DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	08/27/2010 - 09/20/2010* FEI NUMBER 3007575901

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Trent C. Arsenault, Directed Semen Donor

FIRM NAME	STREET ADDRESS
Trent Arsenault	38068 Canyon Heights Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fremont, CA 94536-1810	Directed Semen Donor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

HCT/P donors were not determined to be eligible based on the results of donor screening and testing.

Specifically,

From December 2006 to present, donor eligibility was not determined based on donor screening and testing by your firm for Donor T.A. During this time period, your firm screened Donor T.A. by utilizing a "Lifestyle Questionnaire" on three occasions: 01/25/2008, 10/17/2009, and 08/01/2010. Your firm collected a blood specimen for communicable disease testing from Donor T.A., seven times on the following dates: 10/04/2006, 12/18/2006, 01/21/2008, 12/29/2008, 05/05/2009, 08/28/2009, and 07/28/2010. You stated on 08/27/2010 to the FDA, that from December 2006 to present you never determined Donor T.A. eligible to donate semen. From December 2006 to present, your firm has recovered and distributed **approximately** 328 semen donations from Donor T.A. Those 328 semen donations were distributed to ~~47~~ **approximately 46** different recipients intended for artificial insemination as described in your firm's "Directed Donor Agreement" which was signed by each recipient.

OBSERVATION 2

Donors were not screened by a review of relevant medical records for risk factors and clinical evidence of communicable disease agents and diseases.

Specifically,

On August 27, 2010, you stated to the FDA that from December 2006 to present your firm did not perform a physical assessment on Donor T.A., to ensure the donor was free from clinical evidence of communicable disease agents and disease. From December 2006 to present, your firm has recovered and distributed **approximately** 328 semen donations from Donor

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Aneel K. Sandhu, Investigator Daniel Velasquez, Investigator Andres S. Diaz, CST	09/20/2010

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T.A. Those 328 semen donations were distributed to ~~47~~ **approximately 46** different recipients intended for artificial insemination as described in your firm's "Directed Donor Agreement" which was signed by each recipient.

From December 2006 to present, your firm did not adequately screen Donor T.A. for risk factors related to relevant communicable diseases. During this time period, your firm screened Donor T.A. with a "Lifestyle Questionnaire" on three occasions dated 01/25/2008, 10/17/2009, and 08/01/2010. Screening of Donor T.A. for risk factors associated with communicable diseases was not conducted once every six months. For the three occasions that the "Lifestyle Questionnaire" was used, it did not adequately screen Donor T.A. for disease risks associated with xenotransplantation and Creutzfeldt-Jakob disease. During this timeframe, your firm recovered and distributed **approximately** 328 semen donations from Donor T.A. Those 328 semen donations were distributed to ~~47~~ **approximately 46** different recipients intended for artificial insemination as described in your firm's "Directed Donor Agreement" which was signed by each recipient.

OBSERVATION 3

Donor specimens used for testing of communicable disease agents were not collected at the appropriate time.

Specifically,

From December 2006 to present, your firm collected a blood specimen for communicable disease testing from Donor T.A., seven times on the following dates: 10/04/2006, 12/18/2006, 01/21/2008, 12/29/2008, 05/05/2009, 08/28/2009, and 07/28/2010.

Your firm recovered and distributed, from Donor T.A., **approximately** 328 semen donations to ~~47~~ **approximately 46** different recipients. The chart below illustrates the number of recoveries and recipients that were within appropriate testing time frames for each of testing date:

Date of blood specimen collection	Number and date of semen recoveries	Number and initials of recipients
10/04/2006	0	0
12/18/2006	2 (12/22/2006, 12/23/2006)	1 (A.E.)
01/21/2008	1 (01/22/2008)	1 (V.F.)
12/29/2008	2 (12/30/2008, 01/05/2009)	2 (K.J., T.S.)

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05/05/2009	4 (05/09/2009, 05/10/2009, 05/11/2009, 05/12/2009)	2 (K.T., A.N.)
08/28/2009	6 (08/21/2009,08/25/2009, 08/26/2009, 08/27/2009, 09/03/2009, 09/04/2009)	3 (N.M.,M.D., K.D.)
07/28/2010	4 (07/25/2010, 07/26/2010, 07/27/2010 08/01/2010)	2 (L.M., M.R.)

Of the **approximately** 328 semen donations, **approximately** 19 were recovered within the 7 day time frame for when blood specimens must be collected for donor testing based on the date of semen recovery.

OBSERVATION 4

Donors were not tested for evidence of infection with communicable disease agents.

Specifically,

From December 2006 to present, your firm collected a blood specimen for communicable disease testing from Donor T.A., seven times on the following dates: 10/04/2006, 12/18/2006, 01/21/2008, 12/29/2008, 05/05/2009, 08/28/2009, and 07/28/2010.

The blood specimens collected on the following dates did not adequately test for all required communicable diseases:

Date	Required disease not tested for
10/04/2006	Hepatitis B, Hepatitis C, ~~Syphilis~~, HTLV Type 1 and 2, CMV and HIV Type 2
12/18/2006	Hepatitis B, HIV Type 1 and 2, Syphilis, HTLV Type 1 and 2, Chlamydia, Gonorrhea, CMV
01/21/2008	Hepatitis B, Hepatitis C, HIV Type 1 and 2, HIV Group O, HTLV Type 1 and 2, CMV
12/29/2008	HIV Group O, HTLV Type 1 and 2, CMV
05/05/2009	Hepatitis B, Hepatitis C, HIV Type 1 and 2, HIV Group O, Chlamydia, Gonorrhea

From December 2006 to August 21, 2009 your firm recovered and distributed **approximately** 171 semen donations, from Donor T.A., to **approximately** 32 different recipients.

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EMPLOYEE(S) SIGNATURE

Aneel K. Sandhu, Investigator AKS
Daniel Velasquez, Investigator
Andres S. Diaz, CST

DATE ISSUED

09/20/2010

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OBSERVATION 5

After completion of the donor-eligibility determination, HCT/Ps were not accompanied with the summary of the records used to make the donor-eligibility determination.

Specifically,

From December 2006 to present, donor eligibility was not determined based on donor screening and testing by your firm for Donor T.A. From December 2006 to present, your firm recovered **approximately** 328 semen donations from Donor T.A. and distributed them to ~~47~~ **approximately 46** different recipients intended for artificial insemination as described in your firm's "Directed Donor Agreement" which was signed by each recipient.

You are required to document and maintain the following records related to each semen donation you recovered and distributed:

a. Statement of donor eligibility based on screening and testing.
b. Summary of records containing:
   - statement that testing was conducted at a CLIA certified laboratory or equivalent.
   -a list and interpretation of communicable disease tests performed.
   -name and address of the establishment where donor eligibility was determined.

You stated on 08/27/2010, to the FDA that **approximately** all 328 semen donations were distributed without the required accompanying records.

OBSERVATION 6

Procedures for all steps performed in the testing, screening, and determining of donor eligibility of HCT/Ps were not established, maintained, defined, documented, implemented, and followed.

Specifically,

Your firm has not developed written procedures related to testing, screening, and determining donor eligibility of semen Donor T.A.

a. There no written procedures for determining donor eligibility including a written procedure for obtaining relevant medical history and a history of social behavior including risk factors or conditions for

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communicable disease and disease associated with xenotransplantation.

b. Failure to establish a written procedure for appropriate timeframes for collecting and testing Donor T.A. blood samples for required communicable diseases.
c. There is no procedure to ensure that laboratories performing communicable disease testing used in determining donor eligibility are using appropriate FDA licensed and approved donor screening test kits.
d. There is no procedure to ensure that testing laboratories are performing communicable disease testing and interpreting test results in accordance with the manufacturer's directions.
e. There is no procedure to determine that testing laboratories are CLIA certified or meet requirements as determined by CMS.

*** DATES OF INSPECTION:**
08/27/2010(Fri), 09/02/2010(Thu), 09/09/2010(Thu), 09/16/2010(Thu), 09/20/2010(Mon)

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