

Residual DNA CHO 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 CHO kit is designed and validated for detection of residual CHO 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 Chinese Hamster Ovary (CHO) cell lines fast and reliable*. It was developed to meet sensitivity requirements defined by WHO and U.S. FDA (10 ng CHO DNA per therapeutic dose).

Achieve high sensitivity and specificity through improved tests*

- Linearity: 4 pg/ml to 400 ng/ml
- Lower Quantitation Limit: 4 pg/ml (20 fg/reaction)
- Lower Detection Limit: 0.4 pg/ml (2 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

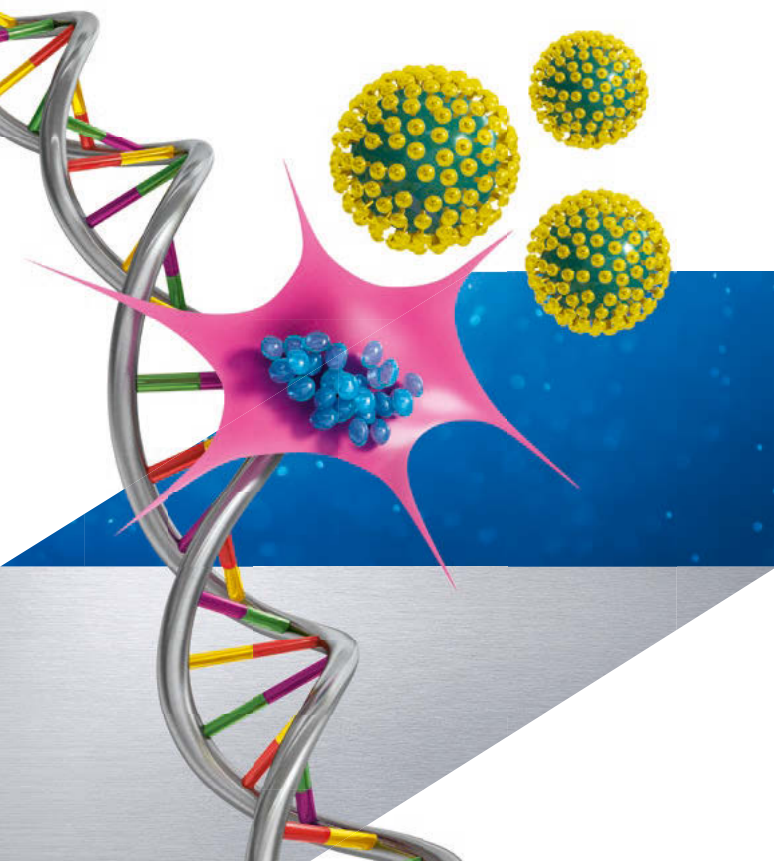
Save time with proven real-time qPCR technology

- Time to result <5 hours*

Characteristics

Residual DNA CHO 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 also available upon request.



*Data on file.

For use in quality control/manufacturing process only.

Ordering information

Products

Residual DNA CHO Kit

QC Sample Preparation Kit

Catalog number

07 427 689 001

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 *E.coli* Kit

07 728 735 001

Instrument

LightCycler® 480 Instrument II

05 015 278 001

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

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

LIGHTCYCLER, HIGH PURE, MYCOTOOL are trademarks of Roche. All other product names and trademarks are the property of their respective owners.

custombiotech.roche.com

Please contact your local CustomBiotech representative

Europe, Middle East, Africa, Latin America

Phone +49 621 759 8580

Fax +49 621 759 6385

mannheim.custombiotech@roche.com

United States

Phone +1 800 428 5433, ext. 14649 (toll-free)

Fax +1 317 521 4065

custombiotech.ussales@roche.com

Canada

Phone +1 450 686 7050

Fax +1 450 686 7012

custombiotech.can@roche.com

Japan

Phone +81 3 6634 1046

Fax +81 3 5479 0585

japan.custombiotech@roche.com

Asia Pacific

Phone +65 6371 6638

Fax +65 6371 6601

apac.custombiotech@roche.com

Published by

Roche Diagnostics GmbH

Sandhofer Straße 116

68305 Mannheim

Germany

© 2020 Roche Diagnostics GmbH
All rights reserved.

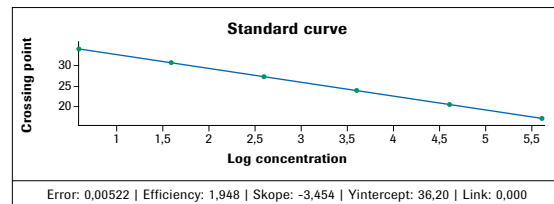
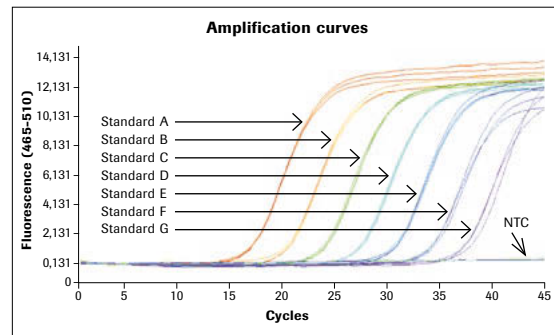


Figure 1: Typical analysis result with Standard A (400,000 pg/ml) to G (0.4 pg/ml). The standard curves should be linear and the PCR efficiency at least 1.85 or higher.

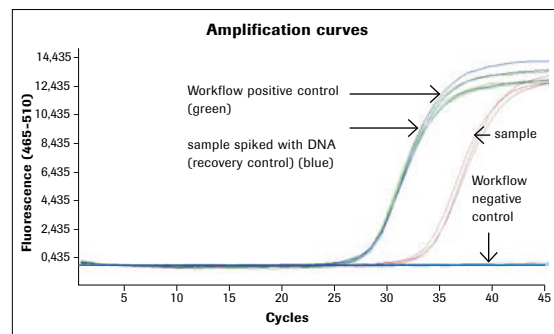


Figure 2: Typical analysis result for one sample, one sample spiked with DNA, one workflow positive control, and one workflow negative control. DNA recovery = 90%