

Non-invasive Prenatal Paternity Test Package

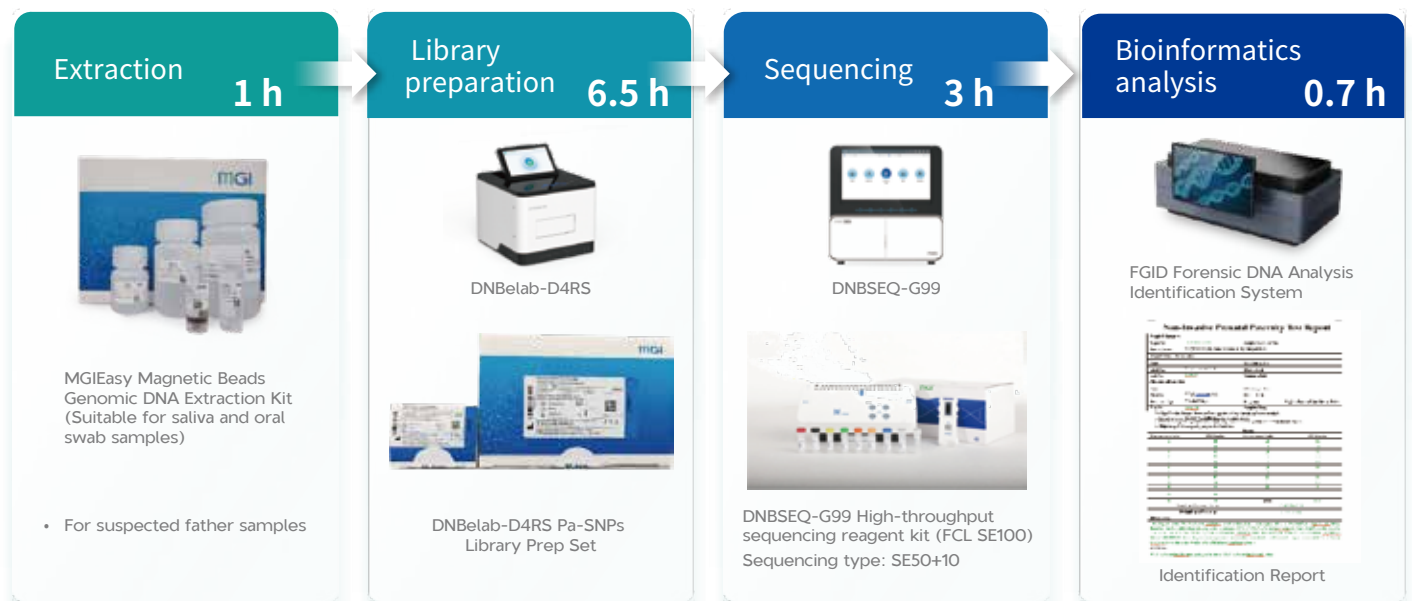
—Safer. Simpler. Swifter

Features

- Instant Insights**
 The identification report is ready in 12 hours after the sample receipt.
- Seamless Integration**
 Experience a comprehensive, one-stop solution encompassing nucleic acid extraction, library preparation, sequencing, and analysis—all streamlined into a Non-invasive Prenatal Paternity Test Product Package.
- Simplified Operations**
 Embrace a Digital Sample Preparation Platform that significantly reduces manual intervention, streamlining processes, cutting library preparation time, and easing laboratory contamination standards for a more accessible experimental setup.
- Fortress of Privacy**
 The analysis system is fortified with a tiered account management structure, safeguarding user information with privacy and security, complemented by offline capabilities that ensure data autonomy and completeness.
- Precision Assurance**
 Rely on product's identification accuracy, with a cumulative non-exclusion probability (CPE) exceeding 99.999999%, for results you can trust.

Introduction

MGI Non-invasive Prenatal Paternity Testing Package is based on the self-developed MGIEasy Magnetic Beads Genomic DNA Extraction Kit, DNBelab-D4RS Pa-SNPs Library Preparation Set, DNBelab-D4 Digital Sample Preparation Platform, DNBSEQ-G99 Sequencer, and FGID Forensic DNA Analysis Identification System. It covers the entire process from sample processing to analysis and identification report, enabling rapid and accurate analysis of suspected fathers, pregnant women, and fetal samples in the peripheral blood of pregnant women, providing a Swift, Secure, and Simple tool for non-invasive prenatal paternity testing.



Note: FGID Forensic DNA Analysis Identification System is a third-party product.

Performance

Sample Requirement

Table 1. Sample Requirement

	Sample Concentration	Input(ng)
gDNA	≥0.2ng/μL	2
cfDNA	≥0.4ng/μL	4

Paternal samples can be gDNA extracted from blood, oral swab, hair, fingernails, and other sample types, maternal samples can be gDNA extracted from peripheral blood, and fetal samples can be cfDNA extracted from 1mL of plasma.

Library preparation

A total of 257 libraries including alleged mother gDNA extracted from 1mL blood, alleged father gDNA extracted from hair, oral swab, blood or fingernail, and cfDNA extracted from 1mL plasma of pregnant women, with gestational weeks from 6 to 30 weeks. The whole process from DNA sample to DNB output on DNBelab-D4RS is 5h15min. The success rate were 97.50%, 98.68% and 97.03% for father, mother and fetus samples respectively.

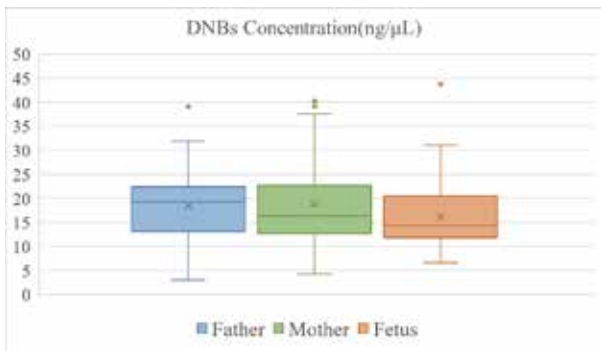


Figure 1. DNBelab-D4RS DNB Concentration

Sequencing Performance

Up to 3 families were mixed for sequencing per flow cell.

The sequencing performance of all 33 flow cells was satisfactory, resulting in an average of TotalReads>90M, Q30>92%, Split rate>91%.

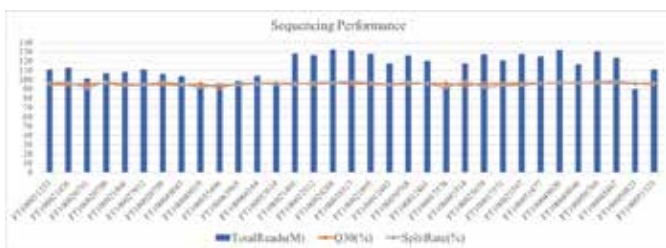


Figure 2. Sequencing Performance

Table 2. The average and minimum values of Sequencing performance

	TotalReads(M)	Q30(%)	SplitRate(%)
Average value	114.26	95.57	95.69
Minimum value	90.19	92.00	91.50

Sample QC Result

The sample QC results of both gDNA and cfDNA were qualified. The sample QC result of gDNA were MappedRate(>95), TargetOnMap(>98), Coverage=>100X(>95), Uniformity(0.1>(>95). And the sample QC result of cfDNA were MappedRate(>97), TargetOnMap(>98), Coverage=>1000X(>96), Uniformity(0.1>(>97).

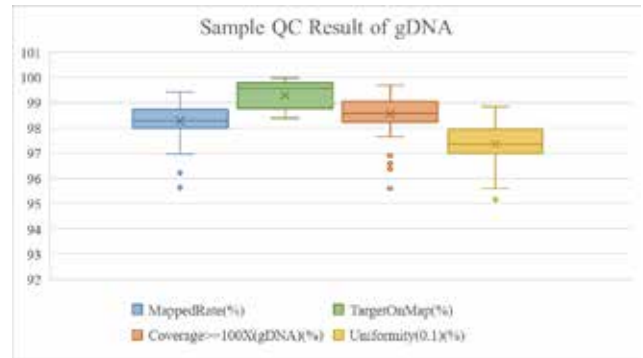


Figure 3. Sample QC Analysis Result of gDNA

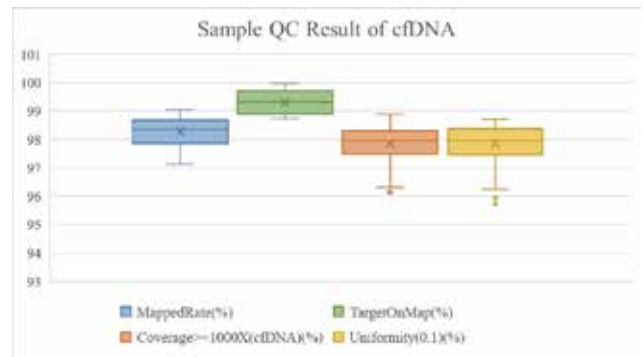


Figure 4. Sample QC Analysis Result of cfDNA

Table 3. The average and minimum values of sample QC

gDNA	MappedRate(%)	TargetOnMap(%)	Coverage=>100X(gDNA)(%)	Uniformity(0.1)(%)
Average Value	98.27	99.28	98.55	97.35
Minimum Value	95.63	98.39	95.60	95.16

gDNA	MappedRate(%)	TargetOnMap(%)	Coverage=>100X(gDNA)(%)	Uniformity(0.1)(%)
Average Value	98.27	99.30	97.83	97.85
Minimum Value	97.12	98.73	96.15	95.73

Paternity result

The paternity results includes a Word format report file.



Figure 5. Paternity Analysis Report

Table 6. Paternity Analysis Result

Family	Gestational weeks(W)	Paternity	CPI	Z-Score	PP	Fetal(SNPs)	Err(SNPs)	PI(SNPs)	CPE	Sample Type of Father	Comparing result
FAM3	6	Inclusion	1.31826E+20	6.55	>99.999999%	3.03%(182)	0.41%(505)	198e-02(1015)	1-(6.522564e-104)	Blood	TRUE
FAMT	7	Inclusion	4.7863E+101	16.65	>99.999999%	7.71%(178)	0.25%(492)	1.03e-01(984)	1-(3.171166e-101)	Blood	TRUE
FAMT-1	7	Inclusion	1.47911E+87	20.59	>99.999999%	7.67%(174)	0.32%(495)	8.69e-02(1003)	1-(1.888985e-103)	Blood	TRUE
FAMT2	7	Inclusion	1.9498E+100	16.69	>99.999999%	9.05%(177)	0.48%(495)	9.91e-02(1012)	1-(3.199023e-104)	Blood	TRUE
FAMT3	7	Inclusion	3.9811E+104	21.59	>99.999999%	7.74%(178)	0.22%(492)	1.09e-01(964)	1-(3.705323e-99)	Blood	TRUE
Fam546	7	Inclusion	1.44544E+43	13.68	>99.999999%	1.95%(165)	0.44%(472)	4.13e-02(1046)	1-(1.737247e-107)	Blood	TRUE
Fam331	7	Inclusion	1.4454E+144	24.63	>99.999999%	4.90%(182)	0.27%(515)	1.41e-01(1021)	1-(5.253407e-105)	Fingernail	TRUE
FamY-1	8	Inclusion	2.63E+53	15.16	>99.999999%	5.81%(167)	0.97%(529)	1.124864e+00(1045)	1-(3.427569e-107)	Blood	TRUE
FamY-2	8	Inclusion	1.07E+31	11.02	>99.999999%	7.94%(168)	1.06%(527)	1.074732e+00(990)	1-(1.249807e-101)	Blood	TRUE
Fam552	10	Inclusion	7.24E+57	20.03	>99.999999%	4.43%(285)	0.83%(377)	6.10e-02(948)	1-(3.125932e-97)	Oral swab	TRUE
Fam551	11	Inclusion	5.62E+155	28.83	>99.999999%	9.45%(175)	0.30%(473)	1.60e-01(971)	1-(4.504435e-100)	Hair	TRUE
Fam553	11	Inclusion	1.58E+100	24.76	>99.999999%	5.51%(193)	0.58%(383)	1.04e-01(962)	1-(1.109576e-98)	Oral swab	TRUE
FAM_1l-normal_input	12	Inclusion	2.29087E+55	10.13	>99.999999%	3.64%(169)	0.43%(520)	5.55e-02(998)	1-(3.570589e-102)	Blood	TRUE
FAM1l_large_input-10ng	12	Inclusion	2.6915E+130	32.96	>99.999999%	3.94%(171)	0.22%(524)	1.27e-01(1024)	1-(7.256127e-105)	Blood	TRUE
FAM1l_large_input-5ng	12	Inclusion	4.1687E+110	24.49	>99.999999%	3.94%(171)	0.24%(526)	1.10e-01(1004)	1-(7.240742e-103)	Blood	TRUE
Fam559	13	Inclusion	8.13E+152	34.81	>99.999999%	15.79%(261)	1.11%(385)	1.438799e+00(969)	1-(2.843214e-99)	Blood	TRUE
Fam560	13	Inclusion	2.88E+120	26.48	>99.999999%	6.65%(228)	0.71%(397)	1.330454e+00(972)	1-(4.087546e-100)	Blood	TRUE
Fam591	13	Inclusion	1.51E+96	27	>99.999999%	5.18%(179)	0.68%(421)	1.282331e+00(890)	1-(1.312866e-91)	Fingernail	TRUE
FAM10-1	17	Inclusion	5.37E+81	14.35	>99.999999%	11.51%(162)	0.46%(526)	8.04e-02(1017)	1-(3.245887e-104)	Blood	TRUE
FAM10-2	17	Inclusion	1.05E+64	13.42	>99.999999%	10.36%(164)	0.28%(529)	6.51e-02(984)	1-(7.934765e-101)	Blood	TRUE
FAM10-3	17	Inclusion	1.74E+114	17.11	>99.999999%	12.21%(165)	0.44%(528)	1.15e-01(993)	1-(9.461867e-102)	Blood	TRUE
FAM0	19	Inclusion	2.09E+56	13.45	>99.999999%	8.11%(163)	0.34%(476)	5.92e-02(951)	1-(6.304447e-98)	Blood	TRUE
FAM8	22	Inclusion	2.29E+55	17.69	>99.999999%	10.69%(159)	0.33%(520)	1.20e-01(949)	1-(3.357143e-97)	Blood	TRUE
FAM1-1	27	Inclusion	1.29E+147	21.38	>99.999999%	10.25%(187)	0.36%(506)	1.46e-01(1010)	1-(2.943725e-103)	Blood	TRUE
FAM1-2	27	Inclusion	3.80E+133	19.6	>99.999999%	11.38%(187)	0.36%(508)	1.31e-01(1016)	1-(1.085511e-103)	Blood	TRUE
*SF-1%	/	Inclusion	3.24E+35	13.72	>99.999999%	1.18%(172)	0.25%(526)	3.54e-02(1002)	1-(1.964674e-103)	/	TRUE
SF-2%	/	Inclusion	3.09E+100	23.96	>99.999999%	2.85%(173)	0.20%(526)	9.82e-02(1023)	1-(1.392609e-105)	/	TRUE
SF-5%	/	Inclusion	2.14E+136	24.03	>99.999999%	6.98%(175)	0.28%(527)	1.36e-01(1005)	1-(1.046725e-103)	/	TRUE
SF-10%	/	Inclusion	2.34E+156	24.57	>99.999999%	11.74%(175)	0.24%(527)	1.56e-01(1001)	1-(1.551561e-103)	/	TRUE
SF-20%	/	Inclusion	5.50E+163	24.31	>99.999999%	20.93%(175)	0.20%(527)	1.62e-01(1008)	1-(4.327775e-104)	/	TRUE
FAM5	12	Inclusion-WrongMother	7.24E-196	11.02	<0.00000001%	13.70%(177)	1.49%(480)	-1.97e-01(991)	1-(1.010353e-101)	Blood	TRUE
FAM4	30	Inclusion-WrongMother	<1.0e-300	13.18	<0.00000001%	45.51%(188)	4.74%(500)	-1.03e+00(946)	1-(8.992615e-97)	Blood	TRUE
FAM4-1	30	Inclusion-WrongMother	<1.0e-300	13.41	<0.00000001%	45.62%(188)	4.75%(499)	-1.02e+00(951)	1-(3.279183e-97)	Blood	TRUE
FAM2-1	7	Exclusion	5.01187E-65	-0.92	<0.00000001%	4.85%(53)	0.95%(271)	-1.52e-01(423)	1-(2.462240e-44)	Blood	TRUE
FAM2-2	7	Exclusion	6.45654E-57	1.06	<0.00000001%	3.53%(53)	0.96%(275)	-1.27e-01(443)	1-(1.660563e-46)	Blood	TRUE
FAM2-3	7	Exclusion	2.88403E-62	-0.49	<0.00000001%	4.00%(52)	0.95%(272)	-1.46e-01(422)	1-(2.735855e-44)	Blood	TRUE
FAM6	7	Exclusion	3.54813E-60	-0.35	<0.00000001%	2.27%(191)	0.67%(509)	-6.12e-02(972)	1-(1.345520e-99)	Blood	TRUE
FAM9	8	Exclusion	1.74E-79	1.26	<0.00000001%	2.64%(179)	0.87%(480)	-8.24e-02(956)	1-(4.683766e-98)	Blood	TRUE
FAM9-1	8	Exclusion	4.37E-185	0.2	<0.00000001%	4.17%(181)	1.12%(485)	-1.87e-01(986)	1-(2.806712e-101)	Blood	TRUE
FAM7	13	Exclusion	3.24E-260	0.92	<0.00000001%	5.97%(173)	1.58%(503)	-2.61e-01(994)	1-(4.607186e-102)	Blood	TRUE
FAM7-1	13	Exclusion	3.24E-260	1.16	<0.00000001%	5.42%(173)	1.58%(504)	-3.62e-01(1011)	1-(4.185197e-104)	Blood	TRUE

* *SF: Simulated Family, 1% means the fetal concentration is 1%.

PI: Paternity index. stands for the probability of that a random man is the biological father.

CPI: Combined Paternity Index. the product of all the individual PI values for each locus.

CPE: Cumulative probability of exclusion.

PP: probability of paternity. $PP = (CPI / (CPI + 1)) \times 100$

Z-Score: Standard deviation between the suspected father's CPI and the non-paternal database's CPI dataset. A higher score means that the suspected father has a more paternal bond with the fetus than the other non-paternal samples.

Fetal: Proportion of fetal theoretical typing in maternal plasma.

Err: The statistical noise level.

The paternity results from 5 simulated families with varying concentrations of fetal DNA and a total of 36 tests on actual families. including 25 Inclusion family tests. 8 Exclusion family tests and 3 surrogate family tests. were all accurate when compared to the real results. Samples of family T. Y. 1. 2. 4. 7. 9. and 10 showed consistent performance in the repetition.

Ordering information

Item Number	Product Name	Specification	Brand
Instrument			
900-000607-00	DNBSEQ-G99RS(CE-RUO)	1 set	MGI
900-000822-00	DNBelab-D4 Digital Sample Preparation System(CE-RUO)	1 set	MGI
FGI20230002	FGID Forensic DNA Analysis System	1 set	FGI
Reagent			
940-000633-00	MGIEasy Magnetic Beads Genomic DNA Extraction Kit	96 RXN	MGI
940-002477-00	DNBelab-D4RS Pa-SNPs Library Prep Set	16 RXN	MGI
940-001268-00	High-throughput Sequencing Set (G99 FCL SE100/PE50)	8 Gb	MGI

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