

Summary of New York and California Correspondence with Health-Related Direct-to-Consumer Genetic Testing Businesses

The Genetics and Public Policy Center has reviewed correspondence between New York’s Department of Health (NY-DOH) and genetic testing businesses, and letters sent by California’s Department of Public Health (CDPH) to such businesses.¹ The chart below lists those businesses we identified as engaging either directly or indirectly in direct-to-consumer (DTC) health-related genetic testing, the tests they offer, the location of the company, whether they provide DTC testing themselves or in conjunction with another business, and, in the case of companies contacted by NY-DOH, whether they have responded to the letters by early May 2008. We reviewed but did not include correspondence between NY-DOH and businesses offering non-genetic health-related DTC services (e.g., for sexually transmitted diseases), non-health-related genetic DTC services (e.g., paternity, identity), or non-DTC genetic services.

Since 2005, NY-DOH has sent advisory letters to 32 DTC health-related genetic testing businesses including six laboratories that perform testing for DTC businesses. In most cases, NY-DOH raised all of the following concerns: whether the business had a NY clinical laboratory permit, whether the business was engaging in DTC testing, and whether the business was complying with NY direct billing requirements.

In June 2008, CDPH sent letters to 12 DTC² genetic testing businesses ordering them to stop selling tests in the state until they demonstrate compliance with state and federal regulations. The CDPH letters stated that the companies must have a California license and a CLIA certificate to operate, may not provide tests without a physician order, and must comply with California laws regarding test performance requirements.

Genetic Testing Business	NY/CA letter	Services Include	Location	Business Letter in Response to NY	Other Notes
Acu-Gen Biolabs	2005 NY only	fetal gender	MA	No response letter identified	
DNA Direct	2005 NY only	genetic counseling and testing (e.g., cystic fibrosis, drug response)	CA	Company claims it is in compliance with NY regulations	Uses Myriad and LabCorp for some tests; current Web site states that they "comply with state and federal regulations regarding genetic information and testing services, discrimination, and Internet commerce"
Genelex	2005 NY only	pharmacogenetics, nutrigenetics, predictive genetics (e.g., narcolepsy)	WA	States intent to apply for a permit	Holds NY permit for some categories of tests; current Web site states that some tests "cannot be sold in the U.K. or New York state"
HealthTests Direct	2005 NY only	CF carrier testing, factor V Leiden	CA	No letters of response identified for either of two letters from NY	
Lab21	2005 NY only	skin care	NY	No response letter identified	No longer in business in the U.S. according to news reports
LabCorp	2005 NY only	testing for DNA Direct	NC	States that all testing of NY residents ordered and received by licensed physicians	

¹ The NY-DOH letters were obtained through the Freedom of Information Act, while the CDPH letters to companies were posted on the Department’s website. The Center has not reviewed letters from companies responding to CA.

² CDPH contacted a 13th business, CGC Genetics; however, it is unclear whether they offer any DTC testing.

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Myriad	2005 NY only	laboratory testing for DNA Direct	UT	States that a physician is required to order test and that the laboratory reports results only to that physician; states intent to ask patient state of residence in the future	
One Person Health	2005 NY only	nutrigenetics	Canada	No response letter identified	No longer in business according to news reports
Consumer Genetics	2006 NY only	fetal gender, caffeine and alcohol metabolism	CA	No response letter identified	Current Web site states, "At this time, Pink or Blue® is not available for sale to New York state residents"
Cygene Laboratories	2006 NY only	screen for hereditary diseases (e.g., osteoporosis, thrombosis)	FL	States it is working to identify compliant laboratory and will not do business with NY residents in interim	
Genaissance Pharmaceuticals (PGx Health)	2006 NY only	pharmacogenetics	CT	States it will not process or accept NY specimens	PGx Health currently holds NY permit for molecular genetic testing
GeneLink Biosciences	2006 NY only	nutrigenetics, skin care	NJ	States it is not a clinical or genetic testing laboratory	Uses Genome Quebec for some testing; Current Web site states: "Dermagenetics™ is in transition and is not accepting new orders or customers at this time"
Niagen	2006 NY only	fetal gender, prenatal diagnosis (e.g., Down syndrome, trisomy 18)	NY	No response letter identified	
Sciona	2006 / 2008 NY / CA	nutrigenetics	CO	States it is not a clinical laboratory or testing facility because services are not intended to diagnose disease; claims it will not accept NY specimens	According to NY-DOH as of July 1, 2008, application to NY is pending; current Web site states: "THE PRODUCTS LISTED BELOW ARE NOT AVAILABLE FOR SALE IN THE STATE OF NEW YORK"
Suracell	2006 / 2008 NY / CA	nutrigenetics	NJ	States it has "no presence in New York" and does not provide laboratory services	Current Web site states that either BioServe or Metamatrix hold NY certification; Metamatrix claims to hold a permit
23andMe	2007 / 2008 NY / CA	personal genome scan	CA	States it is not clinical laboratory because testing is not intended for diagnosis, treatment, or prevention	Uses Illumina for testing
Graceful Earth	2007 NY only	Alzheimer genome test	HI	No response letter identified	Current Web site states: "These tests are not available to New York residents"

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Holistic Health Consultants	2007 NY only	nutrigenetics	ME	States it does not meet clinical laboratory definition but will stop offering nutritional assessment to NY residents	Current Web site states: "This test is not available to residents of New York. Any orders originating from the state of New York will automatically be canceled. Any samples originating from the state of New York will be discarded."
Navigenics	2007 / 2008 NY / CA	personal genome scan	CA	At the time of the letter, Navigenics was not yet commercially offering testing; letter states that it does not operate a clinical laboratory	Uses Affymetrix for testing
Smart Genetics (HIV Mirror)	2007 NY only	HIV progression	PA	No response letter identified	See also letter to Smart Genetics for ALZ Mirror (below)
Affymetrix	2008 NY only	laboratory testing for Navigenics	CA	No response from Affymetrix; however, Navigenics asserts that Affymetrix will submit application for permit	According to NY-DOH as of July 1, 2008, application to NY is pending
BioMarker Pharmaceuticals (Gene Essence)	2008 NY and CA	nutrigenetics	CA	Records not reviewed by GPPC	According to NY-DOH as of July 1, 2008, BioMarker Pharmaceuticals received a letter, but letters were not available to GPPC
BioServe (formerly SeraCare)	2008 NY only	laboratory testing for Suracell	MD	Records not reviewed by GPPC	According to NY-DOH as of July 1, 2008, BioMarker Pharmaceuticals received a letter, but letters were not available to GPPC; current Web site states that either BioServe or Metamatrix hold NY certification; Metamatrix claims to hold a permit
DeCODE Genetics	2008 NY and CA	personal genome scan	Iceland	No response letter identified	According to NY-DOH as of July 1, 2008, application to NY is pending; Web site states: "Some states have laws that do not permit their residents to obtain certain information regarding genetic risk provided by the Genetic Scans. (As of the date of publication of this Service Agreement those states are Arizona, California, Connecticut, Georgia, Maryland, Michigan, New Jersey, New York, Pennsylvania, Rhode Island and Wyoming.) "

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DNA Traits	2008 NY and CA	genetic disorders and susceptibility to inherited diseases	TX	No response letter identified	Current Web site states: "Currently, our services are not available in the States of California and New York, as NYS and CA require their own certification. DNA Traits is in the process of obtaining that certification"
Enterolab	2008 NY only	celiac disease	TX	Records not reviewed by GPPC	According to NY-DOH as of July 1, 2008, BioMarker Pharmaceuticals received a letter, but letters were not available to GPPC
Genome Quebec	2008 NY only	laboratory testing for GeneLink	Canada	No response letter identified	
HairDx	2008 NY and CA	hair loss	CA	Requests more time to respond and claims to be "examining the issues raised"	Current Web site states: "Now available only through doctors," and lists CA and NY physicians from whom test may be ordered
Illumina	2008 NY only	laboratory testing for 23andMe	CA	States it has ceased non-RUO (research use only) genotyping for 23andMe and is therefore exempt from NY clinical laboratory laws	
Psynomics	2008 NY only	diagnostic and therapeutic tests for mental illness	CA	No response letter identified	Current Web site states: "These are diagnostic tests whose results must be interpreted by a psychiatrist."
Qtrait/iGenix, Inc	2008 NY only	nutrigenetics, addiction	WA	States it is no longer offering tests to NY residents	Current Web site states: "Currently, the following states prohibit any direct genetic testing: California, Massachusetts, New York"
Smart Genetics (ALZ Mirror)	2008 NY and CA	Alzheimer risk assessment	PA	No response letter identified	See also letter to Smart Genetics for HIV Mirror (above)
Knome	2008 CA only	personal genome sequencing	MA	N/A	
New Hope Medical	2008 CA only	predisposition testing (e.g., Alzheimer, osteoporosis)	NV	N/A	
Salugen	2008 CA only	nutrigenetics	CA	N/A	

For a list of health-related DTC genetic testing businesses, see <http://www.dnapolicy.org/resources/DTCcompanieslist.pdf>.