

Geneture GenoPro Gene Sequencer



Geneture GenoPro Gene Sequencer employs fluorescence sequencing technology and algorithms based on DNA amplification on the chip surface. It identifies and processes the optical signals of bases to form imaging information. After analyzing the imaging information, the corresponding gene sequence data is ultimately obtained. The device is characterized by good repeatability, high accuracy, fast speed, and stable results. Geneture GenoPro Gene Sequencer is compatible with sequencing chips of various throughputs and supports multiple read lengths, meeting the needs of different application fields.

Key Features



Fast

Run Time

3.5hr



Accuracy

sequencing results accuracy

>99.9%



Flexibility

Open platform, equipped with various sequencing modes, suitable for various application needs.



Stability

Strict control, consistent quality, reliable sequencing results.

Specifications

Chip Type	Reads	Read Length	Throughput	Data Quality	Sequencing Time
Medium Throughput	220M	50bp	11G	Q30>90%	~3.5h
		75bp	16G	Q30>90%	~4.5h
		300bp	66G	Q30>85%	~22h
High Throughput	660M	50bp	33G	Q30>90%	~4.5h
		75bp	50G	Q30>90%	~6h
		300bp	200G	Q30>85%	~24h

*The sequencing time is for dual index (8+8);

*The time mentioned above is the theoretical sequencing time;

*Sequencing time and data quality may fluctuate due to the different libraries used.

Methods	Applications	Data Volume / Sample	Read Length	220M Samples / Run	660M Samples / Run
Low-pass Whole Genome Sequencing	NIPT	~5 M reads	SE 50	44	132
	Targeted Pathogen Sequencing (tNGS)	0.5 M ~ 1 M reads	SE 50	220-440	660-1320
	Small Panel for Tumor Companion Diagnostics	~1 Gb	PE 150	66	198
Targeted Sequencing (Capture / Multiplex Amplification)	Small Panel for Genetic Diseases (Deafness, Metabolism)	3 ~ 5 Gb	PE 150	13.2-22	39.6-66
	16S Sequencing	~0.5 M reads	PE 300	440	1320
	Forensic DNA Identification	~0.5 M reads	SE 400	440	1320
Small Genomes Sequencing (Tuberculosis, Influenza, etc.)	Bacterial / Virus	~1 Gb	PE 150	66	198
Methylation Sequencing	Pan-cancer Early Screening	~1 Gb	PE 150	66	198

*The number of samples is estimated after careful consideration of library pooling bias and is for reference only.

Data Demonstrations

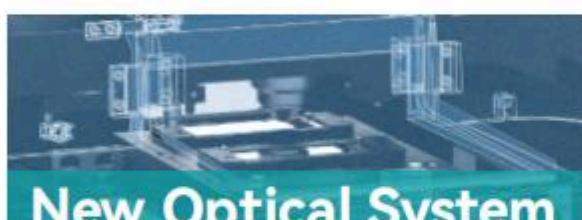
The PE150 WES standard article library test results in different sequencing platforms:

Sample Type	HG001	HG002	HG003	HG004	HG005					
Sequencing Platform	Geneture GenoPro	Novaseq 6000								
RawQ30%	93.9039	94.92	93.8019	94.46	93.9166	94.74	93.669	94.49	93.9675	94.76
Mapping%	99.83	99.87	99.84	99.89	99.83	99.87	99.85	99.87	99.84	99.87
Strict Mapping Proportion%	97.97	97.29	98.08	97.6	98.38	97.87	98.21	97.61	98.27	97.78
Coverage >10X	99.67	99.67	99.87	99.86	99.87	99.77	99.68	99.67	99.86	99.86
Target region fold-80	1.576	1.6	1.602	1.648	1.598	1.633	1.57	1.6	1.592	1.615
Uniformity of Target Region Coverage	0.99	0.99	0.99	0.99	0.9904	0.99	0.99	0.99	0.99	0.99
SNP.F1_score	0.9932	0.9938	0.9901	0.9910	0.9911	0.9913	0.9904	0.9915	0.9903	0.9915
INDEL.F1Score	0.9799	0.9823	0.9751	0.9760	0.9606	0.9706	0.9836	0.9901	0.9721	0.9779

Sequencing Results: Geneture GenoPro exhibits high sensitivity and accuracy in detecting variations (SNPs and INDELS) in the exome genome.

Tech Innovations

R&D capabilities



New Optical System



New Chips



New Enzymes



New Fluorescent Dye



New Chemistry

100% larger field of view and 50% less imaging time

Robustness and better reaction efficiency

Read length up to SE 400 with better quality

Proprietary dyes systems to optimized for better imaging performance

In fast sequencing mode, the SE 50 + 8 + 8 test can be completed in as fast as 3.5 hours

Geneture GenoPro Instrument Specifications

Parameter	Specifications	
Dimensions	825 mm(W) x 687 mm(D) x 788 mm(H)	
Weigh	120Kg	
Power Requirements	Input voltage	AC 220V±22V
	Frequency	50Hz±1Hz
	Power	750VA
Operating Environment	Ambient Temperature	19°C to 25°C
	Altitude	Not exceeding 3000 m
	Humidity, RH (Non-condensing state)	10% to 85% (Nocondensation)
	Air Pressure	700hPa to 1060hPa
Computer Configuration	CPU	Main frequency above 2.3GHz
	Memory	128GB or more
	Solid State Drive	480GB + 4TB
	Monitor	Resolution of 1920×1080 or higher
	Operating System	Compatible with Windows 10 or later versions

Multiple Applications



3.5 hr



3.5 hr



22 hr



4.7 hr

About Geneture

Empower and Cooperate

Geneture focuses on the field of clinical diagnostics, providing customers with mature solutions such as NIPT and NGS for oncology, as well as the products included within these solutions.

Geneture holds 3 authorized invention patents, 26 utility model patents, 3 appearance patents, 10 software copyrights, 11 CE certifications, and 3 inventions under review.

Company Qualifications

CE

DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 - Article 19, And

Manufacturer: Name: Luyang Generac Medical Technology Co.,Ltd.
Address: Rm.302,Building 23,National University Science Park,No.2,Penglai Road,Jianxi District,Luyang City,Henan Province,China,471000.
Tel: +86-379-61266211
Website: www.generatec.com

Where At: Name: Luyang Generac Medical Technology Co.,Ltd.
Address: Rm.302,Building 23,National University Science Park,No.2,Penglai Road,Jianxi District,Luyang City,Henan Province,China,471000.
Tel: +86-379-61266211
SRN: 1

SRN: SRN: 1

We, the manufacturer, herewith declare that the device covered is conformity with the (EU) MDR 2017/745.

Product Name	Sampling Swab(100-001A)
Model	
Intended use	Sampling Swab is intended to use for non-disposable and pre-filled non-swabs.
EMDIN code	A1101
Classification and rule	I, ruled
Conformity Assessment Rule	Conformity Assessment Rule

Applicable Standards:

ISO 13485:2016/A1:2021	ISO 14971:2019
ISO 19993-5:2009	ISO 10993-10:2021
ISO 20417:2021	EN 62366:2015

We, the manufacturer, herewith declare with sole responsibility, meets the requirements of the REGULATION (EU) 2017/745. We maintain a documented pre-production monitoring process.

Name of authorized signatory:

Name of authorized signatory:

EC Declaration of C

Manufacturer: Name: Luyang Generac Medical Technology Co.,Ltd.
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SRN: SRN: 1

We, Luyang Generac Medical Technology CO.,LTD. (Manufacturer), medical device meets the REGULATION (EU) IVDR 2017/746 which conformity is exclusively under the responsibility of Luyang Generac Medical (Manufacturer).

Product Name	Sample Release Reagent
Basic UDI-DI	
Intended Use	It is used for the processing of the sample can be released quickly, to facilitate instruments to detect the analyte
Classification	A (IVDR, Annex VIII Rule 5)

Conformity Assessment Route: Annex IX of REGULATION (EU) 2017/746

Applicable Standards:

EN ISO 14971:2019	EN ISO 10133-2:2013
ISO 14971:2009	IEC 61980-2-100:2018
EN ISO 16151-1:2021	ISO 10122-1:2021
EN ISO 23660:2021	IEC 60601-1:2020+A10:2020

CE

The aforementioned device has been assigned in class 3 according to 2017/746. The above-mentioned declaration of conformity is exclusively under Luyang Generac Medical Technology Co.,Ltd.

Name Of Authorized Signatory	
Position Held In The Company	General Manager
Signature	

Product Name Real-time PCR System GT-96 || **Basic UDI-DI** | |
| **Intended Use** | This instrument is based on the real-time PCR together with the matching detection reagent quantitative detection of target nucleic acids the detection of human pathogenic pathogen |
| **Classification** | A (IVDR, Annex VIII Rule 5) |

Conformity Assessment Route: Annex IX of REGULATION (EU) 2017/746

Applicable Standards:

EN ISO 14971:2019+A1:2021	EN ISO 10133-2:2013
ISO 14971:2019	IEC 61980-2-100:2018
EN ISO 16151-1:2021	ISO 10122-1:2021
EN ISO 23660:2021	IEC 60601-1:2020+A10:2020

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Name Of Authorized Signatory	
Position Held In The Company	General Manager
Signature	

EC Declaration of Conformity

Manufacturer: Name: Luyang Generac Medical Technology Co.,Ltd.
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SRN: SRN: 1

We, Luyang Generac Medical Technology CO.,LTD. (Manufacturer), herewith declare that the below mentioned medical device meets the REGULATION (EU) IVDR 2017/746 which apply to them. The declaration of conformity is exclusively under the responsibility of Luyang Generac Medical Technology Co.,Ltd. (Manufacturer).

Product Name	Real-time PCR System GT-16
Basic UDI-DI	
Intended Use	The kit is used for nucleic acid extraction, enrichment and purification. The extracted nucleic acid used for clinical <i>in vitro</i> detection.
Classification	A (IVDR, Annex VIII Rule 5)

Conformity Assessment Route: Annex IX of REGULATION (EU) 2017/746

Applicable Standards:

EN ISO 14971:2019+A1:2021	EN ISO 10133-2:2013
ISO 14971:2019	IEC 61980-2-100:2018
EN ISO 16151-1:2021	ISO 10122-1:2021
EN ISO 23660:2021	IEC 60601-1:2020+A10:2020

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Name Of Authorized Signatory	
Position Held In The Company	General Manager
Signature	

EC Declaration

Manufacturer: Name: Luyang Generac Medical Technology Co.,Ltd.
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Tel: +86-379-61266211
E-Mail: www.generatec.com

We, the manufacturer, here with declare that the product

Product Name	COVID-19 Neutralizing Detection Kit (Solid)
Intended Use	COVID-19 Neutralizing Antigen detection of Spike Protein A. Mixed serum or plasma and the COVID-19 Neutralizing reagents with COVID-19 as the subject's clinical status
Classification	Others

Conformity Assessment Route: IV DD09/79/EC Annex

Applicable Standards:

EN ISO 14971:2019	EN ISO 10133-2:2013
EN ISO 14971:2009	EN 746
EN ISO 16151-1:2021	EN ISO 10122-1:2021
EN ISO 16151-2:2021	EN ISO 10122-2:2021

CE

We, the manufacturer, here declare with sole responsibility provisions of the Directive 98/79/EC of the European Parliament and Council.

We agree to develop, implement and maintain a document

Name of General Manager	
Signature	
Date	
Place	
Seal (Manufacturer)	

Product Name COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold) || **Intended Use** | The kit is a rapid chromatographic assay for the qualitative and quantitative detection of SARS-CoV-2 IgG and IgM antibodies in human serum, plasma and saliva samples. |
| **Classification** | Others |

Conformity Assessment Route: IV DD09/79/EC Annex

Applicable Standards:

EN ISO 14971:2019	EN ISO 10133-2:2013
EN ISO 14971:2009	EN 746
EN ISO 16151-1:2021	EN ISO 10122-1:2021
EN ISO 16151-2:2021	EN ISO 10122-2:2021

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Seal (Manufacturer)	

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Tel: +86-379-61266211
E-Mail: www.generatec.com

We, the manufacturer, here with declare that the product

Product Name	COVID-19 Freeze-dried Test Kit (CSFvSfQ)
Intended Use	COVID-19 Freeze-dried Test Kit of suspected patients COVID-19 infection, report or occupational risks, spatial disease route, and route, it differentiated by Novel Coronavirus
Classification	Others

Conformity Assessment Route: IV DD09/79/EC Annex

Applicable Standards:

EN ISO 14971:2019	EN ISO 10133-2:2013
EN ISO 14971:2009	EN 746
EN ISO 16151-1:2021	EN ISO 10122-1:2021
EN ISO 16151-2:2021	EN ISO 10122-2:2021

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Signature	
Date	
Place	
Seal (Manufacturer)	

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Tel: +86-379-61266211
E-Mail: www.generatec.com

We, the manufacturer, here with declare that the product

Product Name	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)
Intended Use	This product is used for the qualitative detection of human samples. It is based on the solid and reading with the antigen rapid diagnosis of SARS-CoV-2.
Classification	Others

Conformity Assessment Route: IV DD09/79/EC Annex

Applicable Standards:

EN ISO 14971:2019	EN ISO 10133-2:2013
EN ISO 14971:2009	EN 746
EN ISO 16151-1:2021	EN ISO 10122-1:2021
EN ISO 16151-2:2021	EN ISO 10122-2:2021

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Name of General Manager	
Signature	
Date	
Place	
Seal (Manufacturer)	

EC Declaration of Conformity

Manufacturer: Name: Luyang Generac Medical Technology Co.,Ltd.
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Tel: +86-379-61266211
E-Mail: www.generatec.com

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Product Name	Vial Transport Medium (VTM)
Basic UDI-DI	
Intended Use	For the collection, transportation and storage of samples. Used in Clinical laboratories.
Classification	A (IVDR, Annex VIII Rule 5)

Conformity Assessment Route: Annex IX of REGULATION (EU) 2017/746

Applicable Standards:

EN ISO 14971:2019	EN 61980-5-10:2019
EN ISO 14971:2009	EN 746
EN ISO 16151-1:2021	EN ISO 10122-1:2021
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Name Of Authorized Signatory	
Position Held In The Company	General Manager
Signature	
Date	2022.07.20
Place	Luyang City, China

Manufacturer: Name: Luyang Generac Medical Technology Co.,Ltd.
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Product Name	Antibody Assay Kit (ELISA)
Basic UDI-DI	
Intended Use	For the qualitative detection of antibodies against SARS-CoV-2 in human samples.
Classification	A (IVDR, Annex VIII Rule 5)

Conformity Assessment Route: Annex IX of REGULATION (EU) 2017/746

Applicable Standards:

EN ISO 14971:2019	EN 61980-5-10:2019
EN ISO 14971:2009	EN 746
EN ISO 16151-1:2021	EN ISO 10122-1:2021
EN ISO 16151-2:2021	EN ISO 10122-2:2021

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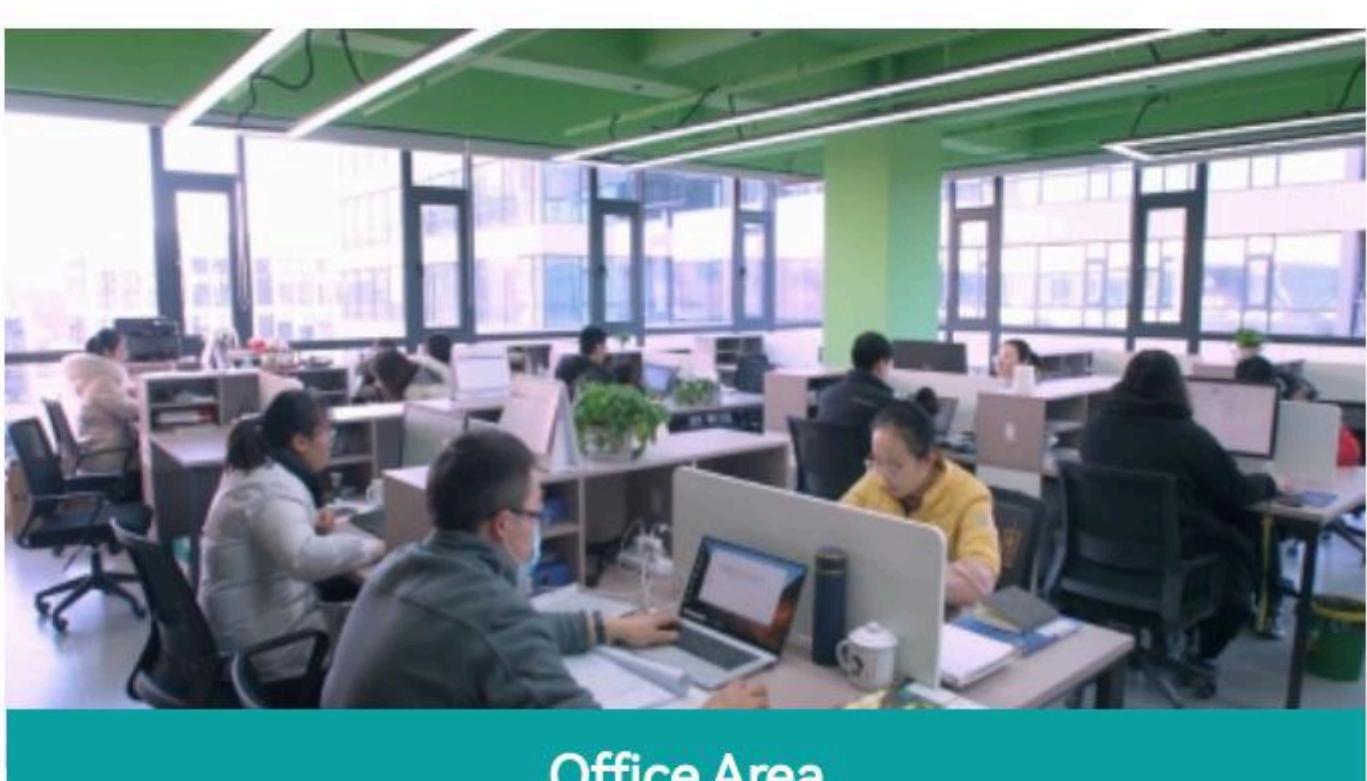
Name of General Manager	
Signature	
Date	
Place	
Seal (Manufacturer)	



Company Environment



Assembly Line



Office Area

LUOYANG GENETURE MEDICAL TECHNOLOGY CO.,LTD.

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