




**Optimizing your biobanking business
with novel liquid biostabilization
technology**

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www.dnagenotek.com © 2013 DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., all rights reserved. *Superior samples • Proven performance* MS-XXXX-Blair 1/2013-04

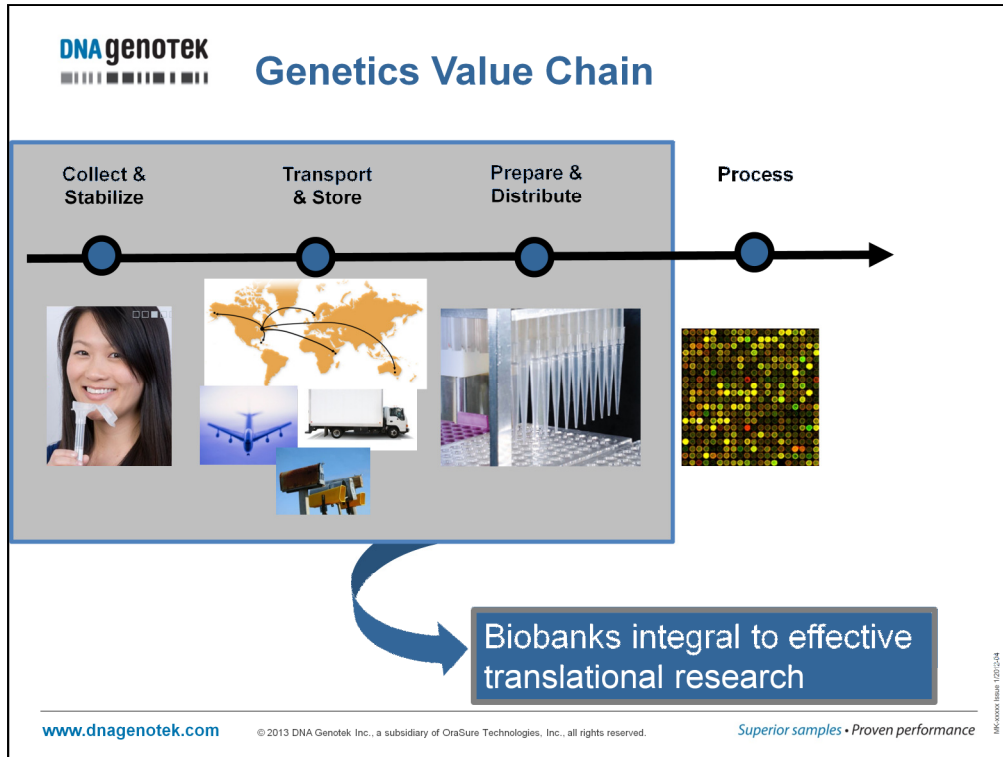
Hallo, Es ist schön, hier zu sein. Ich hoffe, Sie alle hatten bis jetzt eine tolle Konferenz.

Leider ist mein Deutsch ziemlich limitiert und deshalb hoffe ich, dass es ok ist, wenn ich in Englisch weiter mache.

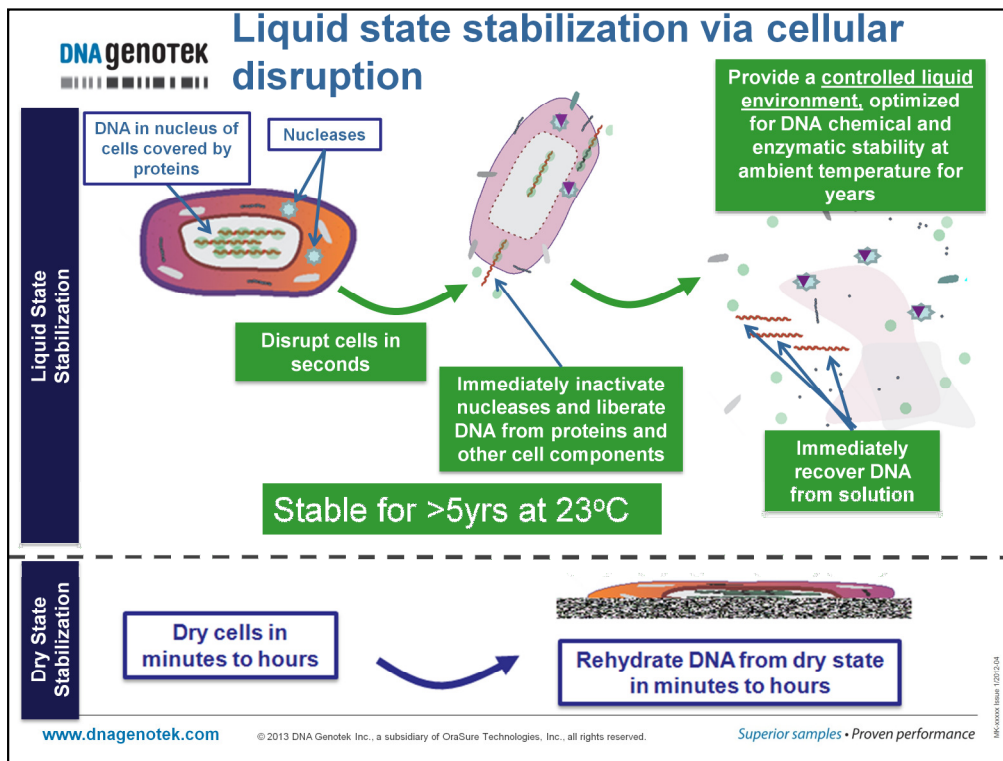
Glauben Sie mir, es ist besser für Ihr Verstehen und aus Respekt vor der deutschen Sprache.

Hello, It is nice to be here. I hope you have all had a great conference.

Unfortunately, my German is rather limited and I hope it is okay if I continue in English. Believe me, it would best for your understanding, and in respect for the language itself.



- A high quality sample is important to maximize the quality and efficiency of a biobank.
- With the massive amount of data that can be produced from a microgram of human cells, these benefits are only realized if the data is accurate and easily analyzed.
- One of the most important factor in biosample quality is the ability to keep samples frozen without disruption. We want to change this.



- At the current time, I imagine most of your plans involve deep freezing your samples, but this comes with risks and expensive back-up precautions.
- From the massive power outages in Hurricane Sandy, many hospitals and biobanks found that even their back-up systems were vulnerable and lost priceless samples. Between this risk, the price of freezers, and cold chain transport, the popularity of ambient temperature stabilization is increasing. In this market, you are left with two options, dry state and liquid state and dry state, while cheaper up front, requires much additional labour in drying, rehydrating and extraction, as well as a lower quality sample.
- After years of optimization and trials, our primary technology, Oragene-DNA, was released. It comprises of a collection system for 2mL of saliva with an automatically released preservative that keeps the DNA stable at room temperature for over 5 years.
- Oragene shuts down molecular machinery, is efficient at liberating DNA of comparable to DNA extracted from blood in both quality and quantity (per ml).
- According to the University of McGill Green Biobanking survey, 25% of respondents have experienced specimen loss as a result of power failures in the past 5 years.”
- “25% of respondents have experienced power failures in the past 5 years that resulted in the loss of specimen”
- [McCarthy, Connor. A survey on long-term storage of biological specimens at McGill University.](#)



Collect & Stabilize

Collect & Stabilize



From Californians' DNA, a Giant Genome Project



130,000+ samples collected by mail

Sheryl Connell, a lab coordinator for Kaiser Permanente in Oakland, scanned bar codes last week on vials for saliva samples. Peter D'Silva for The New York Times

Control preanalytical conditions

- Easy and reproducible collection → scale & reliability

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Superior samples • Proven performance

DNAGENOTEK 12/2012 USA

- Some large organizations are able to examine the economics of this option, and many have gone ahead with a complete switch from blood to saliva for DNA only samples.
- Kaiser Permanente, a large US based health care provider, collected 130,000 samples by mail in 18 months.
- A simplified shipping protocol (at room temperature) will allow decentralized collections to run much easier.
- Collecting by the post, directly from patients/subjects is now easy and scalable.
- Workflow time is reduced vs using blood spots or swabs as no rehydration step is necessary.
- Oragene samples work with most every extraction system.

DNAgenotek
ANTHONY NOLAN
 BE A MATCH, SAVE A LIFE

Driving Transplant Registry Growth

***IMPACT ON SAMPLE ACQUISITION
 160,000 COLLECTED**

New donor Recruitment Cumulative Totals

DNA Genotek provides donor registries with the solution to rapidly expand their donor base, directly translating into more saved lives

- Blood collections cannot drive the growth that registries require to hit their recruitment goals
- Saliva offers flexible home- or event-based recruitment – offering a method to collect thousands of samples in a single day

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•For Anthony Nolan, the largest UK HLA/bone marrow registry, the numbers do not lie. Since adopting the Oragene technology, the number of samples collected have improved due in part to two things: (1) the limitations of blood, and (2) the flexibility of saliva.

•This is a powerful graph, the dark red line shows recruitment going up once Anthony Nolan introduced Oragene, which in 2013 was 3 times the number of recruits in 2009.

•This has directly lead to 100's more life saving matches each year.

DNAgenOTEK Performance on Downstream Applications

Proven performance on downstream applications:

- NGS
- qPCR
- Multiplexed PCR
- RFLP
- TaqMan
- Southern blotting
- SNP/CNV Microarrays
- HLA typing
- Sequencing
- Microsatellite analysis
- Whole genome amplification

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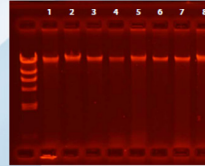
•A big strength of Oragene-DNA and our other technologies is our passion for validation. We would rather do the work once, very well, than have each of our customers waste their budgets doing identical experiments to validate themselves.

•Look online for many in-house and 3rd party publications citing Oragene (1740 unique results on Google Scholar for “Oragene”)



After 7 years room temperature storage (~23°C) the Oragene/saliva samples were purified. The purified DNA was of high yield, quality and molecular weight.

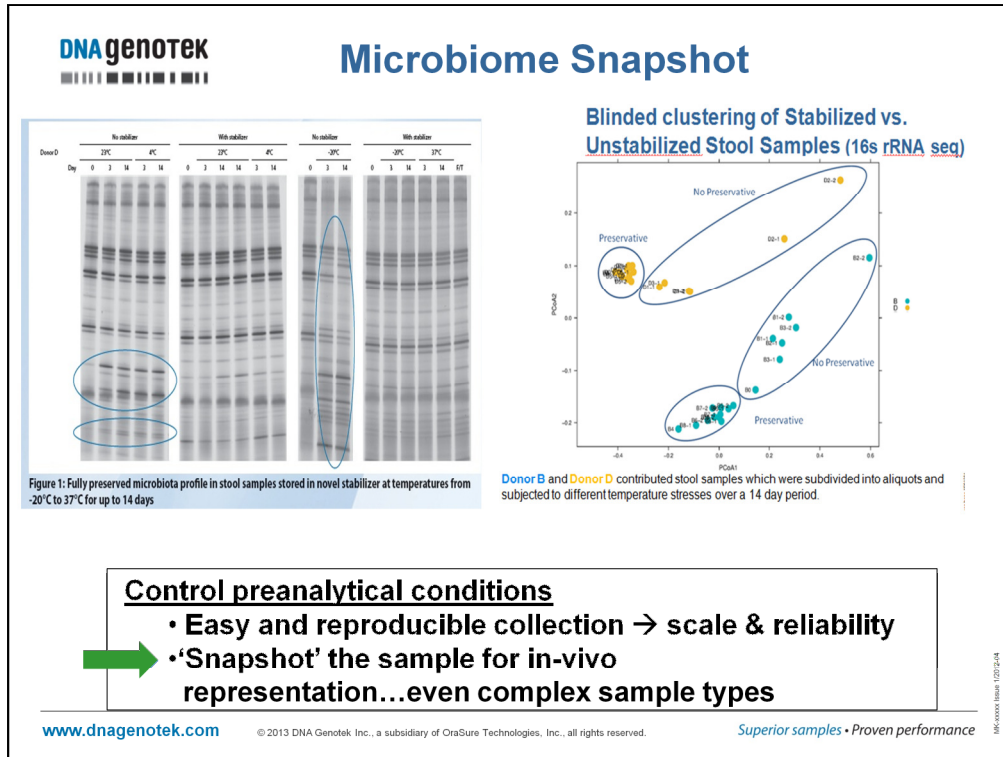
Sample ID	Collection date	Total yield (µg)	Concentration (ng/µL)	A ₂₆₀ /A ₂₈₀	% Bact
1	2006	94.5	236.2	1.86	17%
2	2006	28.6	71.5	1.86	30%
3	2006	52.3	130.7	1.85	18%
4	2006	52.3	130.8	1.86	14%
5	2006	61.7	154.3	1.92	37%
6	2006	192.1	480.2	1.95	45%
7	2006	70.3	175.6	1.84	10%
8	2006	66.0	164.9	1.87	36%



Each sample was barcoded and 4 samples were run per lane on the Illumina HiSeq 2000. The average sequencing yield per sample was 12.5 Gb, with 98% of sequences prior to clipping aligned to the human hg19 reference.

Sample	Sequencing yield (Mb)	% Align genome	Insert mean	Mean quality	% Duplication	Mean depth
1	11610	97.70	223	36.5	0.41	111
2	11145	97.57	246	36.4	0.43	104
3	11936	97.94	220	36.6	0.37	114
4	13989	97.86	234	36.6	0.32	131
5	13399	97.60	265	36.3	0.28	124
6	13428	96.89	256	36.3	0.34	125
7	12271	98.07	213	36.5	0.35	110
8	12718	97.69	246	36.6	0.30	121

- Recent studies show very high performance on Exome arrays after 7 years at room temperature.
- Whole Genome sequencing data is being analyzed, but looks great so far. Bacterial contamination causing no problems in obtaining clear reads and high depth scores. Information available on our website.
- We currently have studies of Oragene sample performance on Next Generation Sequencing (WGS), but the studies are ongoing, analysis takes time. Take a look at our website for the most up-to-date information.



•After several years of working with saliva, we’ve expanded on to other sample types, such as feces to look at the all important microbiome.

•As we look at more complicated biomarkers, such as methylation, transcription and microbiome, we need to know that the sample accurately portrays the in-vivo state.

•Left Graphic – Protected vs unprotected samples at varying temperatures. Protected samples show on average 93% similarity ; unprotected show only a 53% similarity (DGGE – denaturing gradient gel electrophoresis – 16s variable region)

•Right Graphic – principle components analysis of same thing. Algorithms to compare similarity ; protected are grouped, showing high similarity, unprotected are scattered.

•

•Take home message – what you took isn’t necessarily what you have.. Unless it’s preserved.

DNAgenOTEK

Flexible Protection

Collect & Stabilize Transport & Store Prepare & Distribute Process

	% DNA loss after 2 freeze-thaw cycles	% DNA loss after 20 freeze-thaw cycles
HEMAGene-BUFFY COAT	1%	7%
Unprotected buffy coat	75%	91%

Stabilize biomolecules for the long term

- Protect biological material over time and temperature

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- In addition to feces, we also have a product that preserves buffy coat samples at room temperature, either freshly fractionated, or from frozen states.

- Even with the offer of room temperature stability, some biobanks have incorporated HEMAGene into their frozen buffy coat samples to obtain extra stability. This is useful for material transfers, helping to avoid the use of dry ice for shipment, as well as an added layer of protection against power or equipment issues causing thaw.

- Without protection, we found that after only 2 freeze thaw cycles; less than 25% of the DNA was still intact. After 10 cycles, this dropped to around 10%.

- In our HEMAGene kits, even after 20 freeze thaw cycle approx 90% of the DNA is preserved at high MW



Cost effective transport



Buffy coat on dry ice



Figure 1: Packaging for the HEMAgene-BUFFY COAT sample versus buffy coat on dry ice.

Shipment itinerary	Shipment type	Buffy coat on dry ice shipping charges	HEMAgene-BUFFY COAT shipping charges	Savings with HEMAgene-BUFFY COAT
Ottawa to Salt Lake City	DHL Express	\$89.26	\$35.45	\$53.81
Salt Lake City to Ottawa	FedEx International Priority	\$249.96	\$72.50	\$177.46

Table 3: Actual shipping costs for buffy coat on dry ice versus the HEMAgene-BUFFY COAT sample.

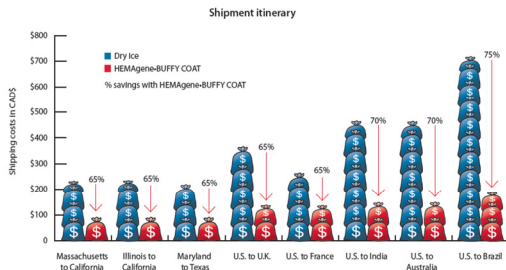
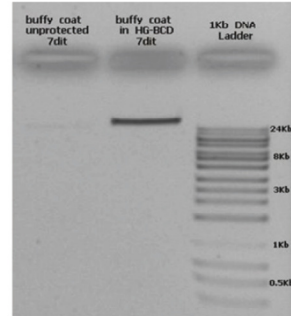


Figure 3: Estimated shipping costs for buffy coat on dry ice versus the HEMAgene-BUFFY COAT sample.



Stabilize biomolecules for the long term

- Protect biological material over time and temperature
- Simplify logistics and reduce costs with flexible operations

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MS-XXXX-Blair 1/2012-048

•To study our preservation method vs the standard of dry ice w/ blood, we sent a sample about 7,000 km across an international border. Not only were the costs an average of 65% less, but our first sample was actually stopped at the border for inspection. During this delay, the dry ice sublimated and the sample was effectively lost, as visualized by the electrophoresis gel on the right.

•HEMAgene•BUFFY COAT reduces shipping costs, simplifies logistics and eliminates risk of freeze-thaw exposure

DNA genOTEK

Flexible & Efficient Integration

Collect & Stabilize Transport & Store **Prepare & Distribute** Process

- Liberate total nucleic acids
- Recover with high efficiency
- Integrate with laboratory batching and automation
- Defer extraction and storage costs
- Extend sharing of samples

23 kb →

Agarose gel of DNA extracted by the QIAasymphony SP from 24 HEMAgene™•BUFFY COAT samples.

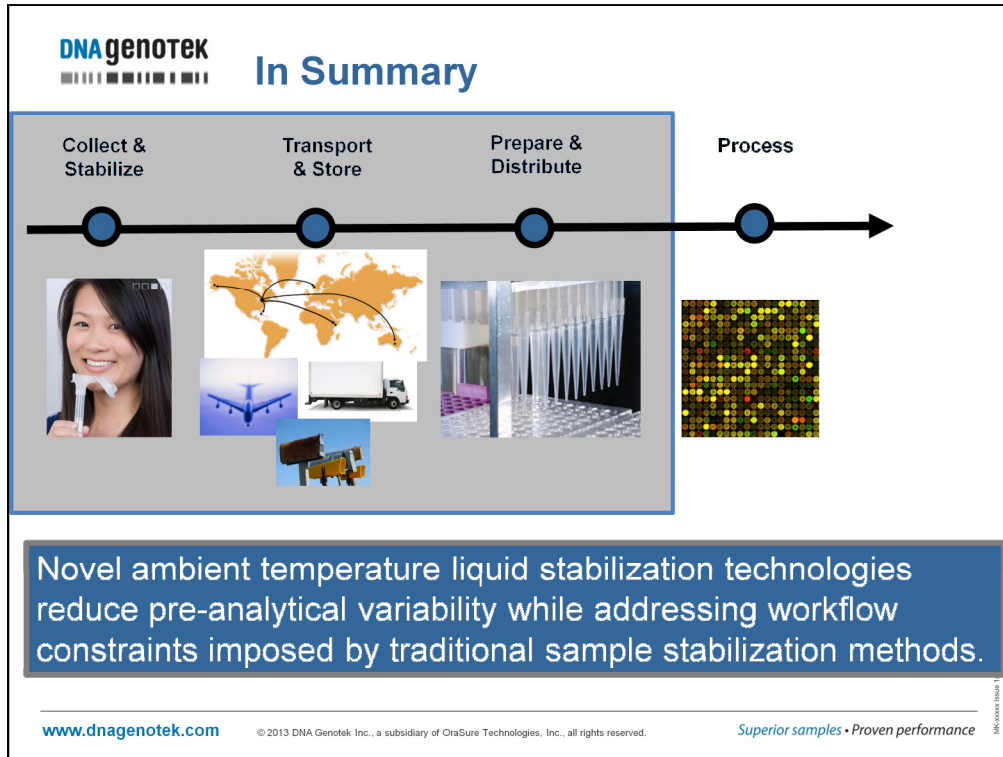
Flexibility enables cost effective operations and maximizes biological information.

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MFC-000001-000001-12/2013-04-08

All of the samples preserved in DNA Genotek chemistries can be extracted using any system, with many validations and protocols already available.

For example, you can see all the 23kb bands visible after extracting a HEMAgene protected buffy coat sample using the QIAasymphony.



- This presentation provides an overview of how DNA Genotek sample collection and stabilization products, in particular, Oragene enable end to end research applications.

- All clinical research and testing is based on the collection of a reliable and high quality sample. Given the breadth of sequencing technologies it is imperative that the input sample is the best possible standard to maximize the reliability of the downstream results.

- After years experience working with biobanks – we’ve learned that taking care of preanalytical conditions is important, and we strive to offer optimal samples at the good cost and easy integration into existing workflows.