

Part No.: H-020-000566-00



Cat No.	Product model
940-000428-00	G99 SM FCL SE100/PE50
940-000431-00	G99 SM FCL PE150
940-000525-00	G99 SM App-C FCL SE100
940-000434-00	G99 SM App-C FCL PE150

Universal Sequencing Reaction Kit

DNBSEQ-G99

Instructions for Use

Version: 1.0

Leading Life Science Innovation

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Wuhan MGI Tech Co., Ltd.

About the instructions for use

This instructions for use is applicable to the Universal Sequencing Reaction Kit. The version of instructions for use is 1.0 and the kit version is 1.0.

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[Product name]

Universal Sequencing Reaction Kit

[Specification]

Applicable sequencer	Cat. No.	Model	Specification
Genetic Sequencer (DNBSEQ-G99)	940-000428-00	G99 SM FCL SE100/PE50	1 Test/Kit
	940-000431-00	G99 SM FCL PE150	1 Test/Kit
	940-000525-00	G99 SM App-C FCL SE100	1 Test/Kit
	940-000434-00	G99 SM App-C FCL PE150	1 Test/Kit

[Intended use]

This kit is a set of commonly used reagents and consumables to sequence the nucleic acid libraries. It is used with the Genetic Sequencer to perform high-throughput sequencing and obtain sample sequence information. The device is specially used with validated assays and analysis software for in vitro diagnostic purpose. The device is especially used by the personnel who has been trained professionally.

[Test principle]

With the Combinatorial Probe-Anchor Synthesis (cPAS) technology^[1], the sequencing reaction kit is to determine the base sequence carried by a DNA Nanoball (DNB) loaded on a sequencing flow cell. The test procedure is mainly divided into three parts, namely DNB preparation, DNB loading and sequencing. Specifically, the DNA libraries are cyclized using the reagents provided in the kit, and then DNB is prepared by rolling circle amplification and loaded into the sequencing flow cell. During sequencing, terminal modified bases are labeled as different fluorescent probes. These probes and DNA molecular anchors are incorporated on the DNBs. The high-resolution imaging system collects the optical signals, and then the sequence to be tested can be obtained after the optical signals are digitized.

[Main components]

Table 1 Main components of sequencing reaction kit for G99 SM FCL SE100/PE50, G99 SM FCL PE150

Component name	Main ingredients	G99 SM FCL SE100/PE50	G99 SM FCL PE150
sequencing flow cell	Silicon slide	1 EA	1 EA
Low TE buffer	Tris (hydroxymethyl) aminomethane, Tris HCl (Powder), and EDTA	100 μ L \times 1 tube	100 μ L \times 1 tube

Component name	Main ingredients	G99 SM FCL SE100/PE50	G99 SM FCL PE150
Make DNB Buffer	Ammonium sulfate, DTT, magnesium chloride, tris(hydroxymethyl) aminomethane, and make DNB primer	20 μL \times 1 tube	20 μL \times 1 tube
Make DNB Enzyme Mix I	dNTP Solution Mix, ammonium sulfate, DTT, magnesium chloride, tris(hydroxymethyl) aminomethane, glycerol, and Tth SSB.	40 μL \times 1 tube	40 μL \times 1 tube
Make DNB Enzyme Mix II (LC)	Tris(hydroxymethyl) aminomethane, EDTA, Phi29 DNA polymerase (LC), and glycerol	13 μL \times 1 tube	13 μL \times 1 tube
Stop DNB Reaction Buffer	EDTA, and molecular grade water	50 μL \times 1 tube	50 μL \times 1 tube
DNB Load Buffer II	Potassium citrate tribasic monohydrate, and citric acid anhydrous	50 μL \times 1 tube	50 μL \times 1 tube
MDA Enzyme Mix	phi29 DNA polymerase, and glycerol	0.125 mL \times 1 tube	0.125 mL \times 1 tube

Component name	Main ingredients	G99 SM FCL SE100/PE50	G99 SM FCL PE150
MDA Reagent	dNTP Solution Mix, DTT, 100% DMSO, sucrose, and glycerol	1.0 mL×1 tube	1.0 mL×1 tube
Micro Tube 0.5 mL (Empty)	PP plastic	1 EA	1 EA
FTAT premixed compaction block	PC plastic	1 EA	1 EA
Sequencing Reagent Cartridge	Tris(hydroxymethyl) aminomethane, NaCl powder, EDTA, magnesium sulfate solution volumetric, tween-20, HCl, ddATP, ddCTP, ddTTP, ddGTP, AD153 Insert Primer link1, cPAS DNA polymerase and glycerol	SE100/PE50×1	PE150×1

Table 2 Main components of sequencing reaction kit for G99 SM App-C FCL SE100

Component name	Main ingredients	G99 SM App-C FCL SE100
sequencing flow cell	Silicon slide	1 EA
Low TE buffer	Tris (hydroxymethyl) aminomethane, Tris HCl (Powder), and EDTA	100 μ L \times 1 tube
App-C Make DNB Buffer	Ammonium sulfate, DTT, magnesium chloride, tris(hydroxymethyl) aminomethane, and App-C make DNB primer	20 μ L \times 1 tube
Make DNB Enzyme Mix I	dNTP Solution Mix, ammonium sulfate, DTT, magnesium chloride, tris(hydroxymethyl) aminomethane, glycerol, and Tth SSB.	40 μ L \times 1 tube
Make DNB Enzyme Mix II (LC)	Tris(hydroxymethyl) aminomethane, EDTA, Phi29 DNA polymerase (LC), and glycerol	13 μ L \times 1 tube
Stop DNB Reaction Buffer	EDTA, and molecular grade water	50 μ L \times 1 tube
DNB Load Buffer II	Potassium citrate tribasic monohydrate, and citric acid anhydrous	50 μ L \times 1 tube
Micro Tube 0.5 mL (Empty)	PP plastic	1 EA


Component name	Main ingredients	G99 SM App-C FCL SE100
FTAT premixed compaction block	PC plastic	1 EA
Sequencing Reagent Cartridge	Tris(hydroxymethyl) aminomethane, NaCl powder, EDTA, magnesium sulfate solution volumetric, tween-20, HCl, ddATP, ddCTP, ddTTP, ddGTP, App-C Insert Primer link1, cPAS DNA polymerase and glycerol	SE100×1

Table 3 Main components of sequencing reaction kit for G99 SM App-C FCL PE150

Component name	Main ingredients	G99 SM App-C FCL PE150
sequencing flow cell	Silicon slide	1 EA
Low TE buffer	Tris (hydroxymethyl) aminomethane, Tris HCl (Powder), and EDTA	100 μ L×1 tube
App-C Make DNB Buffer	Ammonium sulfate, DTT, magnesium chloride, tris(hydroxymethyl) aminomethane, and App-C make DNB primer	20 μ L×1 tube

Component name	Main ingredients	G99 SM App-C FCL PE150
Make DNB Enzyme Mix I	dNTP Solution Mix, ammonium sulfate, DTT, magnesium chloride, tris(hydroxymethyl) aminomethane, glycerol, and Tth SSB.	40 μ L \times 1 tube
Make DNB Enzyme Mix II (LC)	Tris(hydroxymethyl) aminomethane, EDTA, Phi29 DNA polymerase (LC), and glycerol	13 μ L \times 1 tube
Stop DNB Reaction Buffer	EDTA, and molecular grade water	50 μ L \times 1 tube
DNB Load Buffer II	Potassium citrate tribasic monohydrate, and citric acid anhydrous	50 μ L \times 1 tube
MDA Enzyme Mix	phi29 DNA polymerase, and glycerol	0.125 mL \times 1 tube
MDA Reagent	dNTP Solution Mix, DTT, 100% DMSO, sucrose, and glycerol	1.0 mL \times 1 tube
Micro Tube 0.5 mL (Empty)	PP plastic	1 EA
FTAT premixed compaction block	PC plastic	1 EA


Component name	Main ingredients	G99 SM App-C FCL PE150
Sequencing Reagent Cartridge	Tris(hydroxymethyl) aminomethane, NaCl powder, EDTA, magnesium sulfate solution volumetric, tween-20, HCl, ddATP, ddCTP, ddTTP, ddGTP, App-C Insert Primer link1, cPAS DNA polymerase and glycerol	PE150×1

-  **Tips**
- Mixed use of reagent components from different batches of kit is not recommended.
 - The components and packages are batched separately.
 - Keep the components in the packages until use and do not take them out.
 - The kit of SE100 can be used for SE50 or SE35 test, and the kit of PE150 can be used for PE100 test.

[User-supplied equipment, reagent and consumables]

Table 4 User-supplied equipment, reagent and consumables


Equipment & materials	Recommended brand	Catalog number
Qubit 4.0 fluorometer	Thermo Fisher	Q33226
Mini centrifuge	Major Laboratory Supplier (MLS)	/
Vortex mixer	MLS	/
Thermal cycler	Bio-Rad	/
Pipette	Eppendorf	/
Sterile pipette tips	AXYGEN	/
200 μ L wide-bore non-filtered pipette tips	AXYGEN	T-205-WB-C
200 μ L wide-bore non-filtered pipette tips	BIOFOUNT	BI-200K-H
100 μ L sterile pipette tips	AXYGEN	/
Qubit ssDNA assay kit	Thermo Fisher	Q10212
0.2 mL PCR 8-strip tube	AXYGEN	/
1.5 mL micro-centrifuge tubes	AXYGEN	MCT-150-C
2.0 mL micro-centrifuge tubes	SARSTEDT	72.609.003
Ice box	/	/

-  **Tips**
- Avoid making and loading DNBs by the pipette tips with filter. It is necessary to use the pipette tips with recommended brands and catalog number.
 - Recommended brands and catalog number are suggested for other consumables.

[Storage & transportation conditions and validity period]

Table 5 Storage & transportation conditions and validity period

Storage conditions	Transportation condition	Validity period
Temperature: -25 °C to -15 °C Humidity: 20% RH to 80% RH	-80 °C to -15 °C	8 months
Temperature: -25 °C to -15 °C Humidity: 20% RH to 80% RH	-80 °C to -15 °C	8 months

 **Tips** For actual manufacturing date and use-by date, please refer to the labels.

[Applicable device]

Genetic Sequencer (DNBSEQ-G99), Wuhan MGI Tech Co., Ltd.

[Sample requirements]

- For general single-stranded circular DNA libraries, the amount of ssDNA library should be not less than 20 fmol, and the library volume should be not more than 10 μ L.
- For App-C single-stranded circular DNA libraries, the amount of ssDNA library should be not less than 30 fmol, and the library volume should be not more than 10 μ L.

- For the storage and preservation condition of the sample, please refer to the requirements of the supporting clinical application kits.

[Test method]

1. Library concentration and amount requirement

Perform the steps below:

1. Perform ssDNA library quantification (ng/μL) by using Qubit ssDNA Assay Kit and Qubit Fluorometer. The amount of ssDNA library input is determined by the quantification result.
2. Calculate the volume of the library input:
 - For the general ssDNA Library, the volume of each Make DNB reaction is 50 μL and the required library input for each Make DNB reaction is calculated as follow:

$$V (\mu\text{L}) = \frac{N \times 330 \text{ g/mol} \times 20 \text{ fmol}}{1000 \times 1000 \times C}$$

- For the App-C ssDNA library, the volume of each Make DNB reaction is 50 μL and the required library input for each Make DNB reaction is calculated as follow:

$$V (\mu\text{L}) = \frac{N \times 330 \text{ g/mol} \times 30 \text{ fmol}}{1000 \times 1000 \times C}$$

N represents the number of nucleotides (total library length including the adapter). **C** represents the concentration of ssDNA library (ng/μL).

2. Making DNB

2.1 Preparing reagents for DNB making

Perform the following steps:

1. Take out the Low TE buffer, Make DNB Buffer or App-C Make DNB Buffer and Stop DNB Reaction Buffer from package and place them at room temperature.



Tips For App-C ssDNA library, take out the App-C Make DNB Buffer.

2. Take out the Make DNB Enzyme Mix I from package and place it on an ice box.
3. After thawing, mix reagents by using a vortex mixer for 5 seconds. Centrifuge for 5 seconds and place them on ice for use.

2.2 Making DNB

Perform the following steps:

1. Add the following components into a new 0.2 mL PCR tube:
 - If it is for ssDNA of MGI adapter, prepare Make DNB reaction 1 according to the following table:

Table 6 Make DNB reaction 1

Component	Volume(μ L)
Low TE buffer	10-V
Make DNB Buffer	10
DNA library	V
Total volume	20

- If it is for ssDNA of App-C adapter, prepare Make DNB reaction 1 according to the following table:

Table 7 Make DNB reaction 1

Component	Volume(μ L)
Low TE buffer	10-V
App-C Make DNB Buffer	10
DNA library	V
Total volume	20

- Mix the mixture gently by vortexing and centrifuge for 5 seconds by using a mini centrifuge. Place the mixture into a thermal cycler and start the reaction. According to the following table:

Table 8 DNB Reaction condition 1

Temperature	Time
105 °C (Heated lid)	On
95 °C	1 minute
65 °C	1 minute
40 °C	1 minute
4 °C	Hold

- Take out the Make DNB Enzyme Mix II (LC) . Centrifuge the mixture briefly for 5 seconds, and place it on ice.



Tips Do not place the Make DNB Enzyme Mix II (LC) at room temperature or hold the tube for a prolonged time.

- Take the PCR tube out of the thermal cycler when the temperature reaches 4 °C .
- Centrifuge for 5 seconds, place the PCR tube on ice. and add the following components:

Table 9 Make DNB reaction 2

Component	Volume(μL)
Make DNB Enzyme Mix I	20
Make DNB Enzyme Mix II (LC)	2


- Mix the tube gently by vortexing and centrifuge for 5 seconds by using a mini centrifuge.

7. Place the tubes into the thermal cycler for the next reaction. According to the following table :


Table 10 DNB Reaction condition 2

Temperature	Time
35 °C (Heated lid)	On
30 °C	20 minutes
4 °C	Hold

8. Add 10 μL of Stop DNB Reaction Buffer immediately after the reaction enters **hold** at 4 °C. Mix the tube gently by using a wide bore non-filtered pipette tip 5 to 8 times.

-  **Tips**
- It is very important to mix DNB gently by using a wide bore non-filtered pipette tip.
 - Do not centrifuge, vortex, or shake the tube.
 - Store DNBs at 4 °C and use it within 48 hours.

9. Quantify DNB: Take 2 μL of the product of step 8 in 2 *Making DNB on Page 12* and use Qubit ssDNA Assay Kit and Qubit 4.0 fluorometer to quantify the DNB.

-  **Tips**
- The concentration of DNBs is required to be not less than 8 ng/ μL .
 - If the concentration is lower than 8 ng/ μL , make DNBs again and use it within 48 hours.

10. If the concentration exceeds 40 ng/ μL , the DNB should be diluted to 20 ng/ μL with Low TE Buffer before loading.

-  **Tips** If dilution is required, ensure not to dilute it until use.

3. Sequencing

3.1 Preparing reagents for sequencing

Perform the steps below:

1. Take out the sequencing reagent cartridge from storage.
2. Thaw the reagent cartridge in a water bath at room temperature until completely thawed (or thaw them in 2 °C to 8 °C refrigerator 24 hours in advance). Shake and store the reagent cartridge at 2 °C to 8 °C until use.



- **Tips** • The flow cell can be taken out from -25 °C to -15 °C and placed at room temperature at this point.
- After being taken out at -25 °C to -15 °C , the flow cell must be placed at room temperature for 30 minutes to 24 hours before DNB loading.

3. Wipe any water condensation on the cartridge cover with lint-free paper.
4. Press the M1, M2, M3, M4 wells of sequencing cartridge with the premixed compaction block.
5. Shake the sequencing cartridge up and down, left and right 10 to 20 times respectively to mix well.
6. Gently tap the cartridge on the bench to reduce air bubbles in the reagents. At this point, the preparations for SE sequencing are completed. For next step, refer to *3.3 Sequencing on Page 19*.

Perform following step for PE sequencing:

7. Add 125 μL of MDA Enzyme Mix to the MDA Reagent tube with a 200 μL pipette. Invert the tube 4 to 6 times to mix the reagents. Pierce the seal of well MDA by using a 1 mL sterile tip, then add the mixture to the MDA well. For next step, refer to *3.3 Sequencing on Page 19*.



- Tips
- When adding the MDA mixture, the pipette tip should be close to the concave side of the MDA hole, and add it obliquely to avoid air bubbles.
 - When transferring the mixture, operate carefully to prevent the mixture from spilling out of the reagent tube.

3.2 Preparing reagents for DNB loading

Perform the steps below:

1. Take out the flow cell from the inner package, ensure the flow cell is intact and place it at room temperature for 0.5 h.
2. Take out DNB Load Buffer II from storage and thaw the reagents on ice for approximately 30 minutes.
3. Mix reagents by using a vortex mixer for 5 seconds, centrifuge for 5 seconds and place it on ice until use.



- Tips
- If crystal precipitation is found in DNB Load Buffer II, vigorously mix the reagent about 1 to 2 minutes by using a vortex mixer to re-dissolve the precipitation before use.

4. Take out a new 0.2 mL microfuge tube and add the reagents in the table below.

Table 11 DNB loading mix

Component	Volume(μ L)
DNB Load Buffer II	7.0
Make DNB Enzyme Mix II (LC)	1.0
DNB	21.0
Total volume	29.0

5. Use a wide-bore non-filtered tip to mix the mixture gently by pipetting 5 to 8 times.



- Do not centrifuge, vortex, or shake the tube.
- Prepare a fresh DNB loading mix before the sequencing run.

6. Take out the O-ring that is installed in the loader by pressing it from the bottom of the loader and store it in the package.

7. Place the flow cell into the loader and aspirate 10 μ L of DNB loading mixture by using 200 μ L sterile tip instead of a wide-bore tip, and vertically insert the tip into the inlet. For specific operations, please refer to *MGIDL-G99&MGIDL-G99RS Portable DNB Loader Quick Start Guide*.



- Use conventional 200 μ L sterile tip but not wide-bore tip during loading.
- Do not use filtered pipette tips.

3.3 Sequencing

Perform the steps below:

1. Start the Genetic Sequencer.
2. Load the sequencing reagent cartridge and sequencing flow cell.
3. Run the sequencing program following *DNBSEQ-G99&DNBSEQ-G99A Genetic Sequencer User Manual*.

4. Data analysis

When sequencing is completed, the program will generate a standard sequence file for downstream analysis.

[Explanation of test results]

This kit cannot generate test results directly for in vitro diagnostic purpose. For the interpretation of test results, please refer to instructions for use of the applicable downstream molecular detection kit.

[Limitation of test method]

This product is only applicable to DNBSEQ-G99 Genetic Sequencer.

[Product performance indicators]

- Appearance
The outer package of the kit and cartridge should be intact without leakage. The product name, manufacturer, batch number and expiration date are correct.
- Accuracy
Test the enterprise reference Q, and the coincidence rate between the sequence information obtained by sequencing and the known reference sequence information should be not less than 99.0%.
- Repeatability

Repeat the test of the enterprise reference Q 5 times, and the CV value of the coincidence rate between the sequence information obtained by sequencing and the known reference sequence information is not more than 5% (n=5).

- Performance result

Table 12 Accuracy and repeatability about intra-batch variation

/	G99 SM FCL SE100	G99 SM FCL PE50	G99 SM FCL PE150	G99 SM App-C FCL SE100	G99 SM App-C FCL PE150
Accuracy (%)	99.76	99.87	99.82	99.11	99.32
	99.79	99.86	99.83	99.11	99.33
	99.75	99.84	99.81	99.10	99.33
	99.77	99.87	99.81	99.83	99.32
	99.77	99.85	99.82	99.84	99.82
SD	0.01	0.01	0.01	0.40	0.22
CV (%)	0.01	0.01	0.00	0.40	0.22

Table 13 Accuracy and repeatability about Inter-batch variation

/	G99 SM FCL SE100	G99 SM FCL PE50	G99 SM FCL PE150	G99 SM App-C FCL SE100	G99 SM App-C FCL PE150
Accuracy (%) Batch 1	99.82	99.86	99.78	99.03	99.36
	99.78	99.84	99.80	99.04	99.38
	99.78	99.82	99.78	99.02	99.36
	99.79	99.81	99.76	99.76	99.86
	99.80	99.89	99.78	99.75	99.87

/	G99 SM FCL SE100	G99 SM FCL PE50	G99 SM FCL PE150	G99 SM App-C FCL SE100	G99 SM App-C FCL PE150
Accuracy (%) Batch 2	99.77	99.86	99.72	99.08	99.24
	99.78	99.85	99.74	99.08	99.25
	99.76	99.80	99.72	99.08	99.25
	99.75	99.89	99.71	99.77	99.23
	99.76	99.90	99.72	99.85	99.74
Accuracy (%) Batch 3	99.70	99.84	99.78	99.10	99.33
	99.73	99.82	99.79	99.09	99.32
	99.70	99.82	99.78	99.84	99.32
	99.68	99.90	99.77	99.09	99.81
	99.70	99.88	99.78	99.08	99.83
SD	0.04	0.03	0.03	0.36	0.26
CV (%)	0.04	0.03	0.03	0.36	0.26

Table 14 Stability after opening

/	G99 SM FCL SE100	G99 SM FCL PE50	G99 SM FCL PE150	G99 SM App-C FCL SE100	G99 SM App-C FCL PE150
Accuracy (%)	99.67	99.86	99.71	99.09	99.29
	99.70	99.85	99.70	99.08	99.29
	99.65	99.84	99.70	99.08	99.28
	99.64	99.86	99.70	99.08	99.76
	99.66	99.84	99.70	99.08	99.79
SD	0.02	0.01	0.00	0.00	0.27
CV (%)	0.02	0.01	0.00	0.00	0.27

[Warnings and precautions]

- This product is for in vitro diagnostics use only.
- It is especially used by the personnel who has been trained professionally.
- Routine laboratory precautions, proper laboratory practices and good laboratory hygiene are required.
- Please read the instructions for use carefully before use, master the operating method, and get familiar with the warnings and precautions.
- Do not swallow any samples or reagents. Avoid direct contact with skin and eyes. If this happens, rinse them immediately with plenty of fresh water and seek medical advice in time.
- The sequencing reaction kit is highly sensitive. The following conditions may affect the test results, and the effects should be precluded before testing.
 - Samples have been placed for too long.
 - Samples are contaminated with other nucleic acids.
 - Sample fragments are not uniform in size.
- In addition, some operational errors may result in unsatisfactory test results. For example, the sequencing reaction kit exceeds the use-by date, the pipette and loader are inaccurate, the room temperature is too high, and the test is not performed according to the test procedure specified in the *DNBSEQ-G99&DNBSEQ-G99A Genetic Sequencer instructions for use*.
- If the kit has been thawed but cannot be used within 24 hours, it can be frozen and thawed only once.

- This product is for one sequencing run only and cannot be reused.
- For the storage and preservation conditions of the sample, please refer to the requirements of the supporting clinical application kits.
- All samples should be considered potentially infectious and should be handled in accordance with relevant national regulations.
- Contact with the manufacturer for the safety data sheet (SDS).
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

[Reference]

1. Dmitriy, K. et al. Comparative analysis of novel MGISEQ-2000 sequencing platform vs Illumina HiSeq 2500 for whole-genome sequencing. PLoS One. 2020 Mar 16;15(3):e0230301. doi: 10.1371.











[Manufacturer information]






Manufacturer	Wuhan MGI Tech Co.,Ltd.
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After-sale service address	Wuhan MGI Tech Co.,Ltd.
E-mail	MGI-service@mgi-tech.com
Website	www.mgi-tech.com

[European representative]

Name	Shanghai International Holding Corp. GmbH (Europe)
Address	Eiffestrasse 80, 20537 Hamburg, Germany

[Key symbols]

Symbol	Description
	Manufacturer
	Authorized representative in the European Union
	Catalogue number
	CE marking
	In vitro diagnostic medical device
	Serial number
	Consult instruction for use or consult electronic instruction for use
	Keep away from rain
	Temperature limitation
	Use - by date

Symbol	Description
	Batch code
	Keep away from sunlight
	Do not re-use
	Contains sufficient for N tests
	Unique device Identifier

[Latest revision of the instructions for use]

Version	Date	Description
1.0	December 2022	Initial release.

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