BioFlux

Bioer Technology

E.coli Residual DNA Detection Kit (Fluorescence PCR)

Product Introduction

The E. coli Residual DNA Detection Kit (Fluorescence PCR) is designed based on real-time fluorescence PCR technology and is intended for the quantitative detection of residual E. coli host cell DNA which are used for production of biopharmaceutical products. This specialized kit features high specificity, excellent sensitivity, and rapid, convenient operation.

The kit can be used in combination with Bioer's magnetic bead-based sample pre-processing kit, MagaBio plus Residual DNA Sample Purification Kit (BSC132), for efficient detection of E. coli host cell DNA residues.

Product Features

- **Easy to use:** The primer-probe mix is pre-mixed in a single tube—just add the sample and proceed.
- **High specificity:** No cross-reactivity with unrelated DNA.
- **Comprehensive monitoring:** Exogenous internal control detection for process monitoring from sample extraction to PCR.
- **Good stability:** Less susceptible to contaminants in samples.

Technical Specifications

Parameters	Description
Intended Use	Quantitative detection of E.coli host cell DNA residues in the intermediates, semi - finished products, and finished products of various biological products and pharmaceuticals.
Method	qPCR
LOQ	30 fg/μL
Run Time	40 min
Recovery Rate	50%-150%
Recommended Purification Kit	BSC132 MagaBio plus Residual DNA Sample Purification Kit
Compatible Platform	LineGene 9600, QuantGene 9600, FQD-A1600, Roche LightCycler 480, Bio-Rad CFX 96 Real-Time PCR System, Thermofisher ABI 7500
Storage Condition	-25°C~-15°C

Application Cases

1.Linear Range: The linear range of the kit is 30 fg/μL to 300 pg/μL (STD5 - STD1), with an amplification efficiency of 100.3%. The results obtained on the Bioer FQD series fluorescence quantitative PCR instrument are consistent with those obtained on the ABI 7500.

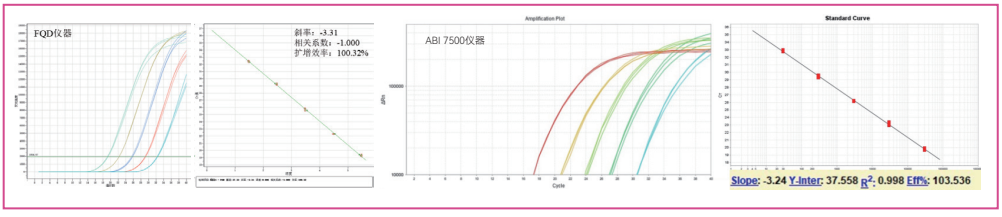

Figure 1. Standard curve of the E.coli Residual DNA Detection Kit

2.Detection Accuracy: The Bioer E.coli DNA reference material (working standard) shows no deviation from the amplification standard curve of the national standard material, with a CV of less than 5%.

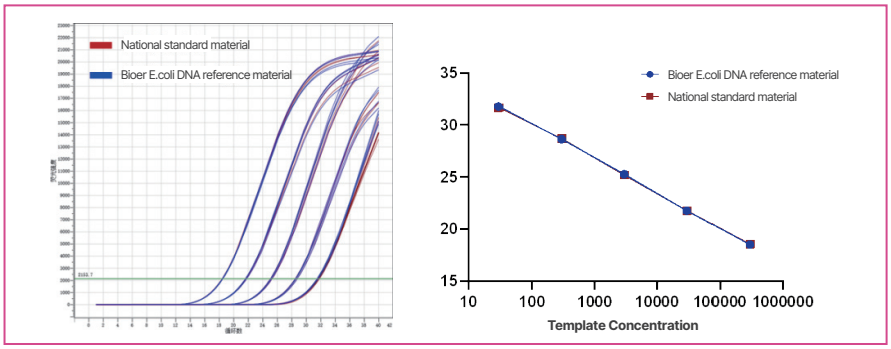

Figure 2. Comparison of Amplification Curves between Bioer reference material and National Standard material

3.Detection Specificity: The genomic DNA from HEK293, Vero, and CHO cells was tested for interference with the kit. The E.coli Residual DNA was unaffected even in the presence of up to 10 ng of background genomic interference.

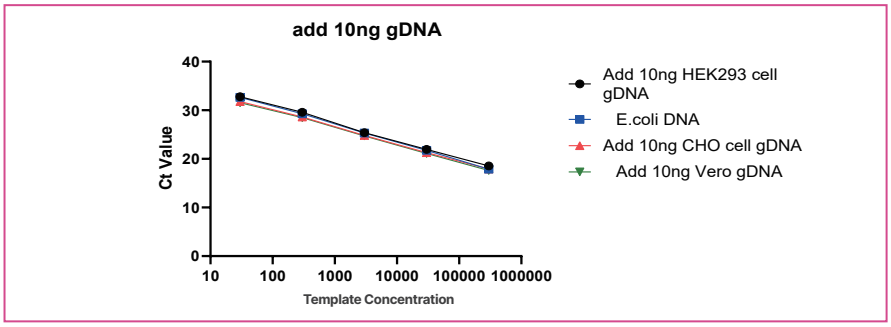

Figure 3. Specificity Detection Analysis of the E.coli Residual DNA Detection Kit

4.Stability:

1.The kit was used to repeatedly test the E.coli DNA concentrations at 30 pg/μL, 3 pg/μL, 300 fg/μL, and 30 fg/μL for 12 times. The Ct values and average concentrations are shown in the table below. The CV values (coefficient of variation) for the Ct values across replicates were all less than 1%, and the CV values for the concentrations across replicates were all less than 10%.

No.	Ct Value	SD	CV(%)
STD1	19.09	0.17	0.87
STD2	22.35	0.06	0.26
STD3	25.66	0.10	0.39
STD4	28.92	0.08	0.29
STD5	31.97	0.13	0.39

Table 1: Repeated Detection Ct Values for E.coli Residual DNA at Different Concentration Gradients

No.	Concentrations (pg/mL)	SD	CV(%)
STD1	302720.48	34392.40	11.36
STD2	29749.07	1207.86	4.06
STD3	2820.95	205.27	7.28
STD4	278.10	16.64	5.98
STD5	31.94	2.82	8.83

Table 2: Repeated Detection of E.coli Residual DNA at Different Concentration Gradients

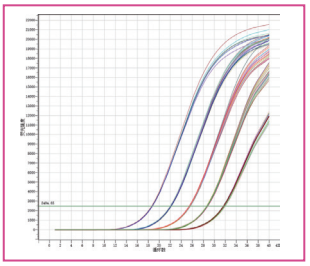

Figure 4. Amplification Curves of E.coli DNA at Different Concentrations from Repeated Detection

2.**Effect of DNA Fragmentation on E.coli DNA Detection:** After E.coli DNA was treated with different degrees of fragmentation, the detection results of DNA fragments greater than 200 bp (Sonicated DQ1 and Sonicated DQ2) were consistent with the control (High Molecular Weight) without fragmentation, indicating that fragmented DNA does not affect the detection of residual E.coli DNA.

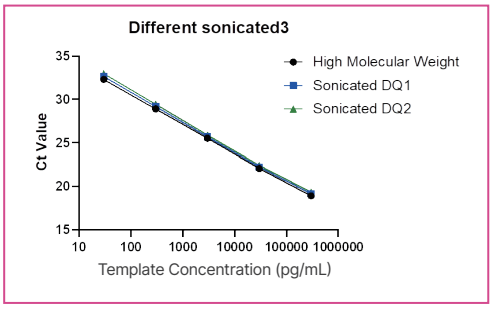

Figure 5. Ct Value Statistics of Amplification Curves for E.coli DNA with Different Degrees of Fragmentation

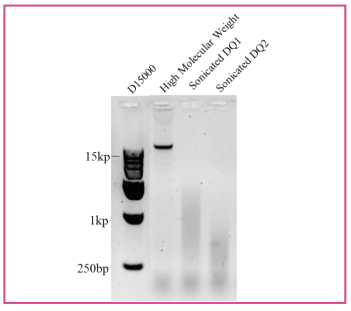

Figure 6. Gel Electrophoresis of E.coli DNA with Different Degrees of Fragmentation

Ordering Information

Product Name	Cat. No.	Package	Storage Condition
E.coli Residual DNA Detection Kit (Fluorescence PCR)	BSB127	50T/100T	-25°C~-15°C

BIOER TECHNOLOGY

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