

Human Residual DNA Fragment Analysis Detection Kit

The Human Residual DNA Fragment Analysis Detection Kit is designed to detect residual Human DNA in biological products during production.

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INTRODUCTION

Human Residual DNA Fragment Analysis Detection Kit is designed for the quantitative detection of the size distribution of Human residual host cell DNA fragments in intermediates, semi-finished and finished products of various biological products.

Human Residual DNA Fragment Analysis Detection Kit adopts the principle of PCR fluorescent probe method to quantitatively detect the size distribution of human residual host cell DNA fragments in the sample. The kit features three different amplified fragments (99 bp, 200 bp and 307 bp), and the Human DNA quantification reference is used to make standard curves for different amplified fragments respectively, and the fragment distribution of Human residual DNA in the sample is analyzed through the ratio of different sizes of fragments. Human Residual DNA Fragment Analysis Detection Kit a rapid, specific and reliable device, with the minimum detection limit reaching fg level.

PRINCIPLE OF THE ASSAY

The Human Residual DNA Fragment Analysis Detection Kit is a test kit that uses quantitative polymerase chain reaction (qPCR) technology to detect residual Human DNA. Human Residual DNA Fragment Analysis Detection Kit includes 3 different base pairs primers and probes that can amplify and detect specific sequences of Human DNA. qPCR is a PCR technique that simultaneously amplifies and detects DNA by monitoring the accumulation of product with the use of a fluorescent dye. The kit has high specificity and sensitivity, is easy to use, and suitable for testing in laboratories.

MATERIALS PROVIDED & STORAGE INFORMATION

Store the unopened kit at -20 °C. Use the kit before expiration date.

Component	Quantity	Storage information
10X Human DNA Standard	60 μl (3ng/μl)	-20°C
Human Primer and Probe Mix (99bp)	300μΙ	-20°C
Human Primer and Probe Mix (200bp)	300μΙ	-20°C
Human Primer and Probe Mix (307bp)	300μΙ	-20°C
2x qRCR Reaction Buffer	4 X 1.25 ml	-20°C
DNA Dilution buffer	4 X 1 ml	-20°C
IPC Mix	450µl	-20°C
ROX (High)	50 μΙ	-20°C
ROX (Low)	50 μΙ	-20°C

MATERIALS REQUIRED BUT NOT PROVIDED

- PCR machine
- Pipettes and pipette tips
- DNase/RNase-Free Water
- PCR tube

TECHNICAL HINTS AND PRECAUTIONS

- Wear protective gloves, clothing, eye, and face protection especially while handling blood or body fluid samples.
- Store the kit at -20°C at all times.
- All reagents must be kept on ice during the entire experiment.
- Once the assay has been started, all steps should be completed without interruption.

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- It is highly recommended that the standards and samples be assayed in triplicates.
- Change pipette tips between the addition of different reagent or samples.

REAGENT PREPARATION

• Standards: Dilute the each 10X Human DNA Standard (99bp / 200bp / 307bp) with DNA Dilution buffer to yield d a stock concentration of 300 pg/μl as standard 1. The DNA Dilution buffer serves as zero standard (0 pg/ml), and the rest of the standard serial dilution can be diluted as according to the suggested concentration below: 30 pg/μl, 3 pg/μl, 0.3 pg/μl, 0.03 pg/μl.

Dilute Human DNA standard as according to the table below:

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Standard	DNA Conc.	μl of DNA Dilution buffer	μl of standard
S1	300 pg/μl	180 μΙ	20 μl (stock)
S2	30 pg/μl	180 μΙ	20 μl (S1)
S3	3 pg/μl	180 μΙ	20 μl(S2)
S4	0.3 pg/μl	180 μΙ	20 μl(S3)
S5	0.03 pg/μl	180 μΙ	20 μl(S4)
S0	0 pg/μl	0 μΙ	200μΙ

ASSAY PROCEDURE

1 Prepare qPCR mix buffer:

2x qRCR Reaction Buffer	15 μΙ
Human Primer and Probe Mix*	3 μΙ
IPC Mix	1.4 μΙ
ROX *	0.6 μΙ
Total	20μl (1 wells)

- * Human Primer and Probe Mix (99bp / 200bp / 307bp) should be test in difference tube, DO NOT mix different Primer and Probe Mix.
- * Choose the appropriate ROX (High or Low) to match the PCR machine. If

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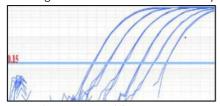
the PCR machine does not require ROX, adjust the volume with DNase/RNase-free water to obtain a final volume of 20µl.

- 2 Mix 20 μ l qPCR mix buffer with 10 μ l diluent standard / sample / blank in PCR tube. The end volume should be 30 μ l.
- 3 Initial denaturation: 95°C, 5 min
- 4 PCR cycle:

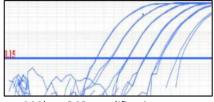
95°C, 15 sec; 58°C, 30sec; 72°C, 1 min, for **45 cycle**, **30 μl**.

EXAMPLE OF TYPICAL STANDARD CURVE

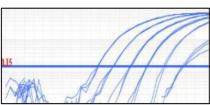
The following data is for demonstration only and cannot be used in place of data generations at the time of assay.



99bp qPCR amplification curve



200bp qPCR amplification curve



307bp gPCR amplification curve