

SHENTEK® Residual Host Cell DNA Size Analysis



Product introduction

Regulatory expectations generally recommend limiting residual host cell DNA to no more than 10 ng per dose, with DNA fragment sizes below 200 bp.

SHENTEK® Host Cell Residual DNA Size Analysis Kits are designed to quantify residual host cell DNA fragments of various lengths using four DNA-specific qPCR assays targeting distinct DNA size ranges: < 100 bp, 100-200 bp, 200-500 bp, and > 500 bp. The kits are used along side with Residual Host Cell DNA Quantitation Kits to analyze extracted DNA from test samples using SHENTEK® Residual DNA Sample Preparation Kits.

This product series is designed for a wide range of host cell lines, including *E. coli*, *Pichia pastoris*, CHO, Vero, MDCK, Sf9, and human cells. The assay quantify residual host cell DNA fragments of varying lengths at multiple stages of the manufacturing process. Assay performance has been independently evaluated by multiple third-party laboratories and validated to meets applicable pharmacopeial requirements.



SHENTEK® Residual DNA Sample Preparation Kits



Residual Host Cell DNA sample preparation kits

The SHENTEK® Residual Host Cell DNA Sample Preparation Kit (Fast) (Cat. NO. 1104201) has been further optimized based on the original version (Cat. NO. 1104191) to enable more 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.

Product Number	Product Name	Quantity
1104191	SHENTEK® Residual Host Cell DNA Sample Preparation Kit	100 Extractions
1104201	SHENTEK® Residual Host Cell DNA Sample Preparation Kit (Fast)	100 Extractions



SHENTEK® Residual Host Cell DNA Size Analysis Kits



Species-specific, sequence-specific host cell residual DNA quantitation and fragment size assessment can be evaluated simultaneously on real-time PCR (qPCR) system. The pre-designed primers and probes target species-specific gene sequences, generating amplicons across four predefined size ranges: <100 bp, 100-200 bp, 200-500 bp, and >500 bp.

Quantitation of cDNA fragment of different lengths in the samples were determined by a standard curve of DNA standard, with sensitivity reaching the fg/μL level. The assay performance has been fully validated, including linear range, accuracy, precision, limit of quantitation and specificity, in compliance with the applicable pharmacopoeia requirements. The kits contain size-specific DNA quantitation standards and can be used in combination with SHENTEK® Residual DNA Sample Preparation Kit, which is optimized for highly efficient residual DNA recovery from complex mixtures of proteins, buffers, salts, and other process-related components.

Product Number	Product Name	Size	rcDNA Fragment Size (bp)
1103170-2	SHENTEK® Residual CHO DNA Size Analysis Kit (2G)	4 × 100 Reactions	<100/100+/200+/500+
1103171-2	SHENTEK® Residual <i>E. coli</i> DNA Size Analysis Kit (2G)	4 × 100 Reactions	<100/100+/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 Residual 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+



Lab Service using standardized platform



1. Residual host cell DNA size analysis and method validation

SHENTEK® offers a comprehensive residual host cell DNA size analysis solution, encompassing method development, method validation, and sample testing services for a variety of biological samples, including in-process samples, bulk products, and final drug products.

2. Sample test

SHENTEK® provides specific sample testing services using its sample preparation and host cell DNA size analysis kits.

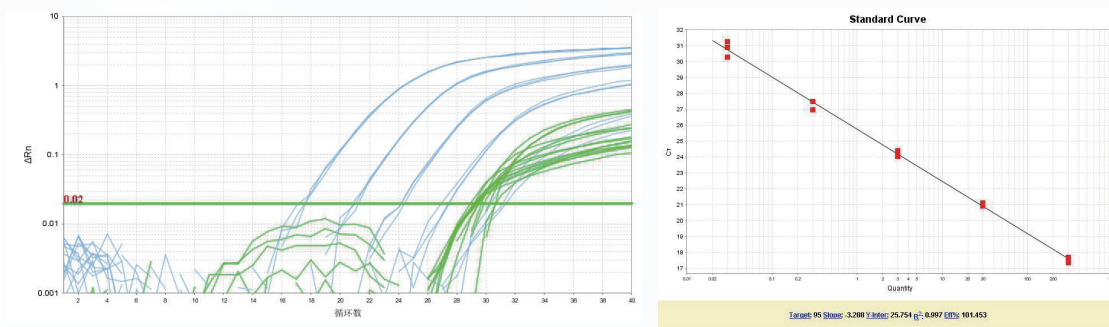
The qPCR assay performance was validated with reference to USP (Chapter 1225), EP (Chapter 2.6.21), ChP (Chapter 9101) and ICH guideline Q2.

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		The intra-assay values met the following acceptance criteria: CV: $< 30\%$; Recovery: 50%–150%;
Precision	Repeatability	The CV of 10 intra-assay values at both high and low concentration levels were less than 30.0%;
	Intermediate precision	The CV of 9 intra-assay values (3 concentration levels for each assay and 3 recoveries at each concentration level) were less than 30%;
Sensitivity		The detection limit met the specific acceptance criteria in the User Guide;
Quantitation Limit		The CV of all replicates at the LOQ level are less than 30.0%;
Specificity		No cross-reactivity with the commonly used production cells, engineered bacteria and fungi, plasmid DNA, etc.
Robustness	Freeze-thaw stability	Stable assay performance for at least 4 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, Bior LineGene 9600, etc.)

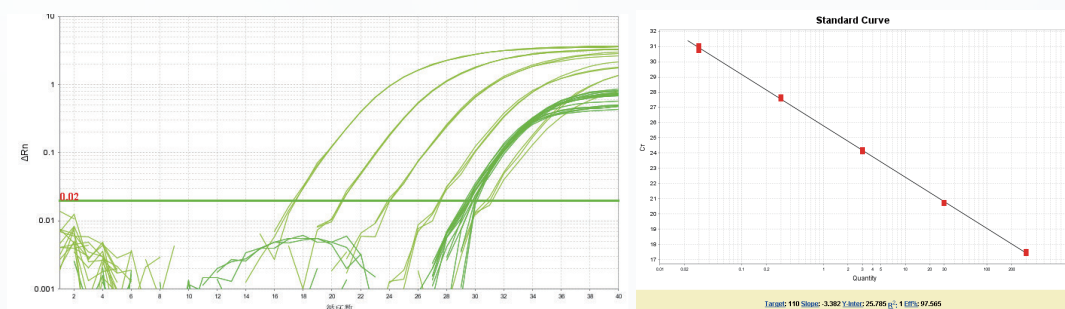
Case Study—CHO Host Cell DNA Size Analysis



Validation performance - standard curve for 95 bp DNA size analysis: Slope -3.288, amplification efficiency 101.5%, correlation coefficient 0.997

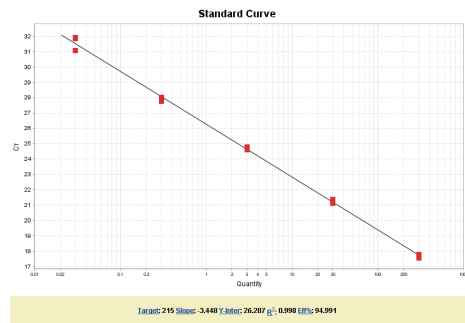
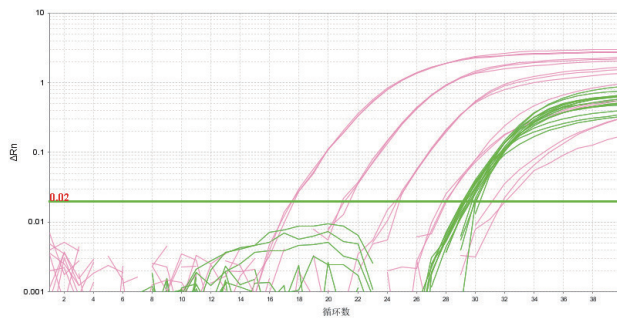


Validation performance - standard curve for 110 bp DNA size analysis: Slope -3.382, amplification efficiency 97.6%, correlation coefficient 1.000



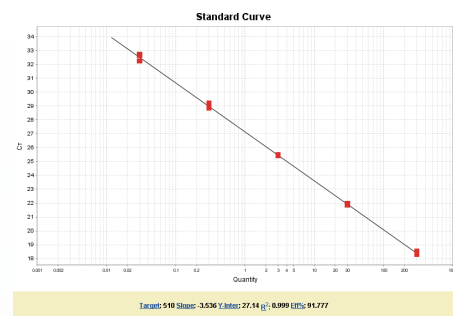
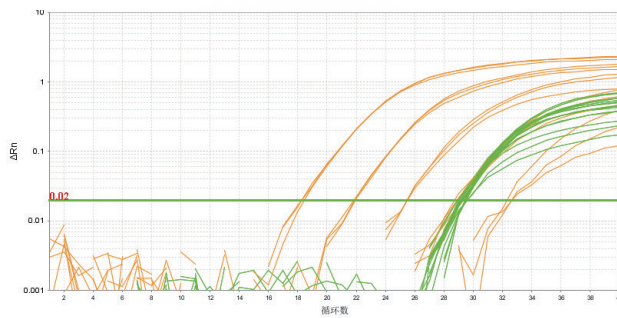
Validation performance - standard curve for 215 bp DNA size analysis:

Slope -3.448, amplification efficiency 95.0%, correlation coefficient 0.998



Validation performance - standard curve for 510 bp DNA size analysis:

Slope -3.536, amplification efficiency 91.8%, correlation coefficient 0.999



Customized Technical Service

Customized kit development for specific-species/sequence residual DNA size analysis and assay validation:

- qPCR assay 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 applicable pharmacopeial requirements;
- Automated sample preparation: Development of automated protocols for DNA extraction and recovery validation for the different sample purification systems.



info@shentekbio.com

US Mobile: +1-908-822-3199

US Tel: +1-800-960-3004 ext 720

CN Tel: +86-400-878-2189

<https://www.shentekbio.com>

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