DiaCarta, Inc.

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COMPARISON OF BLOOD COLLECTION TUBES FROM DIACARTA AND STRECK

ROOM TEMPERATURE STORAGE TESTING

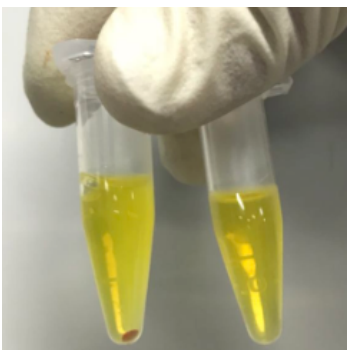
1. Testing Proposal

Take 20 ml venous blood from 4 volunteers using QuantiDNA™ Cell-Free BCT (Blood Collection Tube) and Streck cell-free BCT, 10 ml each tube. When stored at room temperature, 1.2 ml of blood samples were taken for isolation of plasma and cfDNA and construction of library on day 0, 1, 3, 5, 7, and 14. Compare the cfDNA preservation performance from both products.

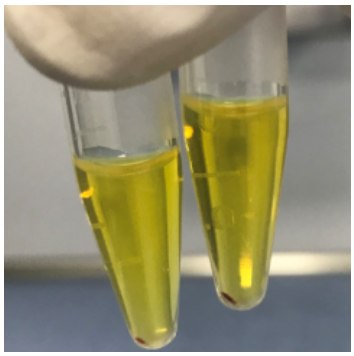
2. Testing Results

2.1. Comparison of Plasma Color

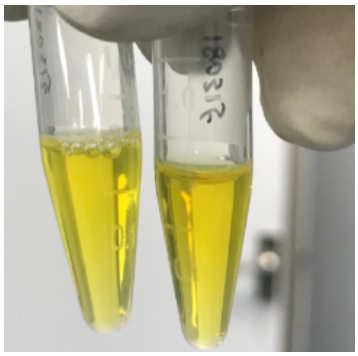
2.1.1. Sample 1: plasma color comparison between DiaCarta and Streck tubes on day 0, 1, 3, 5, 7, and 14. The sample has been centrifuged twice. Left of the pair: Streck tubes; Right of the pair: DiaCarta tubes.



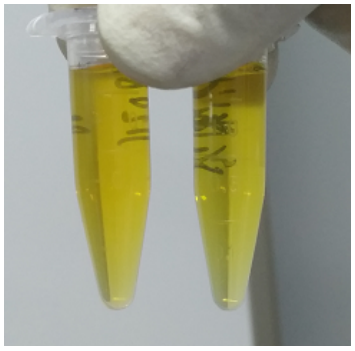
Day 0



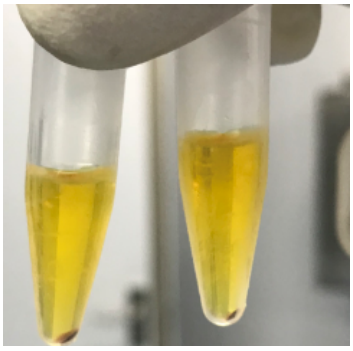
Day 1



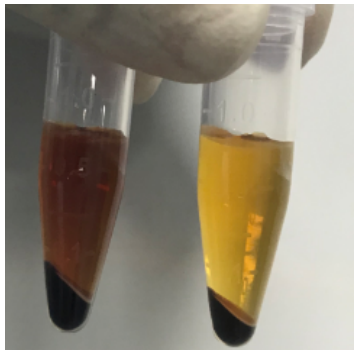
Day 3



Day 5

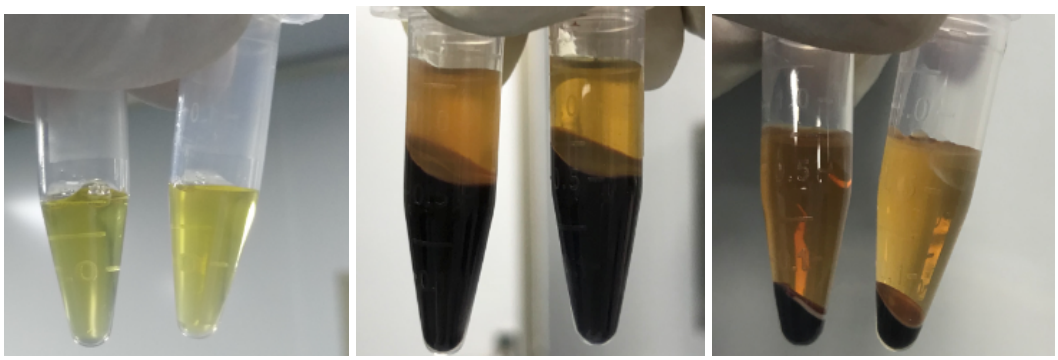


Day 7



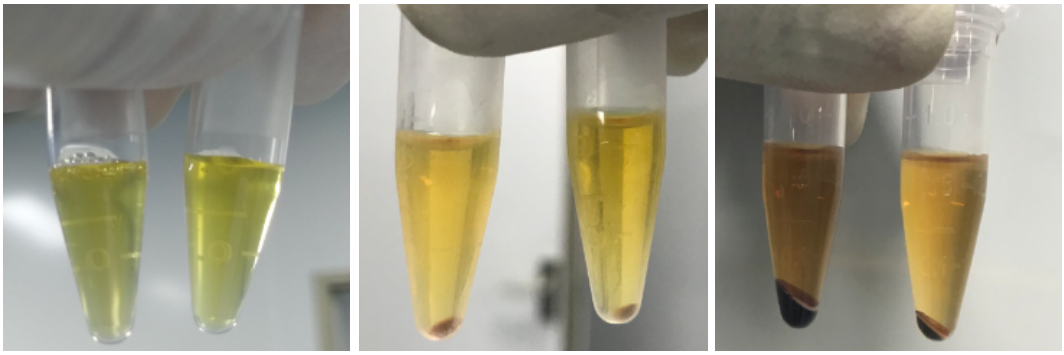
Day 14

2.1.2. Sample 2: plasma color comparison between DiaCarta and Streck tubes on day 5, 7, and 14. The sample has been centrifuged twice. Left of the pair: Streck tubes; Right of the pair: DiaCarta tubes.



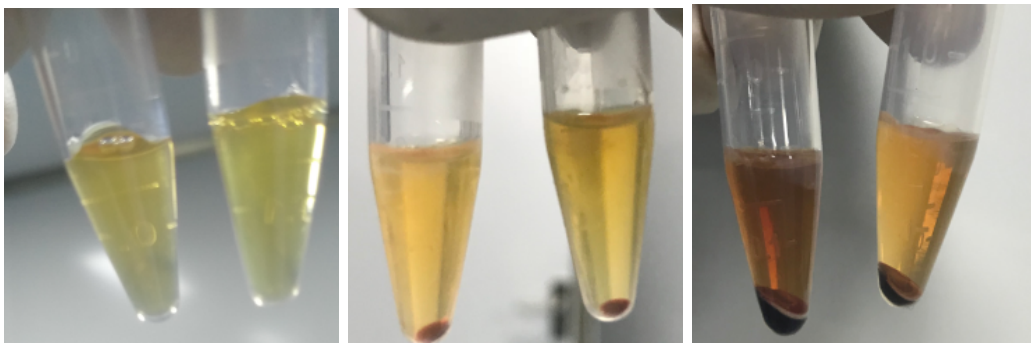
Day 5 Day 7 Day 14

2.1.3. Sample 3: plasma color comparison between DiaCarta and Streck tubes on day 5, 7, and 14. The sample has been centrifuged twice. Left of the pair: Streck tubes; Right of the pair: DiaCarta tubes.



Day 5 Day 7 Day 14

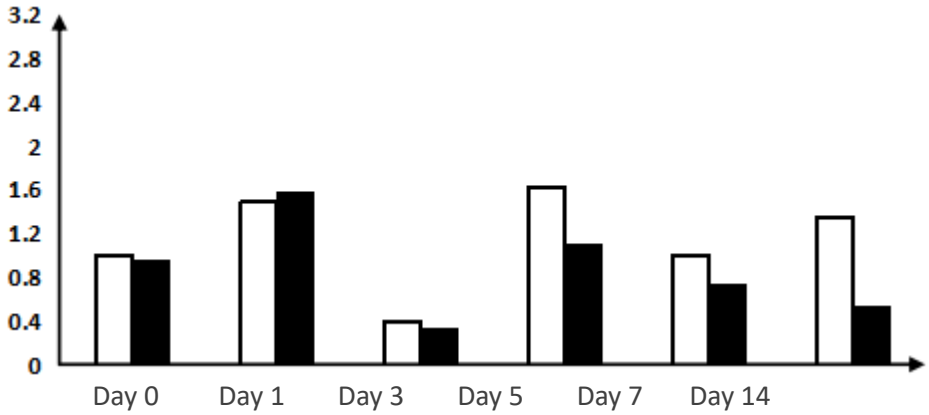
2.1.4. Sample 3: plasma color comparison between DiaCarta and Streck tubes on day 5, 7, and 14. The sample has been centrifuged twice. Left of the pair: Streck tubes; Right of the pair: DiaCarta tubes.



Day 5 Day 7 Day 14

2.2. Plasma cfDNA Concentration Testing

After centrifuge, 500 µl plasma was taken for isolation of cfDNA. The cfDNA was eluted in 35 µl TE buffer and concentration (ng/ µl) was determined.



cfDNA concentration (ng/ µl) (Y-axis) comparison from samples stored in DiaCarta (left bar in the pair) and Streck (right bar in the pair) blood collection tubes.

Conclusion: The concentration of cfDNA extracted from samples stored in DiaCarta or Streck blood collection tubes has no significant difference.

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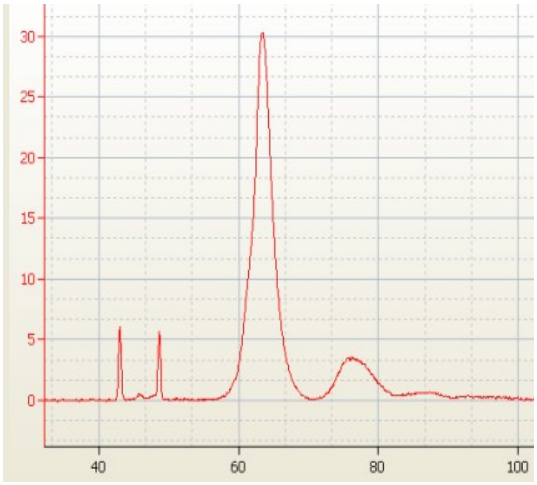
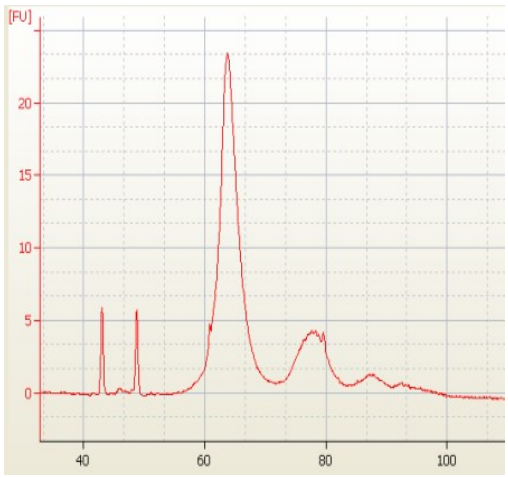
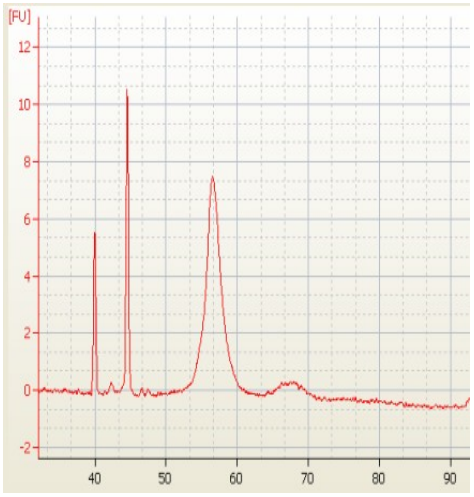
2.3. Testing of DNA Fragments After Library Construction Using cfDNA Isolated from Samples Stored in DiaCarta or Streck Blood Collection Tubes.



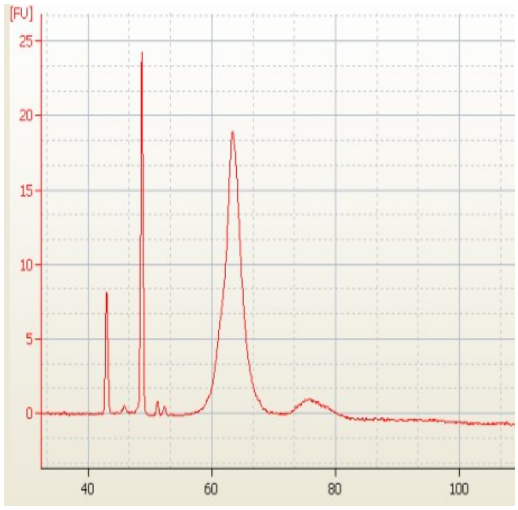
Day 0



Day 1



Day 3



Day 7

Conclusion: The cfDNA from samples stored in DiaCarta or Streck blood collection tubes on day 0, 1, 3, and 7 were used for library construction. The Agilent Bioanalyzer 2100 was used to check the fragment sizes. The major fragments are between 160 and 180bp, and no prominent DNA fragment contamination peaks exist.

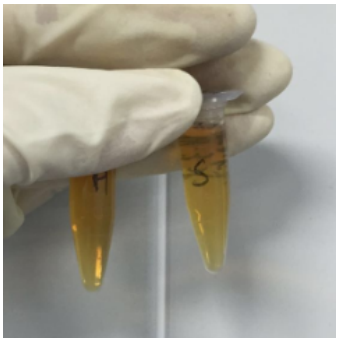
3. Shipping Testing Proposal

Take 20 ml venous blood from 4 volunteers using QuantiDNA™ Cell-Free BCT and Streck cell-free BCT, 10 ml each tube. The samples were shipped to 4 cities and returned to the lab. Isolate plasma and cfDNA from the returned samples, construct cfDNA library, and compare the cfDNA preservation performance between the two products.

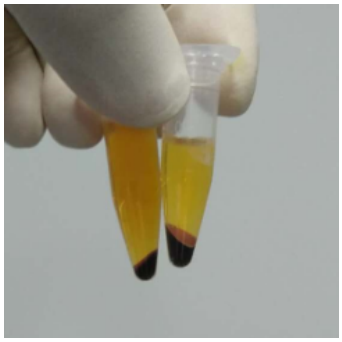
3.1. Plasma Color Comparison

City 1 (4 days in shipping)

City 2 (5 days in shipping)



City 1 (6 days in shipping)



City 2 (8 days in shipping)

Plasma color comparison between the samples stored either in DiaCarta (right in the pair) or Streck (left in the pair) blood collection tubes.

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3.2. Determination of cfDNA Concentration (ng/µl) Stored in DiaCarta or Streck Tube.

Samples	Location	Shipping Date	Return Date	cfDNA	cfDNA
1	City 1	03/12/2018	03/16/2018	0.494	0.534
2	City 2	03/12/2018	03/17/2018	0.158	0.135
3	City 3	03/18/2018	03/25/2018	0.732	0.994
4	City 4	03/19/2018	03/27/2018	0.454	0.776

Conclusion: We do not see significant differences in cfDNA concentration from samples shipped in DiaCarta or Streck tubes. We also tested the two products for prenatal analysis and tumor testing (see the other two documents for details).