



ZHEJIANG FIRSD GROUP CO., LTD.

Certificate of Purity -PCR clean Products:

CODE	PRODUCTS	QTY
GT-GP1000LFR	Pipette tip 1000ul long with filter in rack - Type Gilson - 01 RACK 96UN, Lot: GTGP1000LFR280222, MFG:05/2022/ DUE DATE:05/2027	1000boxes
GT-GP1000LR	pipette tip 1000ul long in rack, Lot: GTGP1000LR202202, MFG:05/2022/ DUE DATE:05/2027	2000boxes
GT-GP200LR	pipette tip 200ul long in rack, Lot: GTGP200LR202202, MFG:05/2022/ DUE DATE:05/2027	10000boxes
GT-GPRK200	RACK 100-200UL, Lot: 20220605, MFG:06/2022/ DUE DATE:06/2027	500PCS

Sample on :2022-06-04 Start of test:2022-06-05 End of test:2022-06-13

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 fluorecence is detected in samples and controls ,for the samples to pass certification, no fluorecence must be found

corresponding to the negative control.



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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-gelectrophoresis. 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-gelectrophoresis. 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.



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The emittance of Sybr Green-induced 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

June 2022

<u>Parameter</u>	<u>Result</u>
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

A handwritten signature in blue ink, appearing to be '施俊' (Shi Jun), written in a cursive style.

NANTONG MICHAEL IRRADIATION CO., LTD

CERTIFICATE OF GAMMA STERILIZATION

Date:2022-6-5

STERILE COMPANY	NANTONG MICHAEL IRRADIATION CO.,LTD
EXPORTER	ZHEJIANG FIRSD GROUP CO., LTD.
IMPORTER	Global Trade Technology – Comércio, Importação e Exportação Ltda - EPP. Av. José Antonio Miziara n 221 - Distrito Ind. José Aparecido Tomé - Jaboticabal – SP. – 14.874-002 Fone/Fax: (16) 4042-4000 CPNJ: 07.610.601/0001-65 INSCRIÇÃO ESTADUAL: 391.173.147.116
灭菌日期 DATE OF STERILIZATION	5 TH May. 2022
Invoice Number: 2022F02J15 Product: AS ATTACHMENT	
要求 GAMMA 剂量 MIN GAMMA DOSE 25KGY MAXIUM GAMMA DOSE:40KGY	
南通市迈克尔辐照有限公司 特此证明上述产品已经本公司 GAMMA 射线消毒 NANTONG MICHAEL IRRADIATION CO., LTD hereby warranty that all products mentioned above have been sterilized by GAMMA RAY	

STAMP:
SIGNATURE

郑建达

ATTACHMENT

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GT-GPRK200	RACK 100-200UL, Lot: 20220605, MFG:06/2022/ DUE DATE:06/2027	500PCS
GTMR-ST01	Rayon swabs with polystyrene (plastic) stick and polypropylene transport tube (13*150mm), with Stuart culture medium, individual peel pack, sterile by Gamma Ray, Lot: GTMRST01220221, MFG:04/2022/ DUE DATE:04/2024	3200bags
GTMR-CB01	Rayon swabs with polystyrene (plastic) stick and polypropylene transport tube (13*150mm), with Cary-Blair culture medium, individual peel pack, sterile by Gamma Ray, Lot: GTMRCB01220221, MFG:04/2022/ DUE DATE:04/2024	500BAGS