

Direct to Consumer Marketing of a Nutrigenetics Testing Product: The Minnesota Experience

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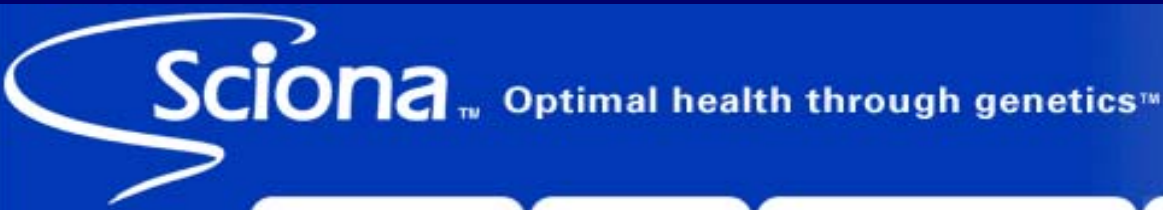
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The Players

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Retail Partners

www.pharmaca.com

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www.hy-vee.com

www.ukrops.com



www.parknicollet.com



The Market for Nutrigenetics Tests: Health Managers

- 12 million people (6% of U.S. population)
- 35-64 yrs of age
- Strong female skew
- College educated
- HHI \$60,000 and up
- No children in the household
- Regular physical fitness program (2x / week)
- Regular users of vitamins / supplements

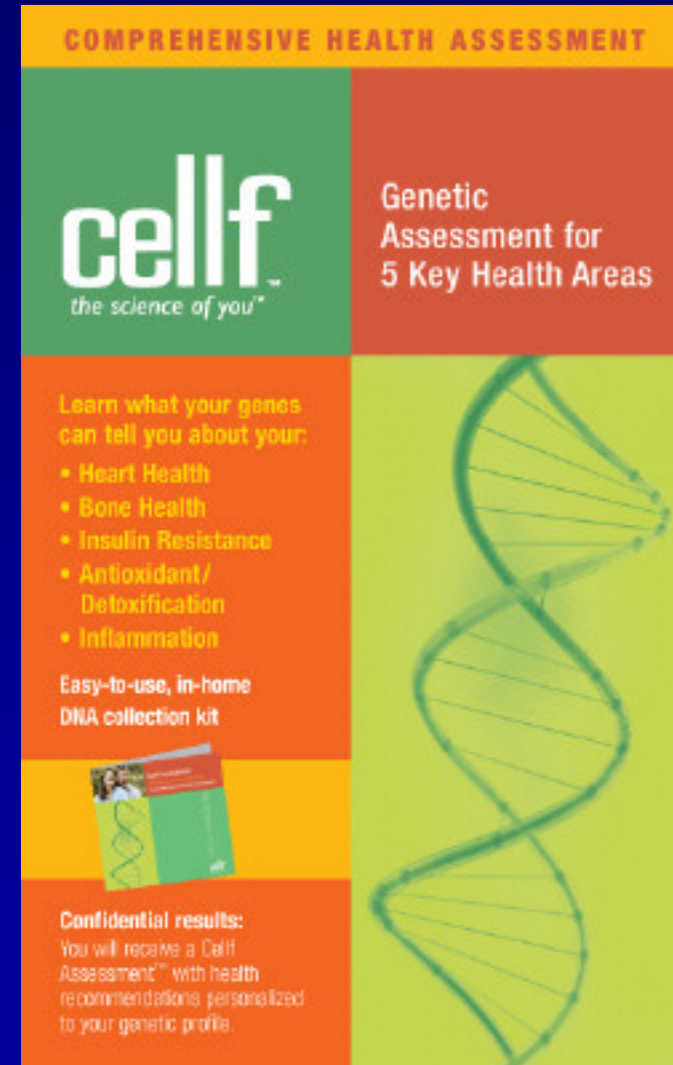


Benoit S. Personal
communication. July 2005

The Product: Cellf Tests

- Heart Health
- Bone Health
- Insulin Resistance
- Antioxidant / Detoxification
- Inflammation Health
- Comprehensive

<http://www.sciona.com>



The image shows the packaging for the Cellf Comprehensive Health Assessment. The top of the box is orange with the text "COMPREHENSIVE HEALTH ASSESSMENT". Below this, the left side is green and features the "cellf" logo in white, with the tagline "the science of you™" underneath. The right side is red and contains the text "Genetic Assessment for 5 Key Health Areas". The middle section is orange and lists the five health areas: Heart Health, Bone Health, Insulin Resistance, Antioxidant/Detoxification, and Inflammation. Below this list, it says "Easy-to-use, in-home DNA collection kit" and shows a small image of the kit. The bottom section is orange and contains the text "Confidential results: You will receive a Cellf Assessment™ with health recommendations personalized to your genetic profile." The right side of the box is light green and features a large, stylized DNA double helix graphic.

COMPREHENSIVE HEALTH ASSESSMENT

cellf
the science of you™

Genetic Assessment for 5 Key Health Areas






























Learn what your genes can tell you about your:

- Heart Health
- Bone Health
- Insulin Resistance
- Antioxidant/Detoxification
- Inflammation

Easy-to-use, in-home DNA collection kit

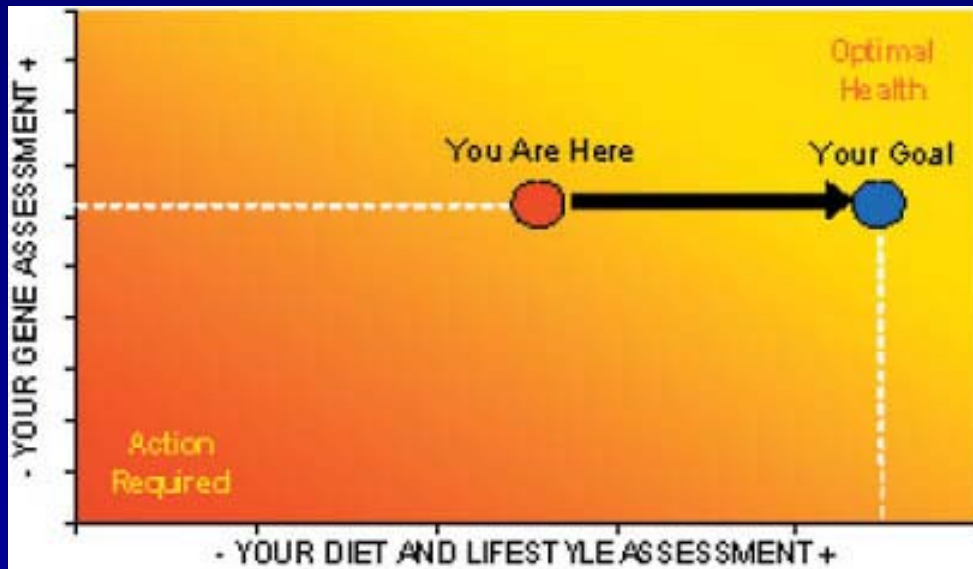
Confidential results:
You will receive a Cellf Assessment™ with health recommendations personalized to your genetic profile.

Genes Included in the Cellf Assessment

- *APOC3* 
- *CETP* 
- *LPL* 
- *MTHFR* 
- *MTR* 
- *MS_MTRR* 
- *CBS* 
- *eNOS*  
- *GSTM1*  
- *GSTT1*  
- *GSTP1*  
- *MnSOD*  
- *SOD3*  
- *COL1A1* 
- *VDR*  
- *IL-6*    
- *TNF α*    
- *ACE*  
- *PPAR γ 2* 

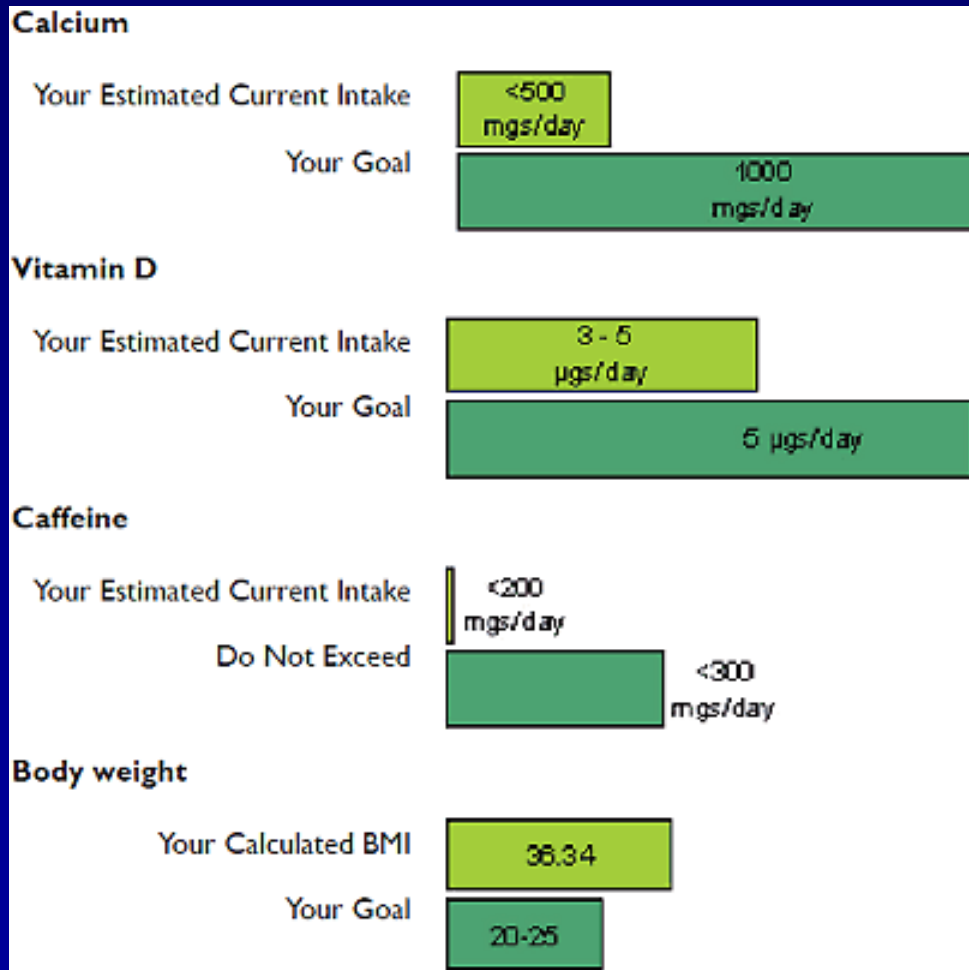


Interpreting the Test Results: Your Action Map



- Presents health risk as point on grid
 - Y axis: Genetic results
 - X axis: Diet and Lifestyle
- You can't change your genes, but other factors are modifiable

Interpreting the Test Results: Your Action Plan



- Analysis based on diet and lifestyle questionnaires and genetic profile
- Does including genetic information modify or change recommendations?
- What is the value added????

Registered Dietitians: Observations From the Field

- RD's classes on the product were not well attended
- RD's services for interpreting test results were not extensively utilized
- Test report did not always take into account what a customer was already doing to improve health
- Range of reactions to test results observed
 - How are customers interpreting the results?
- Sophistication level of consumers is high

Registered Dietitians: Observations From the Field

- Very interested in the potential for nutrigenetics to improve health
- See nutrigenetics as an exciting emerging area of practice for their profession
- Do not feel prepared to confidently incorporate nutrigenetics into practice today
- Need independent sources of information and training--not just marketing materials from the company

What Might Be the Benefits?

- Focus of analysis is on health promotion and wellness
 - May increase focus on a healthy diet and lifestyle
 - Process includes self assessment of modifiable risk factors for common, preventable conditions
 - Personalized advice may support diet and behavior changes in some people

What *Might* Be the Benefits?

- Contribute to understanding of biology of health and disease
 - Dietary interventions may halt disease process or postpone it
 - Identify subgroups who might be particularly responsive or resistant to dietary or other interventions

What Might Be the Benefits?

- First tentative steps to apply emerging knowledge
 - “You’ve got to start somewhere”
 - Puts practitioners on notice to increase understanding and knowledge now
 - Puts educational / training systems on notice to add relevant genetic / genomic material to curricula

Concerns



- Number of genes tested is very limited
- Rationale for gene selection is not clear
- Tests for variations in 19 genes do not detect most genetic risk factors for chronic diseases
 - Is there a possibility that a false sense of well-being or ill health may occur?

Concerns

- Risk assessment algorithm is proprietary and cannot be evaluated
- Value of adding genetic information is equivocal
 - Advice is not significantly different from population-based recommendations
 - Science-base is emerging and is not mature enough for use in practice
 - People are paying for irrelevant information



Concerns

- Published data is conflicting as to degree of association with health outcomes¹
- Nutrigenetics testing industry is not regulated and recent evidence suggests inconsistencies in quality²



¹Haga SB, Khoury MJ, Burke W. (2003) Genomics profiling to promote a healthy lifestyle: not ready for prime time. *Nature Genetics* 34(4): 347-50

² Kutz, G. (2006). NUTRIGENEIC TESTING: Tests Purchased from Four Web Sites Mislead Consumers. U.S. General Accounting Office. Testimony before the U.S. Senate Special Committee on Aging, July 27, 2006.

Lessons Learned

- Ready or not, it is here today
- Need to ask the right questions
 - What do we know and how well do we know it?
 - What don't we know?
 - What are the implications?
- Partnerships and communication
 - A seat at the table is important
 - Connecting with untraditional partners with differing agendas
- Need to monitor, educate, shape and address needs and gaps



Lessons Learned



- Capacity needs in RDs, other practitioners needs to be addressed
- Range of opinions of readiness of current applications
 - Costs and benefits; pros and cons
 - Mainstream opinion: Not ready yet
- Proceed with caution to assure best outcomes
- Anticipate ELSI and address
 - First, do no harm.

What Roles for State and Local Public Health?

- Assessment and Surveillance
 - Monitor uses to identify and solve health problems
 - Identify and monitor health outcomes
- Policy Development and Planning
 - Develop guidelines and best practices
 - Work with all relevant partners
 - Inform and empower people about nutrigenetics
- Assurance
 - Assure competent workforce--build capacity in providers
 - Evaluate effectiveness / safety
 - Link people with systems and services

The Last Word

“These first nineteen genes are just the beginning...I do not doubt that they correctly analyzed the genes from the sample I sent in. But, I do doubt whether you can reach the conclusions about behavior based on the genes they tested.”

A Registered Dietician who worked with the nutrigenetics testing product