

AFFIDAVIT

SAMPLE NO. Not Applicable

STATE OF California

COUNTY OF Alameda

Before me, Aneel K. Sandhu, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Trent C. Arsenault in the county and state aforesaid, who, being duly sworn, deposes and says:

I am Trent C. Arsenault, a directed semen donor and owner of my business legally named Trent Arsenault. I operate my firm from my home located at 38068 Canyon Heights Drive, Fremont, California 94536. My telephone number is (925) 484-4378. My business has been in operation since October 2006. I recover my semen for distribution to known recipients for artificial insemination purposes. As the owner and the sole employee of the company, I have direct knowledge of and am totally responsible for all operations of my firm, including, but not limited to, providing customers with information on directed semen donations via my web site (www.trentdonor.com), recovering semen, screening myself for donation, providing blood specimens for communicable disease testing, labeling and packaging my recovered semen for distribution to recipients. At the current time, I am the only person who conducts all operations related to my business. I AM REGISTERED WITH THE FDA, TCA 09/16/10

On August 27, 2010 Aneel K. Sandhu, Andres S. Diaz and Daniel Velasquez, employees of the United States Food and Drug Administration began an inspection of my business. I explained to Investigator Sandhu, my belief that my operations were exempt from regulations based on 21 CFR Part 1271.15 (f). On August 31, 2010, I spoke with Luis A. Solorzano Director of Investigations Branch who explained to me that my operations did not qualify for the exemption, that I am required to register, and subject to the applicable regulations in 21 CFR 1271.

During the inspection conducted on August 27, 2010, September 2, 2010, September 9, 2010, and September 16, 2010, I told Investigator Sandhu that I do not have any written procedures for my business' operations including procedures for determining donor eligibility, appropriate time frames for collecting and testing donor blood specimens for communicable disease testing, verification that testing laboratories for communicable disease testing are CLIA certified or equivalent, or whether the testing laboratory is testing using the appropriate test kits and following the manufacturer directions.

Since the inception of my business in October 2006, I have screened myself for risk factors associated with communicable diseases through the use of a "Lifestyle Questionnaire" the following three times: 01/25/2008, 10/17/2009, and 08/01/2010. Since October 2006, I have not had a physical assessment.

AFFIANT'S SIGNATURE AND TITLE

Trent C Arsenault

DIRECTED DONOR

FIRM'S NAME AND ADDRESS (Include ZIP Code)

38068 CANYON HEIGHTS DR FREMONT CA 94536

Subscribed and sworn to before me at Fremont, CA (City and State)

this 16 day of Sept, 2010.

Aneel K Sandhu (Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

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~~performed on myself to ensure that I am free of physical manifestations of communicable disease agents.~~
TCA 09/16/10

In ~~early 2009, I do not recall the exact date,~~ I entered into a contractual agreement with Private MD Labs located 1140 Hammond Drive NE, Building 1, Suite 9100, Atlanta, GA 30328-5338. When I need testing for relevant communicable diseases, I log into my account on Private MD Labs website and select the FDA panel. ~~The physicians employed with Private MD Labs evaluate the request and approve it. I rarely have been contacted by the physicians with questions.~~ When the order is approved, I am notified by the system. I proceed to LABCORP's Patient Service Center located at 2147 Mowry Avenue, Suite C1, Fremont, CA 94538 where my blood specimen is drawn and sent by LABCORP's Patient Service Center ~~directly to Laboratory Corporation of America ViroMed Laboratories located at 6101 Blue Circle Drive, Minnetonka, MN for testing. The testing results are reported directly to Private MD Labs.~~ I am of the belief that the physicians of Private MD Labs evaluate the test results and then forward the results to me. ^{above TCA 09/16/10} These procedures only cover the blood specimens collected on August 28, 2009 and July 28, 2010. ~~I do not have a copy of my written contract with Private MD Labs. I provided Investigator Sandhu with my written procedure entitled "STD Policy" implemented on May 1, 2009, that describes these operations.~~
TCA 09/16/10

~~Prior to May 2009,~~ ^{TCA 09/16/10} I did not have written procedures describing my process for collecting or testing samples of blood for communicable diseases. However, I was seen by my primary care physician or other physicians to obtain laboratory orders for communicable disease testing. I determined and informed my physicians of the communicable diseases ~~that I wanted my blood specimen to be tested for.~~ ^{TCA 09/16/10} This was the process in place when the following blood specimens were collected: 10/04/2006, 12/18/2006, 01/21/2008, 12/29/2008, and 05/05/2009. ^{TCA 09/16/2010}

^{TCA 09/16/2010} My firm's business operations ^{include TCA 09/16/10} are as follows. Prospective recipients contact me through my website. Recipients must sign and notarize a "Directed Donor Agreement". ^{Being TCA 09/16/10} Once verified that a signed agreement is in place, recipients schedule a pick up day which corresponds to when they are ovulating.

AFFIANT'S SIGNATURE AND TITLE

Trent C Arsenault

TRENT C ARSENAULT

DIRECTED DONOR

FIRM'S NAME AND ADDRESS (Include ZIP Code)

TRENT C ARSENAULT
38068 CANYON HEIGHTS DR

FREMONT CA 94536

Subscribed and sworn to before me at

Fremont, CA

(City and State)

this

16

day of

Sept

, 2010.

Aneel K. Sandhu
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

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~~Currently, recipients text message me on my phone, the day that they want to pick up the semen donation, I then put their name on the calendar reflecting their scheduled pick up. In the event that a recipient prefers to have their semen donations shipped to them, they pay for the shipping charges and the shipping kit. I direct the recipients to purchase the shipping kit from Northwest Andrology located at 508 W. 6th Avenue, Suite 610, Spokane, WA 99204. My firm does not process the recovered semen; it is not washed or processed in any way. I do not store the recovered semen; it is provided fresh to recipients. The semen is recovered and placed directly into a 4.5 ounce sterile specimen cup. I have purchased sterile specimen cups from Lake Charles Manufacturing located at 4905 Common Street, Lake Charles, LA 70607. The shipping kit from Northwest Andrology comes with 2-4.5 ounce sterile specimen cups; if one is used to ship semen donations to a recipient, I pull the second sterile cup from the kit and add to my inventory. The sterile cup is labeled with "** NOT EVALUTED FOR INFECTIOUS SUBSTANCES ** US FDA WARNING: ADVISE RECIPIENT OF COMMUNICABLE DISEASE RISK. TRENT " and the date and time stamp. My semen is distributed to the recipients with no other accompanying records when the semen is picked up locally. When the semen is shipped to a recipient the shipping kit includes "Instructions for Home Semen Collection, Shipping, and Use." It is a document created by Northwest Andrology and adopted by my business.~~

On September 9, 2010, I provided to Investigator Sandhu copies of 41 directed donor agreements. I provided the Investigator Sandhu with a copy of my calendar which is populated with names of the recipients who received a specimen on the days that their names are denoted on the calendar. The calendar spans the date period of December 22, 2006 to present. The calendar is an accurate reflection of when my semen donations were recovered and distributed. December 22, 2006 was when I recovered and distributed my first semen donation to a recipient. It also denotes when specimens were locally picked up or shipped to recipients. I also provided Investigator Sandhu with a list of the recipient's first name, last name, and the dates that the directed donor agreements were signed. I have kept this list current since December 22, 2006. The list contains the names of 60 recipients, including 13 names of recipients who signed a directed donor agreement who did not receive a semen donation. It also contains 7 names of recipients whose directed donor agreements are missing.

AFFIANT'S SIGNATURE AND TITLE

Trent C Arsenault

DIRECTED DONOR

FIRM'S NAME AND ADDRESS (Include ZIP Code)

38068 CANYON HEIGHTS DR
TRENT ARSENAULT

FREMONT CA
94536

Subscribed and sworn to before me at

Fremont, CA
(City and State)

this 16 day of Sept, 2010.

[Signature]
(Employee Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

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I provided Investigator Sandhu with communicable disease testing results dated 10/04/2006, 12/18/2006, 01/21/2008, 12/29/2008, 05/05/2009, 08/28/2009, and 07/28/2010. On September 2, 2009, I stated to Investigator Sandhu that I ~~was not tested~~ for communicable disease agents in 2007.

do not
could not find copies
TCA 09/16/10

I have read this statement and agree that it is true and accurate.

TCA 09/16/2010

AFFIANT'S SIGNATURE AND TITLE

Trent C Arsenault DIRECTED DONOR

FIRM'S NAME AND ADDRESS (Include ZIP Code)

*TRENT ARSENAULT
38068 CANYON HEIGHTS DR FREMONT CA 94536*

Subscribed and sworn to before me at FREMONT, CA (City and State)

this 16 day of SEPT, 2010.

Aneel K. Sandhu
Trent Arsenault AKS
7/16/2010
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.