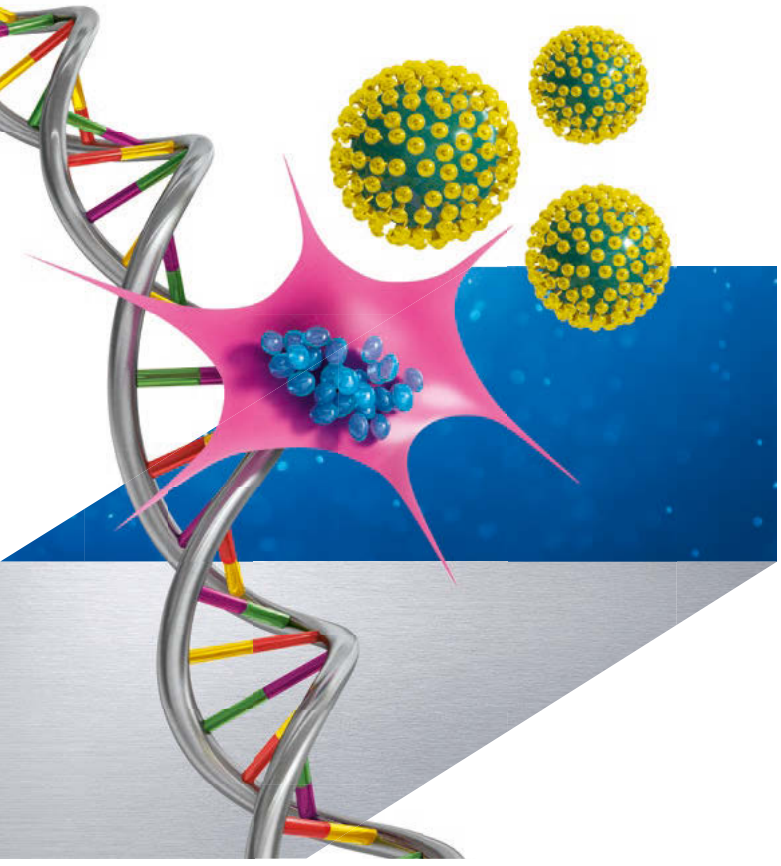
Residual DNA *E. coli* Kit

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.

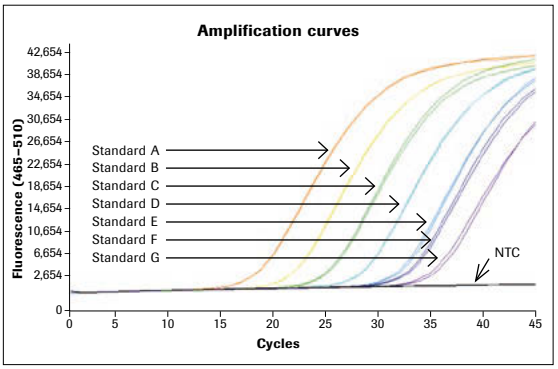
For use in quality control/manufacturing process only.

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 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

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®).



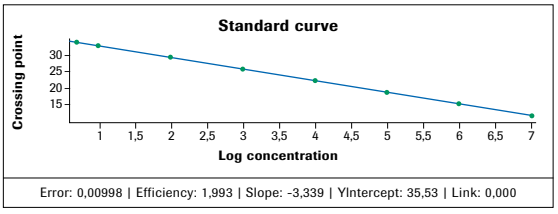


Figure 1: Typical analysis results obtained with Standard A (100 000 pg/ml) to G (1 pg/ml). Standard curve is calculated to Standard F (5 pg/ml LOQ) and should be linear. PCR efficiency should be 1.85 or higher.

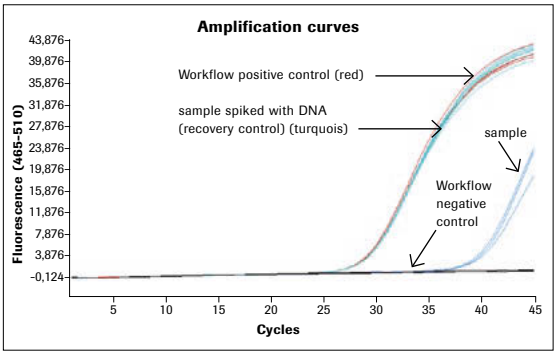


Figure 2: Typical results of a DNA spiked sample, a workflow positive and workflow negative controls. DNA recovery = minimum of 80% required.

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.

Trademark

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