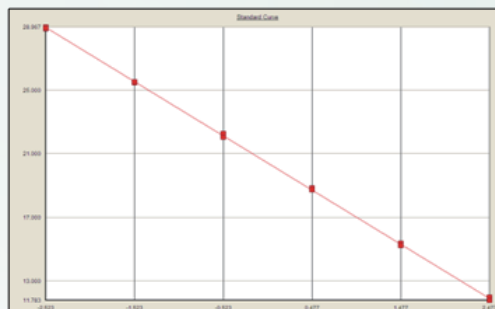
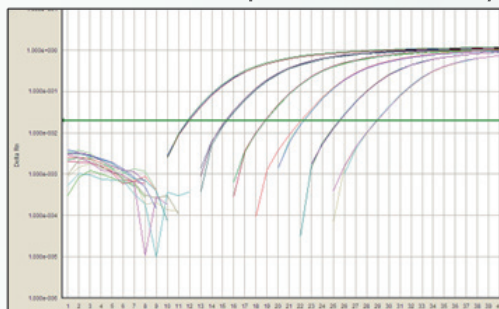
The qPCR assay performance validation was carried out with reference to USP (Chapter 1225), EP (Chapter 2.6.21), ChP (Chapter 9101) and ICH guideline Q2.

Parameters		Acceptance Criteria
Linear Range		3 or 30 fg/μL to 300 pg/μL (Please refer to the specific User Guide); Correlation coefficient: $R^2 \geq 0.990$; %CV (coefficient of variation) and %RE (relative error): < 30%.
Accuracy		DNA recovery using SHENTEK® residual host cell DNA sample preparation kit met the following acceptance criteria: %CV: < 20%; Recovery: 70-130%.
Precision	Repeatability	The values of 10 replicates of the same sample meets $CV \leq 15\%$.
	Intermediate precision	The %CV of 9 inter-assay values at each concentration level (total 3 concentrations) were less than 15% at nominal concentration levels, and 20% at LOQ level.
LOQ		The %CV of all replicates at the LOQ level are less than 20%.
Specificity		No cross-reactivity with nontarget DNA of the commonly used production cells, engineered bacteria and fungi, plasmid DNA, etc.
Robustness	Reference DNA robustness	DNA fragmentation by sonication has no effect on the reference DNA standards.
	Instrument suitability	Good consistency of the assay performance on different qPCR instruments (e.g. SHENTEK-96S, ThermoFisherABI 7500, Bio-RadCFX-96, BioerFQD-96A, etc.)

Case Study—Residual Host Cell DNA Quantitation

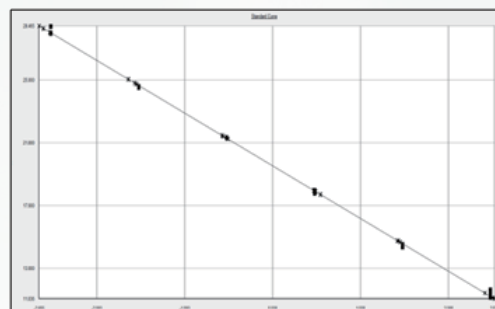
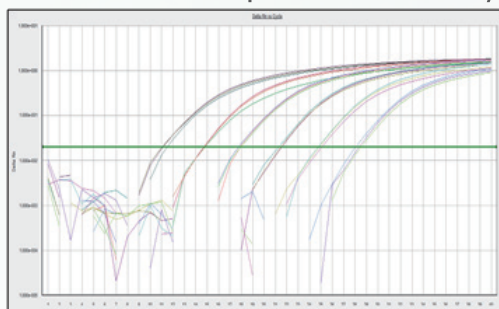
CHO HCD Validation performance—

Standard curve: Amplification efficiency 96.6%, Correlation coefficient 0.999



MDCK HCD Validation performance—

Standard curve: Amplification efficiency 98.2%, Correlation coefficient 0.999



Residual Host Cell Nucleic Acid Technical Service

1. Lab Service using standardized platforms

1) Residual host cell DNA quantitation method validation:

- Integrated SHENTEK® residual host cell DNA and RNA assay validation and sample testing services for a wide range of biological samples, including in-process samples, bulk products, and final products.

2) Sample testing:

- Specific sample testing services using SHENTEK® sample preparation kits and host cell DNA & RNA quantitation kits.

2. Customized Technical Service

1) Customized kit development for specific-species/sequence residual DNA or RNA assay:

- **qPCR method establishment:** Development of qPCR quantitation system, including DNA reference material, DNA extraction methods and specific PCR probe, primer and reagents for amplification and detection;
- **Assay validation:** Validation of linear range, accuracy, precision, quantitation limit, specificity and robustness in compliance with pharmacopeial requirements;
- **Automated sample preparation:** Development of automated protocols for DNA/RNA extraction and recovery validation using different sample purification systems.

2) Development of residual host cell DNA/RNA detection assay for microorganisms that is used for antibiotic fermentation:

- **qPCR assay development:** Species/sequence-specific quantitative PCR assay development for different microorganisms used for antibiotic production, to ensure highly sensitive quantitation with LOQ up to fg/μL DNA level;
- **Automated sample preparation:** Standard or customized automated workflows on different instruments for quantitative recovery and development of an integrated sample-to-result workflow.
- **Regulatory filing:** Expertise in regulatory dossier preparation and submission, including DMF submissions, with successful experience with both FDA and EMA.

3. Consultation & Training Programs

1) Laboratory capability improvement: Integrated QC solutions from laboratory design to test proficiency, to ensure qualified lab capability for the QC needs at different project stages

2) Customized training program: Protocol development and experimental training programs designed to improve specific qPCR assay capabilities.