Certificate of Purity -PCR clean

Sample on :2021-08-20 Start of test:2021-08-20 End of test:2021-08-25

This package contains a high quality consumable manufactured under the PCR clean Purity Standard.

The PCR clean consumables are produced in a Class 100000 clean room environment.

For this product we certificate the following

Free of detectable

Human DNA

DNase

RNase

PCR inhibitors

The certification comprises the following tests:

Human DNA Contamination Test

A PCR master mix is prepared for the detection of human DNA.

15 samples are rinsed one after another with DNA-free water .10ul of this solution is added to 15ul master mix, PCR is done for 30 cycles

The emittance of sybr gerrn-dnduced fluorescence is detected in samples and controls ,for the samples to pass certification, no fluorescence must be found corresponding to the negative control.

DNase Test

15 samples are rinsed one after another with DNA-free water.17ul of these solutions are mixed with 3ul Dnase-buffer containing 100bp DNA-ladder in a DNase-free tube. A positive control is spiked with DNase,a negative control contains DNA-free water. All tubes are incubated for 24houe at 37°C

The DNA is analyzed by agarose-gelelectrophoresis. DNase contamination is indicated by degradation of the DNA ladder.For samples to pass certification,the relative intensities of the DNA pattern of the samples must correspond to the negative control.

RNase Test

15 samples are rinsed one after another with DNA-free water.17ul of these solutions are mixed with 3ul Dnase-buffer containing 100bp DNA-ladder in a DNase-free tube. A positive control is spiked with DNase,a negative control contains DNA-free water. All tubes are incubated for 24houe at 37°C

The RNA is analyzed by agarose-gelelectrophoresis. RNase contamination is indicated by degradation of the RNA ladder. For samples to pass certification,the relative intensities of the RNA pattern of the samples must correspond to the negative control

PCR Inhibitor Test

15 samples are rinsed one after another with DNA-free water.10ul of these solutions is added to 15ul master mix plus 16pg human DNA. PCR is done for 30 cycles.

The emittance of Sybr Green-dnduced fluorescence is detected in samples and controls. For the samples to pass certification , the CT-values of the samples are compared with the positive control(containing 16pg human DNA).The difference of the CT-value between the samples and the control must be in range of ±2 cycles

Aug,2021

QC：郑涛

Parameter	Result
DNase&RNase activity , PCR Inhibitor	not detected

The test was conducted in compliance with GMP guidelines, There were no test-related deviations

浙江福士达集团有限公司
ZHEJIANG FIRSD GROUP CO.,LTD

Attachment

ITEM NO.	DESCRIPTION	QTY/UNIT	LOT NO	MFG date	EXP date
GT-GP10L	pipette tip 10ul long	1,000	GTGP10L202108	08/2021	08/2026
GT-GP200	pipette tip 200ul	1,000	GTGP200202108	08/2021	08/2026
GT-GP200L	pipette tip 200ul long	300	GTGP200L202108	08/2021	08/2026
GT-GP1000	pipette tip 1000ul	1,000	GTGP10002021008	08/2021	08/2026
GT-GP1000L	pipette tip 1000ul long	300	GTGP1000L202108	08/2021	08/2026
GT-GP10LF	pipette tip 10ul long with filter	300	GTGP10LF202108	08/2021	08/2026
GT-GP200F	pipette tip 200ul with filter	300	GTGP200F202108	08/2021	08/2026
GT-GP200LF	pipette tip 200ul long with filter	300	GTGP200LF202108	08/2021	08/2026
GT-GP1000F	pipette tip 1000ul with filter	300	GTGP1000F202108	08/2021	08/2026
GT-GP1000LF	pipette tip 1000ul long with filter	300	GTGP1000LF202108	08/2021	08/2026
GT-GP10LFR	pipette tip 10ul long with filter in rack	5,000	GTGP10LFR202108	08/2021	08/2026
GT-GP200LFR	pipette tip 200ul long with filter in rack	5,000	GTGP200FR202108	08/2021	08/2026
GT-GP1000LFR	pipette tip 1000ul long with filter in rack	1,000	GTGP1000LFR202108	08/2021	08/2026
GT-GP20LFR	pipette tip 20ul long with filter in rack	1,000	GTGP20FR202108	08/2021	08/2026
GT-GP100LFR	pipette tip 100ul long with filter in rack	5,000	GTGP100LFR202108	08/2021	08/2026
GT-GP10LR	pipette tip 10ul long in rack	5,000	GTGP10R202108	08/2021	08/2026
GT-GP20LR	pipette tip 20ul long in rack	1,000	GTGP20R202108	08/2021	08/2026
GT-GP100LR	pipette tip 100ul long in rack	5,000	GTGP100R202108	08/2021	08/2026
GT-GP200LR	pipette tip 200ul long in rack	5,000	GTGP200LR202108	08/2021	08/2026
GT-GP1000LR	pipette tip 1000ul long in rack	1,000	GTGP1000LR202108	08/2021	08/2026
GT-GP1000LR	pipette tip 1000ul long in rack	1,000	GTGP1000LR202108	08/2021	08/2026
WE14	Cryotube Vol. 1.8mL, PP material, graduated up to 2mL, leak-proof, silicon rubber liner mounted in cap	1620	WE1420210512	05/2021	05/2026
GT-GP15	Centirfuge tube		GTGP15202108	08/2021	08/2026
GT-GP50	cenmtrifuge tube 50ml		GTGP50202108	08/2021	08/2026

CERTIFICATE OF EO STERILE

COMPANY OF STERILIZATION	HAIMEN XIN CHUANG STERILIZATION SERVICE
IMPORTER	GLOBAL TRADE TECHNOLOGY COMERCIO IMPORTACO E EXPORTACAO LTDA Avenida Doutor José Antônio Miziara, 221 - Distrito Industrial Jaboticabal SP - city Zip code 14874-002
DATE OF STERILIZATION	27TH MAY 2021

GOODS	QTY	
WE14 Cryotube Vol. 2mL, PP material, 500 pcs/pkg. LOT: WE1420210512 MFG DATE:2021-05 EXP DATE:2026-05	4080pack	

EO DOZE:18KG

INVOICE NO: 2021F022-1

We hereby certificate that the above goods have been sterilized by EO,with the lowest temperature of 45℃,highest temperature of 60℃sterilization duration of 12 hours

2021-05-28

HAIMEN XINCHUANG STERILIZATION SERVICE CO.,LTD.