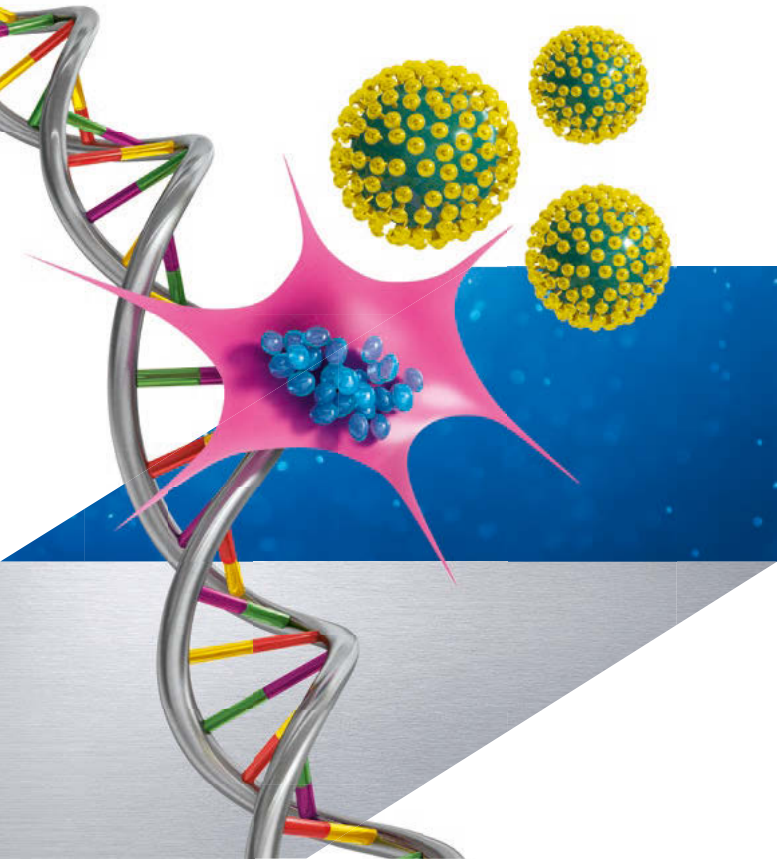
Residual DNA *E. coli* Kit

High sensitivity for optimal product safety

The removal of host cell impurities is a critical step in the production of biopharmaceutical products.
The Roche Residual DNA *E. coli* Kit is designed and validated for detection of residual *E. coli* DNA in biopharmaceutical products (protein solution, antibodies, etc.) as required by regulatory authorities.



Based on proven real-time qPCR technology, this kit makes detection of residual DNA from *E. coli* bacteria fast and reliable*. It was developed to meet sensitivity requirements defined by WHO and FDA (10 ng *E. coli* DNA per therapeutic dose).

Achieve high sensitivity and specificity through improved tests*

- Linearity: 10 µg/ml to 5 pg/ml
- Lower Quantitation Limit: 5 pg/ml (50 fg/reaction)
- Lower Detection Limit: 1 pg/ml (10 fg/reaction)
- No cross-reactivity with unrelated DNA

Rely on a robust test procedure for a wide range of sample types

- Suitable for different matrices and a broad range of sample types from both in-process samples to bulk drug substances
- High lot-to-lot consistency of kit reagents, leading to reproducible results

Save time with proven real-time qPCR technology

- Time to result <5 hours*

Characteristics

Residual DNA *E. coli* Kit	
Sample prep	Manual protocol optimized for excellent DNA recovery (min 80%).
Control concept	DNA stock solution for preparation of extraction controls and internal controls for PCR performance included in kit.
All reagents included	Supplied and ready-to-use reagents jump start your assay.
High quality	Roche is certified according to ISO 13485. Change notification available upon request.

*Data on file.

For use in quality control/manufacturing process only.

CUSTOMBIOTECH

Ordering information

Products	Catalog number
Residual DNA *E. coli* Kit	07 728 735 001
QC Sample Preparation Kit	08 146 829 001
Additional Quality Control or In-Process Manufacturing Kits	
MycoTOOL Mycoplasma Real-Time PCR Kit (160 PCR reactions)	06 495 605 001
MycoTOOL PCR Mycoplasma Detection Kit (Block PCR analysis via gel)	
MycoTOOL Mycoplasma Detection Prep Kit	05 184 592 001
MycoTOOL Mycoplasma Detection Amplification Kit	05 184 240 001
Residual DNA CHO Kit	07 427 689 001
Instrument	
LightCycler® 480 Instrument II	05 015 278 001

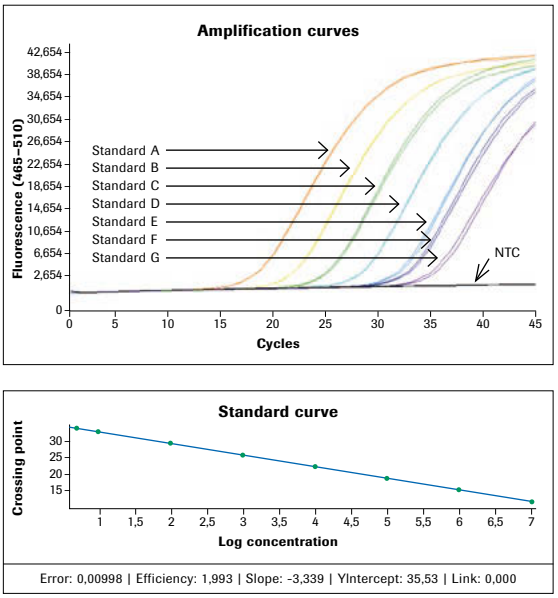


Figure 1: Typical analysis results obtained with Standard A (100 000 pg/ml) to G (1 pg/ml). Standard curve is calculated to Standard F (5 pg/ml LOQ) and should be linear. PCR efficiency should be 1.85 or higher.

The Residual DNA *E. coli* Kit can also be used with other real-time PCR platforms (e.g., QuantStudio™ 6 Flex PCR System from Applied Biosystems®).

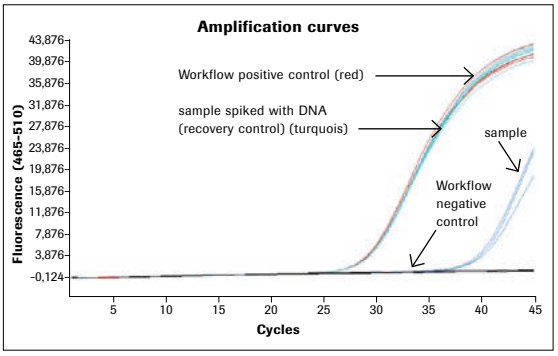


Figure 2: Typical results of a DNA spiked sample, a workflow positive and workflow negative controls. DNA recovery = minimum of 80% required.

Regulatory disclaimer
For use in quality control/manufacturing process only. The LightCycler® 480 Instrument is for life science research only. Not for use in diagnostic procedures.

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