August 24, 2010

LabCorp
Laboratory Corporation of America

Seattle Sperm Bank
4915 25th Ave Ne Ste 204
SEATTLE, WA 98105

Test Results of: 8671, DONOR
DOB: [redacted] Age: 31.8 Y Sex: M
Collected on: 08/19/2010
Received on: 08/19/2010
Reported on: 08/24/2010

Branch Number: WAB55
Account Number: 46857540
Specimen Number: 231-129-5174-0
Specimen Type: Blood

Patient ID#: 8671

Physician:

Test: Cystic Fibrosis, DNA Analysis

Result:

Negative for 32 mutations

Interpretation:
This individual is negative for the 32 most common cystic fibrosis (CF) mutations. This includes the mutations recommended by ACOG/ACMG for routine carrier screening. The detection rate varies with ethnicity and is listed below. In the absence of a family history, the remaining risk that a person with a negative result could be a carrier is listed in the table. If there is a family history of CF, these risk figures do not apply. Please contact LabCorp- Esoterix at 1(888) 690-3935 for a revised report. Diagnosis of cystic fibrosis should not rely on DNA testing alone, but should take into consideration clinical symptoms and other test results, such as sweat chloride analysis. The presence of a rare mutation cannot be ruled out. The diagnostic criteria for cystic fibrosis are:

At least one characteristic clinical feature, *or* Family history of CF, *or* Positive neonatal screening test	**AND**	Positive sweat chloride on 2 separate occasions, *or* Presence of 2 *CFTR* mutations, *or* Positive nasal transmembrane potential

Cystic fibrosis is a common genetic disorder resulting in chronic pulmonary and gastrointestinal/pancreatic disease. There is wide variability in clinical symptoms. CF is inherited in a recessive manner, which means that both parents must be carriers to have an affected child. When both parents are carriers, there is a 25% chance with each pregnancy that the child will be affected. Genetic counseling and CF molecular testing are recommended for the reproductive partners and at-risk family members of CF carriers.

Ethnicity	Detection Rate	Carrier Risk	Remaining carrier risk given a negative result
Ashkenazi Jewish	97%	1/25	1/800
Caucasian (non-Hispanic)	90%	1/25	1/240
African-American	69%	1/65	1/207
Hispanic	73%	1/46	1/168
Asian	55%	1/90	1/198

Mutations:

G85E	A455E	S549N	R1162X	711+1 G→T	2184delA	3876delA
R117H	ΔI507	S549R	W1282X	1078delT	2789+5 G→A	3905insT
R334W	ΔF508	G551D	N1303K	1717-1 G→A	3120+1 G→A	
R347H	V520F	R553X	394delTT	1898+1 G→A	3659delC	
R347P	G542X	R560T	621+1 G→T	2183AA→G	3849+10kb C→T	

Methodology:
DNA analysis of the *CFTR* gene was performed by the oligonucleotide ligation assay. Molecular-based testing is highly accurate, but as in any laboratory test, rare diagnostic errors may occur. When R117H is positive, reflex testing for 5T is performed. Reflex testing for the F508C, I506V and I507V polymorphisms is performed to rule out false positive ΔF508 homozygotes, using Tm Bioscience/Luminex primer extension chemistry. The assay provides information intended to be used for carrier screening in adults of reproductive age, as an aid in newborn screening, and as a confirmatory test for another medically established diagnosis in newborns and children. The test is not indicated for use in fetal diagnostic testing, pre-implantation screening, or for any stand-alone diagnostic purposes without confirmation by another medically established diagnostic product or procedure.

References:

1. Watson, et al. (2004) *Genet Med* 6:387-91
2. Richards, et al. (2002) *Genet Med* 4:379-391
3. Preconception and prenatal carrier screening for cystic fibrosis: (2001)ACOG.ACMG publication

Results Released By: Frank K. Fujimura, Ph. D., FACMG, Director
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4915 25th Ave Ne Ste 204
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Ph: (206)588-1484
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LCLS Specimen Number:	**231-129-5174-0**	Account Number:	46857540
Patient Name:	**8671, DONOR**	Ordering Physician:	**J OLLIFFE**
Date of Birth:	[redacted]	Specimen Type:	**BLOOD**
Gender:	M	Date Collected:	08/19/2010
Patient ID:	8671	Date Received:	08/20/2010
Lab Number:	(J10-5057 L	CoPath Number:	
Indications:	DONOR	Client Reference:	

Test: **Chromosome, Blood** Date Reported: **09/08/2010**

Cells Counted:	20	Cells Karyotyped:	2
Cells Analyzed:	20	Band Resolution:	500

CYTOGENETIC RESULT: 46,XY

INTERPRETATION: NORMAL MALE KARYOTYPE

Cytogenetic analysis of PHA stimulated cultures has revealed a MALE karyotype with an apparently normal GTG banding pattern in all cells observed.

This result does not exclude the possibility of subtle rearrangements below the resolution of cytogenetics or congenital anomalies due to other etiologies.

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National Director of Cytogenetics

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