FGI Forensic Genomics For A Better Future

Non- Invasive Prenatal Paternity Paternity Test

1 . Sample Submission and Delivery

1 Samples should be delivered and submitted to PROVIDER with the requirements and shipment address detailed in Appednix A.

2 Every sample submitted shall be accompanied with the " Request Form" , " Informed Consent Form" and " Infection Control Agreement" (due to current pandemic) in the format provided by PROVIDER. ss

3 Every sample should be labeled with client' s name.

4 After the samples being picked up by Logistic Company, DISTRIBUTOR shall send an email with details of tracking no . , client' s name and attached document . (i. e. Request Form)

2 . Sample Arrival

1 When the samples are received by PROVIDER, Lab personnel shall investigate the quality and quantity of the samples . A received email shall be sent by PROVIDER .

2 If the samples are qualified, PROVIDER shall send an email to confirm the samples are received with the details of client' s name and turnaround time (" TAT") (7 - 1 2 working days for normal case and 5 - 6 working days for express case) .

3 If the samples are not qualified (e. g. maternal blood hemolyzed, insufficient quality and quantity of the sample) , PROVIDER shall send an email to request a recollection of the sample with attached photo.

3 . Report

1 PROVIDER shall prepare and deliver the final soft copy report to DISTRIBUTOR via Email within the agreed turnaround time

2 DISTRIBUTOR acknowledges that the reports provided by PROVIDER are sole for reference and are not for legal documents .

4 . Inconclusive Result - Recollection of sample

1 After the data analysis, there are several reasons that can cause the result inconclusive (e. g. low cfDNA concentration, sample contaminated) . Therefore, DNA test for Africa shall request a recollection of sample via email with client' s name, reason of recollection.

5 . Inconculstive Result - Resequencing

1 For resequencing case, TAT is extended to 1 5 working days . PROVIDER shall give an email notice on 1 0 th working day or earlier if resequencing needed.

2 After the resequencing, if the result still inconclusive, recollection of the sample is needed. PROVIDER shall request a recollection of sample via email.

6 . Termination of the case

1 If the clients wish to terminate the case before the extraction is started (i. e. , the samples are not qualified once it arrived at our lab, and recollection is needed) , The case shall be free of charge .

2 If the clients wish to terminate the case after the extraction and analysis (i. e. , the result is inconclusive and recollection is needed) , The case shall be charged 1 / 3 of the original price .

SAMPLE REQUIREMENT

Blood (for cf DNA)

1 Requirements of blood sample collection

Ensure the pregnant maternal sample have at least full 7 weeks of gestational age . Ten (l0) mL peripheral blood is required to be stored in Streck Cell - Free DNA BCT tubes, immediately upside down ten (1 0) times gently(fierce inversion can lead to hemolysis which will influence the test results) to fully mix the blood with the contents of the tube as any delay could lead to failed test . The Streck Cell - Free DNA BCT tubes must be kept in room temperature (6 ~ 3 5 ° C) . All items in the Request Form must be properly completed.

Requirements of blood sample transportation

2 Package the Streck Cell - Free DNA BCT sample tubes in 6 - 3 5 ° Cenvironment . During summer (> 3 5 ° C) , wrap an ice bag thoroughly with proper stuffing to cover the ice bag thoroughly, and place it packed ice bag together with the wrapped samples into the foam box . Use soft fillings to avoid direct contact between the ice bag and the samples . Stuffing and foam need to fill up the rest room and also to fill the rest of the spaces . During winter with temperature below 6 ° C, the Streck Cell - Free DNA BCT tubes are not recommended . Make sure that the top of the sampling box faces upward during transportation, and blood separation takes place within 9 6 hours to obtain the plasma.

Blood (for genomic DNA)

1 Requirements of blood sample collection

5 mL capillary blood, EDTA anticoagulation

2 Requirements of blood sample transportation

Shipment together with ice bag or dry ice is recommended . Shipment at room temperature is allowed only if the delivery time is within 3 days

3 Fingernail: at least 5 complete pieces or fragmented pieces from 5 fingernails

4 Bloodstain card: air- dry, 2 × 8 mm^2

5 Semen stain: air- dry, 1 0 mm^2

6 Hair with follicle: at least 5 hairs with follicle

Non- Invasive Prenatal Paternity Test (NIPPT) Request Form

Referring Personal Detail (If any)			
Agent		Contact No.	
Clinic		Physician	
Address			

Alleged Paternal Information			
*Name			
*ID./ Passport No.		Client No.	
DOB(DD/ MM/ YYYY)		* Sampling Date	
* Population Information	☐ Asian ☐ Caucasian ☐ Hispanic ☐ African ☐ Other:		
* Sample type	☐5ml EDTA Blood ☐Bloodstain ☐Nails ☐ Semen stain ☐ Hair with follicle ☐ Swab		
* Did you received a blood transfusion or stem cell transplantation? ☐Yes Date:_____☐No			
Maternal Information			
*Name			
*ID./ Passport No.		Client No.	
DOB(DD/ MM/ YYYY)		* Sampling Date	
* Gestational Age	Weeks + Day(s)		
* Pregnancy	☐ Singleton	Twins ☐ Fraternal ☐Identical	☐ IVF ☐ Surrogate
* Termination of Pregnancy (within one year)	☐ No	☐ Yes, Date: Gestational Age:	
* Delivery Record (within one year)	☐ No	☐ Yes, Date:	☐ Male ☐ Female
* Population Information	☐ Asian ☐ Caucasian ☐ Hispanic ☐ African ☐ Other:		
* Did you received a blood transfusion or stem cell transplantation? ☐Yes, Date:_____☐No			
Additional sample Information (If applicable)			
☐ Additional alleged father ☐Biological mother for Surrogacy case only ☐Other:_____			
*Name			
*ID./ Passport No.		Client No.	
DOB(DD/ MM/ YYYY)		* Sampling Date	
* Ethnicity	☐ Asian ☐ Caucasian ☐ Hispanic ☐ African Americans ☐ Other: _____		
* Sample type	☐5ml EDTA Blood ☐Bloodstain ☐Nails ☐ Semen stain ☐ Hair with follicle ☐ Swab		
* Did you received a blood transfusion or stem cell transplantation? ☐Yes Date:_____☐No			

* indicates MUST be filled
* Read and sign the " Notice to Client" and " Informed Consent" on second page

Notice to Client

1. The result of this DNA test is affected by the gestation period, method of sample storage, process and transport.
2. The result can be affected by mutation of individual DNA and contamination during sample collection.
3. Due the limitation of current techniques, result can be false positive, false negative or inconclusive for the test.
4. The report will be available within 7- 12 working days since received date, express case within 5- 6 working days.
5. Since there is insufficient genetic information from the fetus that develops less than 6 weeks, we do not accept any sample less than 6 gestational weeks.
6. The following health conditions are inappropriate for the test: pregnancy with 3 or more fetuses, pregnant woman is suffering from tumour disease, toxaemia of pregnancy, blood transfusion, bone marrow or organ transplant, stem cell therapy.
7. If the process of test is affected by unexpected cause, DNA test for Africa may re- collect sample and extend the date of process.

Informed Consent

1. I authorize DNA test for Africa to use my sample for the purpose of paternity test.
2. I agree DNA test for Africa to use the data of my test for research purpose.
3. I provided correct and reliable personal detail for the test.
4. I am willing to hold all the risks of the test.
5. I understand the content of informed consent. I have had the opportunity to ask questions and discuss the capabilities, limitations, and possible risks of the test(s) with my healthcare provider or someone who has designated.
6. I agree and shall release, indemnify and hold harmless to all of DNA test for Africa' s officers, employees, advisors, and agents against any and/ or all direct, incidental, special, consequential, indirect or punitive claims, liabilities and / or damages relating to or arising out of in any way to test service.

*Signature: *Date(DD/MM/YYYY) :

Notice to Client

8. The result of this DNA test is affected by the gestation period, method of sample storage, process and transport.

9. The result can be affected by mutation of individual DNA and contamination during sample collection.

10. Due the limitation of current techniques, result can be false positive, false negative or inconclusive for the test.

11. The report will be available within 7- 12 working days since received date, express case within 5- 6 working days.

12. Since there is insufficient genetic information from the fetus that develops less than 6 weeks, we do not accept any sample less than 6 gestational weeks.

13. The following health conditions are inappropriate for the test: pregnancy with 3 or more fetuses, pregnant woman is suffering from tumour disease, toxaemia of pregnancy, blood transfusion, bone marrow or organ transplant, stem cell therapy.

14. If the process of test is affected by unexpected cause, DNA test for Africa may re- collect sample and extend the date of process.

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*Signature: *Date(DD/MM/YYYY) :

Infection Control Agreement for COVID- 19

Due to the problematic situation of the pandemic novel coronavirus (COVID- 19), we follow the World Health Organization (WHO). When collecting a sample for our test, please follow the requirements below:

1. Before the patient enters the sample collection site, the body temperature must be checked if the body temperature of the patient is average (37.3 degrees Celsius or below, ≤37.3°C), he or she can enter. Suppose the body temperature of clients is higher than >37.3°C. In that case, he or she is advised to visit the hospital and have a diagnosis or treatment to rule out the susceptibly of novel coronavirus before he or she returns for the sample collection.

2. To avoid the spread of infection, apart from taking a photo, the client must wear a surgical mask during the entire process of sample collection on the site.

3. Sample collector needs to register personal information of the patient and inform the health status of the patient.

4. The patient shall report whether he or she has visited any epidemic area or countries in the past two weeks (14 days) or has any close contact with a suspected patient or patient with the novel coronavirus.

5. The patient shall report if he or she has any symptoms such as fever, fatigue, dry cough, diarrhea, etc., within the past two weeks (14 days).

6. To protect the health of all personnel, please provide the information truthfully. We have the right not to conduct the test for those who do not cooperate, such as refusing to measure the body temperature, not wearing the surgical mask, deliberately concealing travel and contact history, and being unable to explain their recent health condition.

I agree and provide truthful information about my current health condition, travel, and contact history within the past two weeks (14 days). My signature below indicates my agreement.

Signature: Date：

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Signature: Date：

Non-Invasive Prenatal Paternity Test Report

Sample Information			
Report No.	LHK*****	Samples Received Date	**/**/2022
Sample Source			
Alleged Paternal Information			
Name	AA	ID./ Passport No.	*****
Client No.		Date of Birth	*****
Tube No.		Sampling Date	**/**/2022
Maternal Information			
Name	BB	ID./ Passport No.	*****
Client No.		Date of Birth	*****
Gestational Age	**weeks +**days	Pregnancy	Singleton
Tube No.		Sampling Date	**/**/2022

The Non-Invasive Prenatal Paternity Test is performed by using the following methods:

1. Extraction of cell-free DNA from the maternal plasma sample.
2. Extraction of paternal genome DNA from samples and maternal genome DNA from blood samples.
3. Sequencing DNA and genotyping the SNP markers.

Result					
Chromosome Code	**SNP Marker**	**Corresponded Marker**	**Chromosome Code**	**SNP Marker**	**Corresponded Marker**
1	47	47	13	35	35
2	38	38	14	19	19
3	32	32	15	14	14
4	40	40	16	18	18
5	27	27	17	15	15
6	34	34	18	27	27
7	29	29	19	0	0
8	22	22	20	15	15
9	18	18	21	20	20
10	23	23	22	3	3
11	24	24			
12	21	21	**Total**	521	521
Combined Paternity Index			4. 19×10^{90}		
Probability of Paternity			99.999999%		

Interpretation

The alleged father AA, is not excluded as the biological father of BB's fetus. Based on the Mendelian Inconsistency and the detected SNPs of AA, the Paternity Index is 4. 19×10^{90} and the probability of Mr.AA being the biological father of BB's fetus is >99.999999%. According to our analysis and the biostatistical evaluation of the result, they indicate that Mr.AA is the biological father of BB's fetus.

Conclusion

AA is biological father of BB's fetus.

Report Date: **//****

Report Notes

Result

- The accuracy of this genetic DNA test result is limited by gestational week, sample storage period, mean of sample collection, and transportation condition.
- The test result may also be affected by individual variation and possible contamination during sample collection.
- Due to the limitation of the latest molecular technology, the test result may be inconclusive.

SNP Marker

- Single Nucleotide Polymorphism
- It indicates the detected markers of the fetus and the parents.

Chromosome Code

- Chromosome X, Y is omitted.

Corresponded Marker

- Based on the detected SNP markers, they represent the relationship between the fetus and parents.

Total

- It includes tested chromosomes in the human nucleus.
- The numbers are the sum of the markers.

Disclaimer

The client has agreed and released, indemnify, and held harmless to all of DNA test for Africa's officers, employees, advisors, and agents against any or all direct, incidental, special, consequential, indirect, or punitive claims, liabilities or damages relating to or arising out of in any way to test service.

Non-Invasive Prenatal Paternity Test Report

Sample Information			
Report No.	LHK****	Samples Received Date	**/**/2022
Sample Source			
Alleged Paternal Information			
Name	AA	ID./ Passport No.	******
Client No.		Date of Birth	******
Tube No.		Sampling Date	**/**/2022
Maternal Information			
Name	BB	ID./ Passport No.	******
Client No.		Date of Birth	******
Gestational Age	**weeks +**days	Pregnancy	Singleton
Tube No.		Sampling Date	**/**/2022

The Non-Invasive Prenatal Paternity Test is performed by using the following methods:

1. Extraction of cell-free DNA from the maternal plasma sample.
2. Extraction of paternal genome DNA from samples and maternal genome DNA from blood samples.
3. Sequencing DNA and genotyping the SNP markers.

Result					
Chromosome Code	**SNP Marker**	**Corresponded Marker**	**Chromosome Code**	**SNP Marker**	**Corresponded Marker**
1	76	20	13	49	12
2	82	20	14	43	7
3	70	16	15	36	11
4	80	22	16	38	8
5	83	21	17	23	4
6	65	16	18	48	15
7	55	16	19	7	0
8	52	14	20	27	4
9	42	11	21	18	5
10	52	19	22	12	3
11	37	14			
12	61	12	**Total**	1056	270
Probability of Paternity			<0.000001%		

Interpretation

The alleged father, AA, is excluded as the biological father of BB's fetus. Based on the Mendelian Inconsistency and the detected SNPs of AA, the probability of AA being the biological father of BB's fetus is <0.000001%. According to our analysis and the biostatistical evaluation of the result, they indicate that AA is not the biological father of BB's fetus since AA does not provide the allele in genetic markers to the fetus.

Conclusion

AA is not biological father of BB's fetus.

Report Date: **//2022**

Report Notes

Result

- The accuracy of this genetic DNA test result is limited by gestational week, sample storage period, mean of sample collection, and transportation condition.
- The test result may also be affected by individual variation and possible contamination during sample collection.
- Due to the limitation of the latest molecular technology, the test result may be inconclusive.

SNP Marker

- Single Nucleotide Polymorphism
- It indicates the detected markers of the fetus and the parents.

Chromosome Code

- Chromosome X, Y is omitted.

Corresponded Marker

- Based on the detected SNP markers, they represent the relationship between the fetus and parents.

Total

- It includes tested chromosomes in the human nucleus.
- The numbers are the sum of the markers.

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The client has agreed and released, indemnify, and held harmless to all of DNA test for Africa's officers, employees, advisors, and agents against any or all direct, incidental, special, consequential, indirect, or punitive claims, liabilities or damages relating to or arising out of in any way to test service.